Islet Sciences, Inc Form 10-K August 13, 2013

# U.S. SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-K

(Mark One)

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

For the Fiscal Year Ended April 30, 2013

o 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 001-34048

Islet Sciences, Inc. (Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation or organization) 87-0531751 (IRS Employer Identification No.)

641 Lexington Avenue, 6th Floor New York, New York 10022 (Address of principal executive offices)

Issuer's telephone number, including area code: (646) 863-6341

Securities registered pursuant to Section 12(b) of the Act: None.

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.001 Par Value.

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

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 b

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 b No "

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was Required to submit and post such files).  $\flat$  Yes "No

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 "

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

Large accelerated filer	••	Non-accelerated filer	••	
Accelerated Filer		Smaller reporting company	þ	
Indicate by check mark whe	ther the registrant	is a shell company (as defined in Rule 12b-2	of the Act).	Yes" No b

As of October 31, 2012, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the shares of the Registrant's common stock held by non-affiliates (based upon the closing stock price of \$3.10 as reported on the Over-the-Counter Bulletin Board) was approximately \$106,144,461. Shares of the Registrant's common stock held by each executive officer and director and by each person who owns 10 percent or

Registrant's common stock held by each executive officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of August 12, 2013, there were outstanding 56,715,117 shares of the registrant's common stock, \$.001 par value. Documents incorporated by reference: None.

Islet Sciences, Inc.

# Form 10-K

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#### PART I

#### ITEM 1. BUSINESS

#### Corporate History

Islet Sciences, Inc. (the "Company") was incorporated under the name One E-Commerce Corporation on September 14, 1994 in the State of Nevada. Effective February 23, 2012, the Company changed its name to Islet Sciences, Inc.

On September 15, 2011, Mr. John Welch, the then majority shareholder, director and chief executive officer of the Company, and Islet Sciences, Inc., a Delaware corporation ("ISI") entered into a Stock Purchase Agreement, pursuant to which Mr. Welch sold to ISI, (a) an aggregate of 9,902,180 shares of the Company's common stock representing approximately 54.06% of the then issued and outstanding shares of common stock, and (b) convertible promissory notes in the aggregate principal amount of \$514,458 previously issued by the Company, for an aggregate purchase price of \$250,000. The notes were convertible into 30,573,664 shares of common stock.

On December 30, 2011, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with ONCE, Inc., a Delaware corporation which was wholly owned by the Company ("Merger Sub"), and ISI. Pursuant to the Merger Agreement, on December 30, 2011, Merger Sub was merged with and into ISI, the holders of common stock of ISI received an aggregate of 38,005.87 shares of the Company's Series B preferred stock, \$.001 par value per share ("Series B Preferred") in exchange for the cancellation of all of the shares of common stock of ISI formerly owned by them, and the holders of Series A preferred stock of ISI received an aggregate of 1,173 shares of the Company's Series A preferred stock, \$.001 par value per share ("Series A Preferred") in exchange for the cancellation of all of the shares of Series A preferred stock of ISI formerly owned by them (the "Merger").

Effective February 23, 2012, the Company completed a 1-for-45 reverse stock split (the "Reverse Split") of shares of its common stock. Upon effectiveness of the Reverse Split, shares of Series A Preferred were automatically converted into an aggregate of 1,173,000 shares of common stock at a conversion ratio of one share of Series A Preferred for one thousand shares of common stock, and shares of Series B Preferred were automatically converted into an aggregate of 38,005,870 shares of common stock, at a conversion ratio of one share of Series B Preferred for one thousand shares of common stock. Upon conversion of Series A Preferred, the holders received the Company's warrants to purchase an aggregate of 586,500 shares of Common Stock at an exercise price of \$1.00 per share.

In connection with the closing of the Merger, ISI agreed to cancel the shares and the outstanding notes of the Company purchased from Mr. Welch, and the interest accrued thereon effective upon the effectiveness of the Reverse Split which occurred on February 23, 2012.

Acquisition of DiaKine Therapeutics, Inc.

On February 23, 2012, the Company and ISI, entered into a Share Exchange Agreement with DiaKine Therapeutics, Inc., a Delaware corporation ("DTI"), and shareholders of DTI, whereby the Company agreed to issue to the DTI shareholders an aggregate of 200,000 shares of its newly designated shares of Series C preferred stock, par value \$0.001 per share ("Series C Preferred") in exchange for all issued and outstanding shares of DTI. The Company also agreed to issue to DTI 100,000 shares of its common stock for no additional consideration in satisfaction of DTI's liabilities outstanding at the closing under the agreement. The closing of transactions contemplated by the Share Exchange Agreement occurred on March 14, 2012. As a result, DTI became a wholly-owned subsidiary of the Company.

DTI is a development stage biotechnology company engaged in the research and development of treatments for diabetes. The therapies under development from DTI's drug platform are small molecules with unique anti-inflammatory and immune modulating properties that represent a novel approach to treating type 1 and type 2 diabetes and many related complications. Because of this novel approach to therapy this class of drugs has the potential to become the standard of care by arresting the disease, restoring insulin production and halting long term complications. Safety and potential therapeutic effects are supported by numerous pre-clinical studies including those with human beta cells.

DTI's compounds are small-molecule drugs that block the destructive, inflammatory actions of immune agents called cytokines. Cytokines have been shown in numerous studies to be components in the inflammation pathway that destroy insulin producing beta cells found in the pancreatic islets – a hallmark of type 1 diabetes and Latent Autoimmune Diabetes of Adults (LADA). Additionally, there is clear evidence that lipotoxicity, glucotoxicity, and other inflammatory factors induces progressive beta cell drop out in type 2 diabetes.

A number of studies with DTI's drugs have shown the immune modulating effects on the cytokine network and in protecting pancreatic beta cells from immune attack. In addition to blocking autoimmune attack, these drugs enhance beta cell function and insulin production, according to pre-clinical studies using human islets. Several lead compounds are well tolerated and have presented no major toxicity in animal toxicology and clinical studies performed so far.

The diabetes and diabetic complications market opportunities for these oral compounds are large and growing including such segments as islet cell transplant therapy, type 1 diabetes, LADA, insulin-using type 2 diabetes, and diabetes-related complications such as nephropathy and retinopathy.

#### Lead indications are:

As an adjunct therapy for islet cell or any other cellular transplantation engineered to reverse type 1 diabetes. Pre-treatment of isolated islet cells in transplant media and ongoing therapy for transplant patients.

Reversing or arresting the progression of diabetes in type 1, LADA and insulin using type 2 patients.

Treatment of diabetic nephropathy and diabetic retinopathy.

#### Company's Corporate Structure

Below is the Company's current corporate structure:

#### **Recent Developments**

Effective July 9, 2013, Mr. John Steel resigned as the Chairman, Chief Executive Officer, Treasurer and Secretary of the Company, and as an officer and director of ISI and DTI. Mr. Steel's resignation was pursuant to that certain Separation Agreement and Release dated as of July 1, 2013 (the "Effective Date") by and between Mr. Steel and the Company (the "Separation Agreement").

Pursuant to the Separation Agreement, Mr. Steel resigned effective on the eighth day from the Effective Date. Mr. Steel forfeited an unvested stock grant of 433,334 shares of common stock. He is entitled to receive \$270,000 in cash or common stock at the Company's option and a number of shares of common stock equal to 1.0% of the Company's total outstanding common stock if there is a change of control of the Company. In connection with the Separation Agreement, Mr. Steel and the Company entered into a Consulting Agreement dated as of July 1, 2013 (the "Consulting Agreement") whereby Mr. Steel will provide business development services to the Company as my be directed by its CEO. Under the Consulting Agreement, Mr. Steel will receive a monthly consulting fee of \$15,000. The Consulting Agreement expires on June 30, 2014 and may be extended by the parties.

On July 15, 2013, Mr. Michael Earley was appointed as the Chief Executive Officer, Director and Chairman of the Company, and Mr. Mark Foletta was appointed as an Advisor to the CEO and the Board of the Company. On July 30, 2013, Mr. Earley and Mr. Foletta resigned from their positions at the Company.

On August 4, 2013, Dr. Jerry Nadler resigned as a director of the Company.

**Our Business** 

Overview

We are a development stage biotechnology company engaged in the research, development, and commercialization of patented technologies in the field of diabetes.

We are developing the following therapeutic product candidates:

Islet Sciences-PTM, an injectable suspension of microencapsulated insulin-producing, pancreatic islet cells harvested from pathogen free pigs, for the treatment of insulin-dependent diabetes;

Diagnostic tests to identify early stages of diabetes; and

Small molecules that block inflammatory actions of cytokines that destroy insulin-producing beta cells, for diabetes and diabetes-related complications. The drugs reduce activation of a gene switch called STAT4. Preclinical and genetic studies link STAT4 to several autoimmune diseases such as type 1 diabetes as well as insulin resistance and atherosclerosis.

We are initially focused on developing Islet Sciences-PTM. We believe that Islet Sciences-PTM, a xenotransplantation (transplantation between different species) product, has significantly more commercial potential than human-to-human (allotransplantation) islet replacement approaches, due to the high cost and inherently limited supply of human islets. Islet Sciences-PTM is intended to be administered by injection into the patient's abdominal cavity, where the transplanted islet cells are expected to produce insulin in response to increases in blood glucose, much like the patient's original pancreatic islet cells did prior to being destroyed by disease. Our development plans include the following with respect to the development of Islet-Sciences-PTM:

file an investigational new drug, or IND, application with the Food and Drug Administration, or FDA; and

initiate an open-label Phase I/II clinical trial in patients with insulin-dependent diabetes.

We believe that Islet Sciences-PTM should enable the patient to produce insulin within 24 hours after injection. As a result, we anticipate that the Phase I/II trial may provide an objectively measurable clinical effect on patients within a relatively short period of time after the initiation of the trial.

We also plan to develop novel, small molecule immune modulators for diabetes and diabetes-related complications. One lead compound, Lisofylline (LSF) has been the subject of a completed Phase I/II clinical trial and five Phase I clinical trials. In these trials, LSF was well tolerated with no subject experiencing a serious adverse event. In the Phase I/II trial, LSF significantly reduced the plasma levels of several major inflammatory cytokines linked to autoimmunity.

We also licensed the exclusive rights to certain technologies related to the treatment and diagnosis of diabetes, including:

a technology for the measurement of hypomethylated beta cell-derived DNA as a biomarker of beta cell (cells in pancreas that form islets for insulin production) death that may be applied to identify diabetes and islet cell dysfunction at early stages before symptoms arise licensed from Yale University. This groundbreaking technology published by the American Diabetes Association and sponsored by JDRF, (http://diabetes.diabetesjournals.org/content/early/2013/02/14/db12-1207.abstract) describes the potential for this

technology to provide a non-invasive and effective means to detect and monitor the progression of beta-cell death associated with diabetes, with the goal of guiding treatment and identifying the disease at a much earlier stage. Current diagnosis often occurs only after substantial loss of beta-cell function.

a noninvasive method for evaluating beta cell death in the diagnosis of diabetes licensed from Winthrop University that complements the Yale diagnostic. The goal of these combined technologies is to identify the onset of diabetes at an early stage, before the onset of high blood sugar levels (hyperglycemia) associated with the long-term complications of the disease, such as kidney and eye damage.

small molecules for islet expansion licensed from the University of California.

We intend to develop these technologies in partnership with large pharmaceutical or biotechnology companies.

#### Market Opportunity

Diabetes is the sixth leading cause of death in the United States, contributing to more than 193,000 deaths per year. An estimated two million Americans are insulin-dependent diabetics. Currently, each diabetic patient costs the U.S. health care system more than \$10,000 per year. We believe that the market will support a price significantly higher than \$10,000 per year for a product that can effectively treat insulin-dependent diabetes. We estimate the potential market size is \$14 billion for the United States and an additional \$18 billion for the top six industrialized foreign countries.

# Our Strategy

Our strategy is to become a leading innovator, developer and provider of therapeutics and diagnostics for diabetes. The key elements of our strategy are as follows:

develop Islet Sciences-PTM for insulin-dependent diabetes patients with end stage renal disease;

establish infrastructure to provide scale and logistics for clinical trials and commercialization;

execute clinical trials and obtain FDA and EMEA approvals for Islet Sciences-PTM;

develop LSF to block autoimmune damage to insulin-producing cells;

form development and commercialization partnerships; and selectively acquire and develop complementary technologies.

The Company intends to seek the FDA approval for marketing in the U.S. a first product, called Islet Sciences-PTM. Islet Sciences-PTM will be an injectable suspension of microencapsulated insulin-producing, pancreatic islet cells which are harvested from designated pathogen free pigs. We believe that Islet Sciences-PTM, a xenotransplantation (transplantation between different species) product, has significantly more commercial potential than human-to-human (allotransplantation) islet replacement approaches, due to the high cost and inherently limited supply of human islets. In the past, we researched the use of our technology for allotransplantation, and we may continue such research for use in select patient populations. We refer to this potential product as Islet Sciences-HTM. Both of these product candidates are intended for the treatment of insulin-dependent diabetes, and both are intended to be administered by injection into the patient's abdominal cavity, where the transplanted islet cells will produce insulin in response to increases in blood glucose, much like the patient's original pancreatic islet cells did prior to being destroyed by disease.

The primary function of microencapsulation is to protect the islets from the host's immune system. The microcapsule coating is composed of layers of biocompatible materials. In addition to developing its products and delivery systems, the Company and its management are collaborating with research staff at University of Oxford, UK, University of Virginia, and the University of California to further develop its products and technologies.

## Intellectual Property

The Company's patent estate is focused on enabling and protecting the first commercially viable treatment for type 1 diabetes and consists of the following intellectual property and patent initiatives. The Company seeks patents and other intellectual property rights to protect and preserve our proprietary technology and our right to capitalize on the results of its research and development activities. The Company is pursuing patents in the US and in foreign countries. The Company may also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to provide competitive advantages for its eventual products in various markets and to accelerate new product introductions.

Islet Sciences, Inc.

Below is a list of the US patent applications held by the Company.

Title	Patent Application Number	Status
Ex Vivo Maturation of Islet Cells	PCT/US2012/058087	Pending Enters National Phase March 2014
Multilayered Polyelectrolyte-Based Capsules for Cell Encapsulation And Delivery of Therapeutic Compositions	US Patent Application 11/868,205	Pending
Multilayered Polyelectrolyte-Based Capsules for Cell Encapsulation And Delivery of Therapeutic Compositions	US Patent Application 13/279,258	Pending

The maturation patent comprises a novel method for isolating islets cells from a porcine animal model in which the pancreas is excised, intact, from the porcine animal model which is then severed into a series of appropriate sizes and volume. The isolated and severed exocrine tissue and islet cells are then treated in-vitro with a non-specific collagenase enzyme exposure for a specific period that results in a partial digestion of the exocrine tissue comprising

islets cells that are embedded within and protected by the partial digested exocrine tissue. It is the partial digestion followed by in vitro maturation that allows islets to function and be able to survive long term. In addition, the present invention further comprises a novel method for maturing a plurality of isolated porcine islet cells that are functional and can respond to glucose stimulation early in the maturation process. This patent further comprises a means for encapsulating the plurality of isolated porcine islet cells to minimize the need for an immunosuppressant during in vivo injection in a human recipient and the unique media that allows maturation of islets and allows the islets to be functional.

The encapsulation patent provides novel, biocompatible matrices for cell encapsulation and transplantation. It further provides methods for delivering agents to encapsulated cells and to the local environment of a host system as well as methods for targeting and manipulating particular cells and/or proteins of the host system.

Patent applications licensed by the Company from Winthrop University Hospital

Title Patent Application Status

Number

Method For Using Probe Based PCR PCT/13/028862 Pending
Detection To Measure The Levels Of Enters National
Circulating Demethylated Beta Cell-Derived Phase

DNA as a Measure Of Beta Cell Loss In September 2014

Diabetes

Detection To Measure The Levels Of Application Circulating Demethylated Beta Cell-Derived 13/279,261

DNA as a Measure Of Beta Cell Loss In

Diabetes

Patent Applications that are licensed by Islet Sciences, Inc. from Yale University

Title Patent Application Status

Number

Compositions and Methods of Diagnosing PCT/US2012/043747 Pending,
Diseases and Disorders Associated With Cell Enters National
Death Phase

December 2013

Patent Applications that are licensed by Islet Sciences, Inc. from Univ. of California, Los Angeles

Title Patent Application Status

Number

Pharmaceutical Compositions and Methods PCT/US13/024695 Pending,

for Restoring Beta-Cell Mass and Function Enters National

Phase August 2014

DiaKine Therapeutics, Inc.

DTI holds an exclusive, world-wide license to develop and market products based on the discoveries associated with Lisofylline and the next generation of orally bioavailable immune modulators with a similar spectrum of action for the treatment of both type 1 and type 2 diabetes and related complications. In December 2004, DTI entered into a license agreement with Cell Therapeutics, Inc. (CTI) to license certain patents, patent applications, technology and know-how relating to compounds and methods used in the treatment of diabetes. Below is a list of the US patents and patent applications held by DTI. DTI has rights in certain corresponding foreign patent applications and patents, if granted.

# US Patents licensed by DTI from CTI

Title	Patent Number	Expiration Date
Enantiomerically Pure Hydroxylated Xanthine Compounds to Treat Inflammatory Diseases	US 5,620,984	2015
Treatment of Diseases Using Enantiomerically Pure Hydroxylated Xanthine Compounds	US 5,629,315	2015
Methods of Using Enantiomerically Pure Hydroxylated Xanthine Compounds	US 5,652,243	2014
Enantiomerically Pure Hydroxylated Xanthine Compounds to Treat Autoimmune Diabetes	US 5,739,138	2015
Enatiomerically pure hydroxylated xanthine compounds	US 5,792,772	2015
Method of Inhibiting Interleukin-12 Signaling	US 6,469,017	2018
Tricyclic Fused Xanthine Compounds and Their Uses	US 6,586,429	2020
Therapeutic compounds for inhibiting interleukin-12 signaling and methods for using same	US 6,774,130	2018
Therapeutic compounds for inhibiting interleukin-12 signals and method for using same	US 6,878,715	2014

DiaKine also has licensed the rights for next generation small molecule immune modulator-anti-inflammatory drugs from the University of Virginia Patent Foundation.

# US Patents licensed by DTI from the University of Virginia Patent Foundation

Title	US Patent Application Number	Status
Lisofylline analogs and methods for use	US Patent 8,481,580	Patent
Lisofylline analogs and methods for use	US 13/477,613	Pending

Foreign Patents and Patent Applications that are licensed by DTI from the University of Virginia Patent Foundation

Title	US Patent	Status
	Application	

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	Number	
Lisofylline Analogs and Methods for Use	CA 2618970	Patent
Lisofylline Analogs and Methods for Use	CA 2679301	Pending
Lisofylline Analogs and Methods for Use	EP 1919867	Patent
Lisofylline Analogs and Methods for Use	EP 2325169	Pending
Lisofylline Analogs and Methods for Use	EP 07757631	Pending
Lisofylline Analogs and Methods for Use	JP 2008-529208	Patent
Lisofylline Analogs and Methods for Use	JP 2012-157360	Pending
Lisofylline Analogs and Methods for Use	JP 2009551980	Pending

## US Patents and patent applications owned by DTI

Title	Patent (Application) Number	Status/Expiration
Pharmaceutical compositions and methodsfor restoring -cell mass and function	US Patent 7,393,827	2025
Encapsulation system	US Patent Application US 12/373,870	Pending
Compositions and methods for treating diabetes using lisofylline and islet neogenesis associated peptide	US Patent Application 12/865,027	Pending
Compositions and methods for treating diabetes using lisofylline analogs and islet neogenesis associated peptide	US Patent Application 13/644,817	Pending
Treatment of Diabetes and Disorders Associated with Visceral Obesity with Inhibitors of Human Arachidonate 12 Lipoxygenase and Arachidonate 15-Lipoxygenase	US Patent Application US 13/522,165	Pending

There can be no assurance that the Company will succeed in obtaining any patent protection from its pending patent applications. No assurance can be given that any patent will be issued or that the scope of any patent protection will exclude competitors or that any patent, if issued, will be held valid if subsequently challenged. There can be no assurance that any steps the Company takes in this regard will be adequate to deter misappropriation of its proprietary rights or independent third parties developing functionally equivalent products. Despite precautions, unauthorized parties may attempt to engineer, reverse engineer, copy, or obtain and use the Company's products or other information. Although management believes that the Company's products do not infringe on the intellectual property rights of others, there can be no assurance that an infringement claim will not be asserted in the future. The prosecution or defense of any intellectual property litigation can be extremely expensive and would place a material burden upon the Company's working capital.

## License Agreements

The Company has entered into certain license agreements with research institutions which will give the Company rights to technology which it believes will further its goal of enabling and protecting the first commercially viable treatment for diabetes. The Company has entered into these license agreements expecting to obtain valuable intellectual property and patents to provide proprietary positions with respect to the licensed technology.

On May 2, 2012, the Company entered into a license agreement with the Yale University ("Yale"). Under the agreement, the Company received an exclusive license to certain "Circulating hypomethylated B cell derived DNA as a biomarker of B cell destruction" technology.

On July 23, 2012, the Company entered into a license agreement with Winthrop Hospital. Under the Agreement, the Company received a worldwide, exclusive license to certain "methods using probe-based PCR detection to measure

levels of circulation demethylated cell derived DNA as a measure of cell loss in diabetes."

The Company is currently in default regarding its payment obligations under the foregoing license agreements in the total amount of approximately \$272,000. The Company is in the process of negotiating provisional forbearance agreements with each licensor.

On February 5, 2013, the Company entered into an exclusive license agreement with Jerry L. Nadler, David Taylor-Fishwick, Anca Dobrian and Swarup Chalrabarti (collectively, "12LO Licensors") for use/screening of 12LO inhibitors in consideration of a payment of a \$10,000 non-refundable royalty fee (plus a \$10,000 annual renewal fee) and issuance of 20,000 shares of the Company's common stock, and additional 160,000 shares of the Company's common stock upon completion of certain milestones. The Company also agreed to pay to 12LO Licensors a royalty of 5% of net sales. The agreement can be terminated by 12LO Licensors if the Company defaults on its obligations under the agreement and fails to cure such default within 60 days of a written notice by the third party. The Company can terminate the agreement upon a six month notice subject to payment of all amounts due under the agreement.

## Suppliers

While the use of porcine-derived biologic materials is established in human therapeutics, including insulin and heart valves, the FDA requires that porcine islets used in clinical studies for transplantation in humans come from designated pathogen free (DPF) pigs raised in a U.S. Department of Agriculture certified facility. The Company has a supply agreement, dated July 23, 2012, with a supplier of DPF pigs to rear and provide suitable juvenile pigs as a supply of islet cells. The term of the contract is two years with an option to renew it for additional 2 years. The Company can obtain suitable pigs from other suppliers and the agreement with the supplier is not exclusive.

The supply agreement provides for DPF tissue in sufficient amounts to meet the Company's planned initial clinical trials. The facility is currently approved by the FDA for production of such porcine products.

#### Manufacturing

On January 10, 2012, the Company entered into an agreement with PCT, which was amended by an agreement dated May 15, 2012 by and between the Company and NeoStem, PCT's parent company. Under the agreements, PCT will be providing the protocols, procedures, systems, equipment, testing, quality controls, and manufacturing and distribution services to support the development and commercialization of the Company's encapsulated porcine islet cells for the treatment of diabetes. As compensation for the services of PCT, the Company agreed to pay to PCT a non-refundable monthly fee of \$63,000 and a non-refundable monthly charge of between \$33,000 and \$54,000. NeoStem was entitled to receive shares and warrants of the Company's common stock, as well as additional shares for no consideration so that NeoStem's ownership is not less than 1% of outstanding shares on a fully diluted basis. PCT has the right for a period of ten years to be the exclusive manufacturer of any product involved in the services to be provided under the agreement. With respect to commercial production of such products, PCT will be entitled to a royalty of 2.85% of gross sales and 5% of any sublicensing fees, royalties, milestone fees or profit sharing payments.

On February 7, 2013, the Company provided to NeoStem Inc. notice of termination of the agreement with Progenitor Cell Therapy, Inc. dated January 10, 2012, as amended by the agreement dated May 15, 2012 by and between the Company and NeoStem. The Company and NeoStem are in negotiations on terms of the termination or possibly renegotiating terms of a new agreement satisfactory to each party.

On July 23, 2012, the Company entered into a long-term supply agreement with Spring Point Project, a source animal facility to purchase pigs for use in the Company's xenotransplantation research. Regardless of the number of pigs supplied under this agreement, the Company is obligated to pay \$100,000 for each month of this agreement, plus an initial and one time facility setup fees of \$25,000, and to pay certain milestones royalties by issuing warrants exercisable into an aggregate of 300,000 shares of common stock. The initial term of the agreement is for two years with an automatic renewal for one additional year, unless terminated prior to the renewal period. It can be terminated by either party if either party defaults on its obligations under the agreement and fails to cure such default within 90 days. The Company is currently in default regarding its payment obligations under the foregoing supply agreements in the total amount of approximately \$161,000. The Company is in the process of negotiating a provisional forbearance agreement with the supplier. On August 12, 2013, the Company received from Spring Point Project a notice of termination of the supply agreement to become effective on November 10, 2013 unless the Company cures the default before that date.

# Competition

The pharmaceutical and biotechnology industries are intensely competitive and technological progress can be rapid. Based upon publicly available information, it appears that there are no other cell transplantation products currently available, or in late stage clinical trials, that can effectively treat insulin-dependent diabetes. Nevertheless, we

anticipate that the development of cell-based and other products that can better treat and manage this disease will remain the focus of intense competition.

The strongest competition is anticipated to come from traditional and alternate insulin delivery systems, such as inhalable insulin or insulin pumps. If successful, such products would offer a moderately improved quality of life for diabetics, but are not likely to eliminate the need for frequent blood glucose monitoring or to address the inevitable long-term complications resulting from exogenous insulin therapies.

There are several other companies engaged in the research of islet transplantation technologies. Some of these companies include:

Living Cell Technologies (LCT) - publicly traded Australian-based biotech company developing an alginate-encapsulated neo-natal porcine islet cell product, reported to be conducting a phase I/IIa clinical trial in Russia;

Islet Sheet Medical - company engaged in the research and development of a bioartificial pancreas;

Revivicor - company engaged in the research and development of animal biotechnology platforms for treatment of human degenerative diseases including diabetes.

Most of our competitors are larger than we are and have greater financial resources, technical expertise, marketing, distribution, or support capabilities. We expect that we will face increased competition in the future as new companies enter the market and advanced technologies become available. Any of our competitors could broaden the scope of their products through acquisition, collaboration or internal development to more effectively compete with us. Our competitors may also develop new, more effective or affordable approaches or technologies which could compete with our products or render them obsolete.

## **Recent Studies**

There has been a significant amount of research activity in academic institutions concerning the concept of using porcine islet cells for transplantation in insulin-dependent diabetes. In 2006, a team at the University of Minnesota published positive data on the use of porcine islets in conjunction with immunosuppression to reverse diabetes in non-human primates. This observation was followed by further work from a collaborative project between scientists at the University of Alberta, Canada, and scientists at Emory University School of Medicine. The results from the project appeared to demonstrate that transplantation of fetal porcine islets, in conjunction with immunosuppression, was able to effectively reverse diabetic conditions for a period of months in non-human primates, further demonstrating the utility of porcine islets for transplantation therapy.

We note that our proprietary encapsulation approach is designed to avoid or minimize the need for chronic immunosuppression, whereas the above findings have relied substantially on immunosuppression or manipulation of the immune system. Nevertheless, we could face increased competition from current or future licensees of technology developed from the above studies.

#### Government Regulation

## Overview

The development and commercialization of our products will be subject to extensive regulation in the United States by a number of regulatory authorities, including the FDA, and by comparable regulatory authorities in foreign countries. These regulatory authorities and other federal, state and local entities will regulate, among other things, the preclinical and clinical testing, safety, effectiveness, approval, manufacturing, labeling, packaging, export, storage, recordkeeping, adverse event reporting, and promotion and advertising of our products. We will require FDA approval of our products, including a review of the manufacturing processes and facilities used to produce our products, before we may market the products in the United States.

Both Islet Sciences-PTM and Islet Sciences-HTM will be classified as combination biological and device products by the FDA. The islets comprise the biological component and the microencapsulation material comprises the device component. The FDA Center for Biologics ("CBER") has jurisdiction, meaning the Islet Sciences-PTM product will be reviewed primarily as a biological product.

Biological products are subject to dual regulation. Their approval for marketing, among other things, is regulated under the Public Health Service Act through a biologics license application, or BLA. However, biological products are also drugs and must meet drug approval standards under the Federal Food, Drug and Cosmetic Act, including good manufacturing practices regulations, good laboratory practices, and regulations governing clinical trials. Combination products are regulated on the basis of product's primary mode of action and can require approval and/or review by more than one regulatory center of the FDA.

#### Clinical Trial Process

Development of a therapeutic product for human use under applicable laws and regulations is a multi-step process. First, in vitro and/or animal testing must be conducted in a manner consistent with good laboratory practices to establish the potential safety and effectiveness of the experimental product with regard to a given disease. Before human clinical trials may begin for new drugs and biologics, and an investigational new drug ("IND") application containing, among other things, preclinical data, chemistry, manufacturing and control information, an investigative plan, must be submitted to the FDA. The Clinical trials following approval of an IND will also require the approval and oversight by an Institutional Review Board ("IRB") to assure proper patient protection. Clinical trials of certain medical devices generally require the same sort of submission in the form of an application for an investigational device exemption ("IDE"). We believe that the submission of an IND will be adequate for Islet Sciences-P(TM) or Islet Sciences-HTM, and that a separate IDE submission will not be required for either product. Once a trial begins, changes to the investigational product or study protocol may require prior approval before implementation. There can be no assurance that submission of an IND application or an IDE will result in the ability to commence clinical trials. In addition, the FDA may place a clinical trial on hold or terminate it at any phase if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Finally, pursuant to the FDA's Bioresearch Monitoring ("BIMO") program, the FDA conducts on-site inspections and data audits of the conduct and reporting of all FDA-regulated research. The FDA's BIMO compliance programs address inspections of non-clinical testing labs, clinical investigators, clinical trial sponsors/monitors and IRBs.

Clinical trials of pharmaceuticals or biologics typically involve three phases, although those phases can overlap.

Phase I is conducted to evaluate the basic safety, metabolism, and pharmacology, and pharmacokinetics, and to identify potential side effects with escalating doses, the maximum tolerated dose of the experimental product in humans, and if possible, to begin to evaluate various routes, dosages, and schedules of product administration. These studies are often conducted in healthy subjects. Phase I trials are not intended to find early indications of effectiveness; however, it is not uncommon to evaluate these endpoints.

Phase I/II clinical trials are conducted to evaluate safety and initial efficacy indications in the patient population afflicted with a specific disease or condition for which the product is intended for use.

Phase II clinical trials are conducted in groups of patients afflicted with a specific disease or condition for which the product is intended for use in order to further test safety, begin evaluating effectiveness, optimize dosage amounts and determine dose schedules and routes of administration.

Phase III studies are usually randomized, double blind studies testing for product safety and effectiveness in an expanded patient population in order to evaluate the overall risk/benefit relationship of the product and to provide an

adequate basis for product labeling. These studies also may compare the safety and effectiveness of the product with currently available products.

## **Biologics Approval Process**

Following our completion of clinical investigations, the preclinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, are submitted to the FDA in a Biologics License Application or BLA. The FDA may refuse to accept a BLA for filing if certain content criteria are not met and may require additional information, including clinical data, before approval. To approve a BLA, the agency must determine, among other things that the product is safe, pure, and potent, and that any facility in which it is manufactured, processed, packed or held, meets standards designed to assure the product's continued safety, purity, and potency.

If the FDA approves a BLA, we will need to continue to be compliant with strict FDA requirements concerning good manufacturing practices, enforced by periodic inspections, and adverse event reporting, as well as with any special requirements imposed as a part of the BLA approval, in addition to numerous other FDA regulatory requirements applicable to drugs and biological products. With certain exceptions, changes to the labeling of approved biological products require approved supplemental applications. In addition, a supplemental application is required to be submitted to the FDA for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as may relate to the safety or effectiveness of the product. These supplemental applications may require the submission of clinical or comparability data and require FDA approval before the product may be marketed as modified. The approval process is lengthy, expensive, and uncertain.

#### Labeling and Advertising

The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in an FDA approval. Claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetics Act. FDA has primary responsibility for enforcing laws against false advertising and promotion of prescription drug products. Violations of the Federal Food, Drug, and Cosmetics Act, Public Health Service Act, or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including voluntary or mandatory recall, license suspension or revocation, pre-market approval withdrawal, seizure of products, fines, injunctions, and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on us.

The advertising of our products will also be subject to regulation by the Federal Trade Commission, under the FTC Act. The FTC Act prohibits unfair methods of competition and unfair or deceptive acts in or affecting commerce.

Violations of the FTC Act, such as failure to have substantiation for product claims, would subject us to a variety of enforcement actions, including compulsory process, cease and desist orders, and injunctions. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, and restitution. Violations of FTC enforcement orders can result in substantial fines or other penalties.

#### Foreign Regulation

Outside the United States our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with FDA approval described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

## **Employees**

As of August 12, 2013, the Company had no employees. The Company utilizes the services of consultants and advisors. These include its principal executive officer, chief financial officer, scientific personnel, accountants, and attorneys. Some of these positions, especially those of a technical nature, may be converted to employment if and when the Company's business requires and resources permit.

## Scientific Advisory Board

The Company also maintains a Scientific Advisory Board of eight outside consultants, six of which have doctoral degrees. These consultants are as follows:

#### Chair - Jonathan Lakey, PhD – MSM

Dr. Jonathan Lakey has had a long history in cell and tissue transplantation with a focus on diabetes and islet transplantation. He has been an associate professor at the Department of Biomedical Engineering, Henry Samueli School of Engineering, University of California, Irvine since 2010, and associate professor at the Department of Surgery, University of California, Irvine since 2008. From 2006 to 2008, Dr. Lakey was the president and chief scientific officer of MicroIslet Inc., a publicly traded company engaged in the development of treatment for diabetes. He is a former Director of the Comprehensive Tissue Bank. His contributions and partnership with Dr. James Shapiro led towards the improvement of islet isolation techniques and the development of the "Edmonton Protocol" for patients with type 1 diabetes, a recognized major advancement in the treatment of diabetes. He has been awarded research grants and awards for diabetes and transplantation research from the Alberta Heritage Foundation for Medical Research (AHFMR), Canadian Diabetes Association and the Juvenile Diabetes Foundation International (JDFI). Dr. Lakey is widely sought after as a speaker in the field of diabetes islet transplantation and regulatory standards of cell and tissue transplantation. He has been widely published with over 250 referred scientific papers, 26 book chapters, submitted over 500 scientific abstracts, and has recently published a technical book on islet isolation. Among his proudest achievements, Dr. Lakey and his team have successfully trained over 40 islet transplant centers worldwide in replicating the Edmonton Protocol, resulting in diabetic patients being freed from exogenous insulin injections. He sits on editorial boards of several diabetes and transplantation journals, reviews manuscripts for several journals, and has served as a Counselor for Cell Transplant Society. He graduated from the University of Alberta (BSc, MSc, PhD) and received postdoctoral training in Indianapolis and Seattle before returning to establish his research program at the University of Alberta.

#### Paul Johnson, MBChB MD FRCS

Director of Oxford Islet Transplant Programme and Professor of Paediatric Surgery, University of Oxford. Dr. Johnson also currently serves as President of the International Pancreas and Islet Transplant Association. Paul Johnson qualified in medicine from the University of Leicester and subsequently trained in General Surgery in Leicester and Derby, followed by higher surgical training in Paediatric Surgery in Oxford, Melbourne, and Great Ormond Street Hospital in London. Between 1993 and 1996 he was a Research Fellow in the Department of Surgery at the University of Leicester, where he undertook a project on the Isolation of Human Islets of Langerhans for Pancreatic Islet Transplantation. This led to a Doctorate of Medicine and started his ongoing interest in the field of Islet Transplantation for reversing type 1 diabetes. He was awarded a Hunterian Professorship from the Royal College of Surgeons of England for this research in 1998. In 2002, Mr. Johnson was appointed Director of the Islet Transplant Programme in Oxford. He is currently Chairman of the Research division of British Association of Paediatric Surgeons Research and Clinical Effectiveness Committee, Founder of the UK Academic Paediatric Surgeons Group and Co-Secretary of the International Pancreas and Islet Transplantation Association. He is also Clinical Tutor at St. Edmund Hall. He has an active research group and his research interests include ways of optimizing the current

methods used for islet isolation with particular reference to pancreatic structure and collagenase, and the developmental biology of the pancreas and foregut with particular relevance to the use of adult stem cells as an alternative source of islet tissue for transplantation. In addition to islet transplantation, his clinical interests include the neonatal and pediatric pancreas (endocrine and exocrine), as well as other aspects of pediatric surgical gastroenterology.

#### Steven Paraskevas, MD PhD

Dr. Paraskevas is a transplant surgeon at McGill University Health Centre, specializing in pancreas and kidney transplantation. Originally from Winnipeg, Dr. Paraskevas obtained a BA in Biology at Harvard University in 1988, and obtained his MD and completed General Surgery Residency at McGill. During that time, he also studied mechanisms of cell death in transplanted human islets, completing a PhD in Experimental Surgery at McGill in 2003. Based on this work, he also earned the Scientific Trainee Award of the Canadian Diabetes Association in 1997. After residency, he completed a two-year fellowship in abdominal solid-organ transplantation at the University of Minnesota, where he was also involved in the clinical islet transplant program under Dr. Bernhard Hering. He returned to McGill in 2002 as Assistant Professor in Surgery, and member of the multi-organ transplant program. He is currently Director of the Pancreas and Islet Transplant Program and of the Human Islet Isolation Laboratory at McGill. His current research focuses on mechanisms of cell survival during ischemia and the effect of metabolic and inflammatory stress on engraftment of human islets. He is a Councillor-at-large of the Canadian Society of Transplant Surgeons.

#### Christian Mende, MD

Dr. Christian Mende is clinical professor of medicine at the University of California, San Diego, and a Fellow of the American College of Physicians, the American Society of Hypertension, Nutrition, and Nephrology. He is board certified in nephrology, internal medicine and clinical hypertension. Dr. Mende has been widely published in scientific journals such as the American Journal of Nephrology, the Journal of Nuclear Medicine and Kidney International. Dr. Mende attended the University of Heidelberg, Germany, and completed his internal medicine residency in Tucson, Arizona. He received postgraduate training as a National Institutes of Health fellow in nephrology, at Peter Bent Brigham Hospital, and Harvard Medical School.

#### Morton Printz, MD, PhD

Dr. Morton Printz is Professor Emeritus in Pharmacology at the University of California San Diego. Dr. Printz trained at the University of Pittsburgh receiving a B.Sc. degree (Pharmacy) and a Ph.D. in Biophysics. Following postdoctoral training at Dartmouth and an appointment at Rockefeller University, he joined the UC San Diego School of Medicine in 1972. His research at Dartmouth and Rockefeller focused on conformational dynamics of nucleic acids, peptides and proteins using the newly developed method of tritium-hydrogen exchange (THX). Conformational studies on angiotensin and angiotensinogen led to research on hypertension, specifically origins of essential hypertension and metabolic syndrome. In addition to NIH RO1 and other grants, he was Director of an NIH-NHLBI funded Specialized Center or Research Program in hypertension (SCOR-Hypertension) and subsequently Director of four NIH Program Project Grants on hypertension mechanisms. He has been involved as collaborator, researcher and advisor in investigations on eicosanoid mechanisms in hypertension, ductus arteriosus, blood vessels, cardiac remodeling and asthma, and biotech-funded special projects related to drug development for metabolic syndrome and hypertension. Using a rat recombinant inbred strain colony he has conducted original, collaborative and advisory studies with these strains on hypertension genetics, stress-cardiovascular response, metabolic syndrome, insulin resistance, behavior, gonadal radiation sensitivity and anthrax toxin. His recent research has focused on brown adipose tissue and the origins of hypertension, insulin resistance and metabolic syndrome.

#### Kevan Harold, MD, PhD

Dr. Harold is a Professor of Immunobiology and Medicine at Yale University. His work in the field of type 1 diabetes is well known, including his pioneering work with Dr. Jeff Bluestone that showed the efficacy of anti-CD3 mAb treatment of type 1 diabetes. His work is translational, bridging the fields of basic immunology, clinical trials, and clinical medicine, which will enable this Program to rapidly move advances in preclinical studies to clinical testing.

Much of his recent work pertains to the mechanisms of immune regulation by anti-CD3 mAb in patients, which forms the basis for studies in this Program. He has long standing collaborations with Dr. Bluestone and with Dr. Mattias von Herrath. Finally, Dr. Herold is the Principal Investigator on 3 clinical trials supported by the Immune Tolerance Network, and TrialNet. Dr. Herold is an Endocrinologist with a special interest in autoimmune diseases and diabetes and sees both adolescent and adult patients with all forms of diabetes and other metabolic disorders. Dr. Herold is conducting research on immunotherapy for treatment of type 1 diabetes. Dr. Harold's laboratory work involves studies of induction of immunologic tolerance to autoimmunity.

Eitan M. Akirav, PhD

Research Scientist and Assistant Professor of Research, Diabetes and Obesity Research Center, Winthrop-University Hospital Research Institute and Stony Brook University School of Medicine.

#### Elliot Botvinick, PhD

Dr. Elliot Botvinick is an Assistant Professor at the University of California, Irvine with appointments in Biomedical Engineering and Surgery. He is on the faculty of the Beckman Laser Institute and the Edwards Lifesciences Center for Advanced Cardiovascular Technology. Dr. Botvinick is also a founder of Metronom Health, Inc., which is developing a next generation monitoring system for the treatment of type 1 diabetes. Dr. Botvinick received his Ph.D. from the University of California, San Diego while conducting research in the Laboratories of Jeffrey Price, M.D., Ph.D. and David Gough, Ph.D. Dr. Botvinick then received the prestigious Arnold and Mabel Beckman Foundation Fellowship to develop laser microbeam instrumentation. With this technology Dr. Botvinick measures the push-pull relationship between cells and their surrounding stroma. Applications include (1) the pancreatic islet cell microenvironment, (2) the molecular biophysics of the Notch1 receptor, a pathway critical in the differentiation of pluripotent cells into pancreatic islets and (3) new strategies to perfuse tissues within immunoisolation devices. Dr. Botvinick has received funding from the National Science Foundation, the National Institutes of Health and the Air Force office of Scientific Research.

## **Emerging Growth Company**

The Company is an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404(b) of the Sarbanes-Oxley Act, and exemptions from the requirements of Sections 14A(a) and (b) of the Securities Exchange Act of 1934 to hold a nonbinding advisory vote of shareholders on executive compensation and any golden parachute payments not previously approved.

The Company has elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We will remain an "emerging growth company" until the earliest of (1) the last day of the fiscal year during which our revenues exceed \$1 billion, (2) the date on which we issue more than \$1 billion in non-convertible debt in a three year period, (3) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement filed pursuant to the Securities Act of 1933, as amended, or (4) when the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter.

To the extent that we continue to qualify as a "smaller reporting company", as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (1) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (2) scaled executive compensation disclosures; and (3) the requirement to provide only two years of audited financial statements, instead of three years.

## ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this report, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. In that

case, the trading price of our common stock could decline, and you may lose all or part of your investment.

No Assurance of Future Successful Development.

Prospects for companies in the medical industry generally are uncertain given the nature of the industry and, accordingly, investments in medical companies should be regarded as highly speculative.

Our products may not be successfully developed or commercialized, which would harm us and force us to curtail our operations.

We may not be able to obtain regulatory approvals for product candidates we develop, to enter clinical trials for any of our product candidates, or to commercialize any products, on a timely basis or at all. If we are unable, for technological or other reasons, to complete the development, introduction or scale-up of manufacturing of potential products, or if our products do not achieve a significant level of market acceptance, we would be forced to curtail or cease operations.

We will require a supply of designated pathogen free pigs in order to commence and continue human clinical trials.

Under the rules of the Food and Drug Administration, islets used for implantation in humans must come from purpose-bred, pathogen free, vaccinated pigs (referred to as designated pathogen free pigs or DPF pigs), raised in a United States Department of Agriculture certified facility specifically designed for biomedical research purposes. Establishing such a herd requires a clean room facility, a significant amount of time, and veterinary expertise. We have an agreement with a supplier of DPF pigs. If at any time the supplier were to cease providing DPF pigs to us in sufficient quantities, we would be required either to locate another facility which is able to supply DPF pigs, which may not be possible, or to construct and operate our own facility. The cost to construct and operate our own farm facility would materially increase our costs of clinical studies and would likely delay the commencement or continuation of clinical studies for a period of two years or more.

We could also experience substantially increased costs and substantial delays if this supplier or any other facility which will supply DPF pigs, including any facility we operate ourselves, were to become contaminated. In such case there would be a substantial delay before such facility could again deliver DPF pigs. Were any of such events to occur before the commencement of clinical trials such trials might have to be delayed. Were any of such events to occur during clinical trials we may have to halt those clinical trials and could lose the benefit of the data gathered and the costs incurred. We could also lose key staff members and collaborators if clinical trials were substantially delayed. We would be required to continue to pay our operating expenses while we waited to recommence clinical trials and the payment of such expenses may deplete our cash reserves and make it more difficult for us to raise capital for future clinical trials. Our ability to execute our business plan could be threatened as a result of any of these occurrences.

Any product candidate we advance into clinical trials may cause undesirable side effects that could delay or prevent its regulatory approval or commercialization.

Undesirable side effects caused by any product candidate we advance into clinical trials could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing these or any other product candidate we advance into clinical trials.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

While we may seek to take advantage of various regulatory mechanisms intended to accelerate development and approval of our products for the treatment of insulin-dependent diabetes, we may not be able to submit a biologics license application ("BLA") for our products until 2014.

The FDA's accelerated approval process provides the opportunity for regulatory approval based on surrogate, or substitute, endpoints that are reasonably likely to predict clinical benefits. Drugs and biological products that are intended to treat serious or life-threatening diseases and that either demonstrate an improvement over available therapy or provide therapy where none exists, are eligible for this accelerated approval process. We may not successfully complete clinical trials. Even if clinical trials were successfully completed, there are no assurances that the FDA will accept a BLA on the basis of a single study or review the BLA under the accelerated approval regulations. Failure to obtain review on the basis of a single study or accelerated approval could require us to complete additional and more extensive clinical trials, which would be costly and time consuming and delay potential FDA approval for several years. Even if we are able to obtain accelerated approval from the FDA, the FDA still may not grant our product full approval for commercial sale. The FDA would likely require that we conduct additional post-approval clinical studies as a condition of any approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address an unmet medical need for this condition, the drug sponsor may apply for FDA fast track designation. In addition to the benefits of accelerated approval, fast track designation may lead to designation for priority FDA review, which can be completed in as short of a period as six months, and the ability to submit portions of an application on a rolling basis, as they become available, for required FDA review. Any fast track designation we may obtain may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data from our clinical development program or if a competitor's product is approved for the indication we are seeking and our product is not determined to offer any additional therapeutic advantage to that competitor's product. Any fast track designation we may obtain will not guarantee that we will qualify for or be able to take advantage of the priority review procedures following the submission of a BLA. Additionally, if fast track designation were to be withdrawn for any product for which we obtain such designation, our ability to receive FDA approval could be delayed considerably.

If we receive regulatory approval we will also be subject to ongoing FDA obligations and continued regulatory review such as continued safety reporting requirements, and we may also be subject to additional FDA post-marketing obligations. FDA and corresponding foreign regulatory requirements could adversely affect our ability to generate revenue and require additional expenditures to bring our products to market.

Any regulatory approvals that we receive for our products may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. In addition we or our third party manufacturers may be required to undergo a pre-approval inspection of manufacturing facilities by the FDA and foreign authorities before obtaining marketing approval and will be subject to periodic inspection by the FDA and corresponding foreign regulatory authorities under reciprocal agreements with the FDA. Such inspections may result in compliance issues that could prevent or delay marketing approval or require the expenditure of money or other resources to correct noncompliance.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators, or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

Moreover, in order to market any products outside of the United States, we and our collaborators must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks described above regarding FDA approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risk that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and adversely impact potential royalties and product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we or our collaborators fail to comply with applicable domestic or foreign regulatory requirements, we and our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

The transplantation of animal cells into humans involves risks which have resulted in additional FDA oversight and which in the future may result in additional regulation that may prevent or delay approval of our potential products and require additional expenditures to bring these products to market.

Our business involves the transplantation of animal cells into humans, a process known as xenotransplantation. Xenotransplantation poses a risk that viruses or other animal pathogens may be unintentionally transmitted to a human patient. The FDA will require testing to determine whether infectious agents, including porcine endogenous retroviruses, also known as PERV, are present in patients who have received cells, tissues, or organs from porcine sources. While PERV has not been shown to cause any disease in pigs, it is not known what effect, if any, PERV may have on humans.

Other companies are currently conducting clinical trials involving the transplantation of porcine cells into humans. The FDA requires lifelong monitoring of all recipients of xenotransplantation products. If PERV or any other virus or infectious agent is detected in tests or samples from these transplant recipients, the FDA may require that we not initiate or halt our clinical trials and perform additional tests to assess the risk of infection to potential patients. This could result in additional costs to us and delay in the trials of our products under development.

The FDA has published guidelines for development of xenotransplantation products and is continuing to monitor closely the development of such products to determine if additional guidelines are required as more data is obtained. Failure to comply with FDA guidelines may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

If our competitors develop treatments for insulin-dependent diabetes that are approved more quickly, marketed more efficiently or demonstrated to be more effective than our product candidates, our ability to generate revenue will be reduced or eliminated.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new diabetes treatment programs, including both therapies with traditional as well as novel mechanisms of action.

Most of our competitors have significantly greater financial, product development, manufacturing, and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. These companies also have significantly greater research capabilities than us. In addition many universities and private and public research institutes are active in diabetes research, some in direct competition with us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, universities, or research institutes. Our competitors may succeed in developing products for the treatment of insulin-dependent diabetes that are more effective, better tolerated, or less costly than any which we may offer or develop. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their product candidates sooner than we do for ours. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

If we are unable to protect effectively our intellectual property, third parties may use our technology, which could impair our ability to compete in our markets.

Our success will depend on our ability to obtain and protect patents on our technology and to protect our trade secrets. The patents we currently license and any future patents we may obtain or license, may not afford meaningful protection for our technology and products. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated, or unenforceable. In addition our current and future patent applications may not result in the issuance of patents in the United States or foreign countries. Competitors might develop products similar to ours that do not infringe our patents. In order to protect or enforce our patent rights, we may initiate interference proceedings, oppositions, or patent litigation against third parties, such as infringement suits. These lawsuits could be expensive, take significant time, and divert management's attention from other business concerns. The patent position of biotechnology firms generally is highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. No consistent policy has emerged from the U.S. Patent and Trademark Office or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. In addition there is a substantial backlog of biotechnology patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications may take several years.

In addition to patent protection we require our employees, consultants, advisors, and collaborators to execute confidentiality agreements. However, these agreements may not provide us with adequate protection against improper use or disclosure of confidential information. In addition, in some situations, these agreements may conflict with, or

be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may gain access to our trade secrets or independently develop substantially equivalent proprietary information and techniques.

Our success will depend partly on our ability to operate without infringing on or misappropriating the proprietary rights of others. If we are sued successfully for infringement or misappropriation of another's proprietary rights, our ability to generate revenue could be substantially reduced or eliminated.

Any of our anticipated products may infringe patent and other proprietary rights of third parties. In addition, our competitors, many of which have substantially greater resources than us and have made significant investments in competing technologies or products, may seek to apply for and obtain patents that will prevent, limit, or interfere with our ability to make, use, and sell products either in the U.S. or international markets. Intellectual property litigation is costly and even if we prevail, the cost of such litigation could adversely affect our business, financial condition, and results of operations. In addition, litigation is time consuming and could divert management attention and resources away from our business. If we do not prevail in any litigation, we could be required to stop the infringing activity and/or pay substantial damages. Under some circumstances in the United States, these damages could be triple the actual damages the patent holder incurs. If we have supplied infringing products to third parties for marketing or licensed third parties to manufacture, use, or market infringing products, we may be obligated to indemnify these third parties for any damages they may be required to pay to the patent holder and for any losses the third parties may sustain themselves as the result of lost sales or damages paid to the patent holder.

If a third party holding rights under a patent successfully asserts an infringement claim with respect to any of our products, we may be prevented from manufacturing or marketing our infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Any required license may not be available to us on acceptable terms, or at all. Some licenses may be non-exclusive, and therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around a patent, we may be unable to market some of our anticipated products, which would adversely affect our ability to generate and grow revenues.

Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition most countries limit the enforceability of patents against government agencies or government contractors. In these countries the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

We have no commercial production capability and we may encounter production problems or delays, which could result in lower revenues.

To date, we have not produced any commercially available products. To produce product to anticipated customer demand levels we will need to develop our commercial production capability and maintain adequate levels of inventory. We may not be able to produce sufficient quantities to meet market demand. We may not be able to maintain acceptable quality standards if we ramp up production. If we cannot achieve the required level and quality of production, we may need to outsource production or rely on licensing and other arrangements with third parties. We may not be able to successfully outsource our production or enter into licensing or other arrangements under acceptable terms with these third parties, which could adversely affect our business. Our inability to identify potential manufacturers, or to enter into or maintain agreements with them on acceptable terms, could delay or prevent the commercialization of our products, which would adversely affect our ability to generate revenues and could prevent us from achieving or maintaining profitability. In addition reliance on third-party manufacturers could reduce our gross

margins and expose us to the risks inherent in relying on others. We may also encounter problems with production yields, shortages of qualified personnel, production costs, and the development of advanced manufacturing techniques and process controls.

We will be required to comply with good manufacturing practice requirements, and our failure to do so may subject us to fines and other penalties that will delay or prevent us from marketing and selling our products.

We, our collaborators, or other third party manufacturers of our products must comply with current good manufacturing practice, or cGMP, requirements demanded by customers and enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance, and the maintenance of records and documentation. We, our collaborators, or other third party manufacturers of our products may be unable to comply with these cGMP 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. A failure to comply with these requirements may result in criminal and civil penalties, including fines, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied by third-parties is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for, or successfully commercialize, product candidates that we may develop.

We may incur substantial liabilities from any product liability claims, including claims made against third parties that we have agreed to indemnify. Our insurance coverage for those claims may be unavailable or inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an adverse effect or injury. These risks will exist even for products developed that may be cleared for commercial sale. If we cannot successfully defend ourselves against any product liability claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in any one or a combination of the following:

- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates;
- loss of revenues; and
- the inability to commercialize our product candidates.

We intend to secure limited product liability insurance coverage, but we may not be able to obtain such insurance on acceptable terms with adequate coverage, or at reasonable or affordable costs. The amount of insurance coverage we obtain may not be adequate to protect us from all liabilities. We may not have sufficient resources to pay for any liabilities resulting from a claim beyond the limit of, or excluded from, our insurance coverage.

We use biological and hazardous materials in our business. If we are subject to claims relating to improper handling, storage, or disposal of these materials, our financial condition would suffer.

Our research and development processes involve the storage, use, and disposal of hazardous materials, including biological hazardous materials that could be dangerous to human health and safety or the environment. We are subject to federal, state, and local regulations governing the use, manufacture, storage, handling, and disposal of materials and waste products. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts.

In the event of an accident we could be held liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms or at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

We have a limited operating history and are a development stage company.

We started our operations in 2010 with the formation of ISI. To date, we have had no sales and profits. We cannot assure investors that we will ever become or remain profitable. An investment in our securities is subject to all of the risks involved in a newly established business venture. Potential investors should be aware of the problems, delays, expenses, and difficulties experienced by companies in the early developmental stage, which generally include unanticipated problems and additional costs relating to the commencement of operation and implementation of a business plan.

If we cease to continue as a going concern, due to lack of funding or otherwise, you may lose your entire investment in the Company.

Our current plans indicate that we will need substantial additional capital for research and development, including costs associated with developing our technology and conducting clinical trials of our product candidates, before we have any anticipated revenue generating products.

When we require additional funds, general market conditions or the then-current market price of our common stock may not support capital raising transactions such as additional public or private offerings of our common stock. If we require additional funds and we are unable to obtain them on a timely basis or on terms favorable to us, we may be required to scale back our development of new products, sell or license some or all of our technology or assets, or curtail or cease operations.

If we experience significant fluctuations in our rate of anticipated growth and fail to balance our expenses with our revenue forecasts, our results could be harmed and the Company's value may decline without advance notice.

Due to the unpredictability of new markets that we enter and deteriorating general economic and financial market conditions, we may not be able to accurately forecast our rate of growth. We plan our expense levels and investment on estimates of future revenue and future anticipated rate of growth. We may not be able to adjust our spending quickly enough if the rate of new or renewed orders falls short of our expectations. As a result, we expect that our revenues, operating results and cash flows may fluctuate significantly on a quarterly basis. We believe that period-to-period comparisons of our revenues, operating results and cash flows may not be meaningful and should not be relied upon as an indication of future performance.

### Inability to Manage Growth

Although no assurance can be given, the Company contemplates that growth will occur as the Company implements its business strategies. The Company expects the expansion of its business to place a significant strain on its limited managerial, operational, and financial resources. The Company will be required to expand its operational and financial systems significantly and to expand, train, and manage its work force in order to manage the expansion of its operations. The Company's failure to fully integrate new employees into its operations could have a material adverse effect on its business, prospects, financial condition, and results of operations. The Company's ability to attract and retain highly skilled personnel in connection with its growth is critical to its operations and expansion. The Company faces competition for these types of personnel from other biotechnology companies and more established organizations, many of which have significantly larger operations and greater financial, marketing, human, and other resources than does the Company. The Company may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If the Company is not successful in attracting and retaining these personnel, its business, prospects, financial condition, and results of operations will be materially adversely affected.

You may experience dilution of your ownership interests due to the future issuance of additional shares of our common stock.

We may in the future issue our previously authorized and unissued securities, resulting in the dilution of the ownership interests of our common stockholders. We are currently authorized to issue one hundred million shares of common stock and ten million shares of preferred stock with such designations, preferences and rights as determined by our board of directors. Issuance of additional shares of common stock may substantially dilute the ownership interests of our existing stockholders. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with the hiring of personnel, future acquisitions, future public or private placements of our securities for capital raising purposes, or for other business purposes. Any such issuance would further dilute the interests of our existing stockholders.

There has been no active public market for the Company's securities.

There has been no active public market for the Company common stock. An active public market for the Company's common stock may not develop or be sustained. The market price of the common stock may fluctuate significantly in response to factors, some of which are beyond the Company's control, such as product liability claims or other litigation, the announcement of new pharmaceuticals or pharmaceutical enhancements by the Company's competitors, developments concerning intellectual property rights and regulatory approvals, quarterly variations in competitors' results of operations, changes in earnings estimates or recommendations by securities analysts, developments in our industry, and general market conditions and other factors, including factors unrelated to our operating performance.

The Company's common stock may be considered a "penny stock" and may be difficult to sell.

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market or exercise price of less than \$5.00 per share, subject to specific exemptions. The market price of the Company's common stock may be below \$5.00 per share and therefore may be designated as a "penny stock" according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell such shares and may affect the ability of investors to sell their shares. In addition, since the Company's common stock is currently quoted on the OTC Bulletin Board, investors may find it difficult to obtain accurate quotations of the stock and may find few buyers to purchase the stock or a lack of market makers to support the stock price.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could prevent the Company from producing reliable financial reports or identifying fraud. In addition, current and potential stockholders could lose confidence in the Company's financial reporting, which could have an adverse effect on the Company's stock price.

Effective internal controls are necessary for the Company to provide reliable financial reports and effectively prevent fraud, and a lack of effective controls could preclude the Company from accomplishing these critical functions. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), which requires annual management assessments of the effectiveness of the Company's internal controls over financial reporting.

If we fail to maintain the adequacy of our internal accounting controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have an adverse effect on our stock price.

### ITEM 2. PROPERTIES

We use office space at 641 Lexington Avenue, 6th Floor, New York, NY 10022, which is our principal place of business, based on our agreement with the investment relations consultant of the Company that provides this office space to us free of charge.

### ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

In April 2012, Sand Dollar Partners, LLC, a shareholder of the Company filed a complaint in the Superior Court of Arizona, Pima County against, among other parties, ISI, our wholly-owned subsidiary, John Steel, our CEO and director, and Jonathan Lakey, our Director. In 2010 Sand Dollar invested \$357,000 in ISI through the purchase of a convertible promissory note which was converted into 3,591,729 shares of the Company's common stock. The plaintiff contends that it was entitled to issuance of additional shares and nomination of one board member. The plaintiff is seeking rescission of its investment and recovery of the paid consideration, together with interest, attorneys' fees and costs, as well as damages incurred as a result. The complaint filed in Arizona court has been dismissed without prejudice. The plaintiff has re-filed the complaint with fewer claims in the U.S. District Court for the Southern District of California. On February 28, 2013, the Company filed a motion to dismiss the claim which was granted in part and denied in part by the court on April 15, 2013. On May 28, 2013, the Company filed its response to the amended complaint. The Company believes the plaintiff's claims to be without merit and intend to vigorously defend against this action.

In July 2012, a complaint was filed against the Company and John Steel for infringement and misappropriation of MicroIslet patent in the United States District Court for the District of Utah, Central Division. The plaintiffs contend that they were the actual purchasers of the MicroIslet patent out of MicroIslet's bankruptcy proceedings in 2009 and that the respective intellectual property rights have been never assigned to either ISI or the Company. As a result, they allege that the Company's claim to the ownership of the MicroIslet patent based on the assignment of the patent

by its founders are baseless. The complaint seeks monetary damages including punitive damages of at least \$12 million, costs, attorneys' fees, and declaratory judgment. The complaint filed in Utah has been dismissed without prejudice. On July 3, 2013, the plaintiffs filed an amended complaint in the United States District Court for the District of Utah, Central Division. The Company believes the plaintiffs' claims to be without merit and intend to vigorously defend against this action.

### **PART II**

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

### Market for Our Common Stock

Our common stock, \$0.001 par value, is quoted on the OTC Bulletin Board under the symbol "ISLT." The following table shows the high and low closing prices for the periods indicated. The quotations provided below reflect inter-dealer prices without retail mark-up, markdown, or commissions, and may not represent actual transactions. The quotations below reflect a 1-for-45 stock split which was effectuated on February 23, 2012.

Year	High	Low
F: 12012		
Fiscal 2013		
Quarter Ended April 30, 2013	\$ 4.75	\$ 0.15
Quarter Ended January 31, 2013	5.00	1.99
Quarter Ended October 31, 2012	3.10	3.00
Quarter Ended July 31, 2012	6.00	3.00
Fiscal 2012		
Quarter Ended April 30, 2012	\$ 6.00	\$ 1.05
Quarter Ended January 31, 2012	10.306	1.8002
Quarter Ended October 31, 2011	3.6004	0.1575
Quarter Ended July 31, 2011	3.1503	0.1440

As of August 12, 2013, we had 312 shareholders of record. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders. Holders of the common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock.

### Dividends

We have not paid dividends on our common stock and do not anticipate paying such dividends in the foreseeable future.

### Sale of Unregistered Securities

On February 5, 2013, the Company issued 20,000 shares of common stock as a consideration under an exclusive licensing agreement.

On April 1, 2013, the Company issued 5,000 shares of common stock as a settlement consideration.

The foregoing issuances of the shares were effectuated pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), provided by Section 4(2) of the Securities Act and/or Regulation D promulgated thereunder.

Securities authorized for issuance under equity compensation plans

As of the date of this Annual Report, we do not have any securities authorized for issuance under any equity compensation plans and we do not have any equity compensation plans.

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

### SPECIAL NOTE OF CAUTION REGARDING FORWARD-LOOKING STATEMENTS

CERTAIN STATEMENTS IN THIS REPORT, INCLUDING STATEMENTS IN THE FOLLOWING DISCUSSION, ARE WHAT ARE KNOWN AS "FORWARD-LOOKING STATEMENTS", WHICH ARE BASICALLY STATEMENTS ABOUT THE FUTURE. FOR THAT REASON, THESE STATEMENTS INVOLVE RISK AND UNCERTAINTY SINCE NO ONE CAN ACCURATELY PREDICT THE FUTURE. WORDS SUCH AS "PLANS", "INTENDS", "WILL", "HOPES", "SEEKS", "ANTICIPATES", "EXPECTS "AND THE LIKE OFTEN IDENTIFY SUCH FORWARD-LOOKING STATEMENTS, BUT ARE NOT THE ONLY INDICATION THAT A STATEMENT IS A FORWARD-LOOKING STATEMENT. SUCH FORWARD-LOOKING STATEMENTS INCLUDE STATEMENTS CONCERNING OUR PLANS AND OBJECTIVES WITH RESPECT TO THE PRESENT AND FUTURE OPERATIONS OF THE COMPANY, AND STATEMENTS WHICH EXPRESS OR IMPLY THAT SUCH PRESENT AND FUTURE OPERATIONS WILL OR MAY PRODUCE REVENUES, INCOME OR PROFITS. NUMEROUS FACTORS AND FUTURE EVENTS COULD CAUSE THE COMPANY TO CHANGE SUCH PLANS AND OBJECTIVES OR FAIL TO SUCCESSFULLY IMPLEMENT SUCH PLANS OR ACHIEVE SUCH OBJECTIVES, OR CAUSE SUCH PRESENT AND FUTURE OPERATIONS TO FAIL TO PRODUCE REVENUES, INCOME OR PROFITS. THEREFORE, THE READER IS ADVISED THAT THE FOLLOWING DISCUSSION SHOULD BE CONSIDERED IN LIGHT OF THE DISCUSSION OF RISKS AND OTHER FACTORS CONTAINED IN THIS REPORT ON FORM 10-K AND IN THE COMPANY'S OTHER FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION. NO STATEMENTS CONTAINED IN THE FOLLOWING DISCUSSION SHOULD BE CONSTRUED AS A GUARANTEE OR ASSURANCE OF FUTURE PERFORMANCE OR FUTURE RESULTS.

Unless the context otherwise requires, the "Company", "we," "us," and "our," refer to (i) Islet Sciences, Inc., a Nevada corporation; (ii) Islet Sciences, Inc., a Delaware corporation ("ISI"), and (iii) DiaKine Therapeutics, Inc. ("DTI").

### Overview

We are a development stage biotechnology company engaged in the research, development, and commercialization of patented technologies in the field of diabetes.

We are developing the following therapeutic product candidates:

Islet Sciences-PTM, an injectable suspension of microencapsulated insulin-producing, pancreatic islet cells harvested from pathogen free pigs, for the treatment of insulin-dependent diabetes;

# Diagnostic tests to identify early stages of diabetes; and

Small molecules that block inflammatory actions of cytokines that destroy insulin-producing beta cells, for diabetes and diabetes-related complications. The drugs reduce activation of a gene switch called STAT4. Preclinical and genetic studies link STAT4 to several autoimmune diseases such as type 1 diabetes as well as insulin resistance and atherosclerosis.

We are initially focused on developing Islet Sciences-PTM. We believe that Islet Sciences-PTM, a xenotransplantation (transplantation between different species) product, has significantly more commercial potential than human-to-human (allotransplantation) islet replacement approaches, due to the high cost and inherently limited supply of human islets. Islet Sciences-PTM is intended to be administered by injection into the patient's abdominal

cavity, where the transplanted islet cells are expected to produce insulin in response to increases in blood glucose, much like the patient's original pancreatic islet cells did prior to being destroyed by disease. Our development plans include the following with respect to the development of Islet-Sciences-PTM:

file an investigational new drug, or IND, application with the FDA; and

initiate an open-label Phase I/II clinical trial in patients with insulin-dependent diabetes.

We believe that Islet Sciences-PTM should enable the patient to produce insulin within 24 hours after injection. As a result, we anticipate that the Phase I/II trial may provide an objectively measurable clinical effect on patients within a relatively short period of time after the initiation of the trial.

We also plan to develop novel, small molecule immune modulators for diabetes and diabetes-related complications. One lead compound, Lisofylline (LSF), has been the subject of a completed Phase I/II clinical trial and five Phase I clinical trials. In these trials, LSF was well tolerated with no subject experiencing a serious adverse event. In the Phase I/II trial, LSF significantly reduced the plasma levels of several major inflammatory cytokines linked to autoimmunity.

We also licensed the exclusive rights to certain technologies related to the treatment and diagnosis of diabetes, including:

a technology for the measurement of hypomethylated beta cell-derived DNA as a biomarker of beta cell (cells in pancreas that form islets for insulin production) death that may be applied to identify diabetes and islet cell dysfunction at early stages before symptoms arise licensed from Yale University. This groundbreaking technology published by the American Diabetes Association and sponsored by JDRF, (http://diabetes.diabetesjournals.org/content/early/2013/02/14/db12-1207.abstract) describes the potential for this technology to provide a non-invasive and effective means to detect and monitor the progression of beta-cell death associated with diabetes, with the goal of guiding treatment and identifying the disease at a much earlier stage.

a noninvasive method for evaluating beta cell death in the diagnosis of diabetes licensed from Winthrop University that complements the Yale diagnostic. The goal of these combined technologies is to identify the onset of diabetes at an early stage, before the onset of high blood sugar levels (hyperglycemia) associated with the long-term complications of the disease, such as kidney and eye damage.

small molecules for islet expansion licensed from the University of California.

We intend to develop these technologies in partnership with large pharmaceutical or biotechnology companies.

Current diagnosis often occurs only after substantial loss of beta-cell function.

### Going Concern

The financial statements included elsewhere in this current report on Form 10-K have been prepared assuming we will continue as a going concern. We incurred operating losses and negative operating cash flows through April 30, 2013, and as of that date our cash position was \$3,589 and our current liabilities were \$2.5 million. We have incurred net losses of \$11.7 million and negative operating cash flows of \$3.9 million for the fiscal year ended April 30, 2013. Currently, management has projected that additional cash will be needed to allow us to continue our operations through April 30, 2014. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, and the cost of product commercialization. We do not expect to generate a positive cash flow from operations at least until the commercial launch of our first product and possibly later given the expected spending for research and development programs and the cost of commercializing product candidates. During fiscal year ended April 30, 2013, we completed private placements of equity securities for aggregate gross proceeds of \$2.0 million. Although we have had success in raising this capital, there cannot be any assurance that this success will

continue in future periods which is necessary to fund our future capital requirements, research and operations.

### **Results of Operations**

Fiscal Years Ended April 30, 2013 and 2012

There were no revenues for the fiscal years ended April 30, 2013 and 2012.

During the fiscal year ended April 30, 2013, general and administrative expenses totaled \$8.1 million, compared to \$1.9 million for the fiscal year ended April 30, 2012. The primary reason for the \$6.2 million increase in general and administrative expenses was an increase in: stock-based compensation expense – related parties of \$2.4 million; stock-based compensation for consulting services of \$2.6 million; travel expenses of \$0.3 million; legal and professional fees of \$0.5 million; along with general increase in the Company's activities and operations.

During the fiscal year ended April 30, 2013, research and development expenses totaled \$4.1 million, compared to \$1.8 million for the fiscal year ended April 30, 2012. In January 2012, the Company entered into a ten year service contract with Progenitor Cell Therapy, LLC ("PCT") for contract research, development, manufacturing, testing and commercialization of its cell-based therapies. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations, \$0.9 million related to this contract. On July 23, 2012, the Company entered into a long-term supply agreement with Spring Point Project, a source animal facility to purchase pigs for use in the Company's xenotransplantation research. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations, \$1.0 million related to this contract. In addition, the Company issued \$0.4 million worth of stock compensation expense for licensing agreements and consulting services that were charged to research and development expense for the year ended April 30, 2013.

During the fiscal year ended April 30, 2013, the Company recognized \$0.4 million of other income as payment from a third party in connection with an agreement to indemnify the Company against litigation. During the fiscal year ending April 30, 2012, other expenses totaled \$1.3 million, which were primarily comprised of acquisition costs related to the Reverse Merger Transaction.

# Liquidity and Capital Resources

We have historically financed our operations primarily through the issuance of common stock and debt and by relying on other financing. We have not generated revenues from sales of products and have had losses since inception. We anticipate that we will incur substantial additional operating losses in future years as we progress in our research and development programs. We do not expect to produce revenues from product sales for the foreseeable future so our revenues will be limited to research grants we are able to obtain.

We will need additional funding, either through equity or debt financings or partnering arrangements, or we will be forced to curtail or cease operations. As of April 30, 2013, we had \$3,589 cash on hand. The Company has no available or negotiated credit facilities with third party lenders.

### **Operating Activities**

During the fiscal years ended April 30, 2013 and 2012, cash used in operating activities was \$3.9 million and \$2.1 million, respectively. The increase in use of cash is primarily attributable to an increase in our research and development efforts and overall general operating expenses which resulted in a net losses of \$11.7 million offset by the accumulation of \$2.0 million of payables for delayed payments to our vendors due our cash position and non-cash expenses from the issuance of common stock issued as compensation and for services of \$5.6 million.

### Financing Activities

During the fiscal year ended April 30, 2013, cash provided by financing activities was \$2.0 million compared to \$4.0 million during the fiscal year ended April 30, 2012. Of the total net cash provided by financing activities, \$1.9 million was from the net proceeds from the private placement of common stock that has both been issued and not been issued at year end.

### **Critical Accounting Policies**

Our significant accounting policies are disclosed in Note 2 to our financial statements. Certain of our policies require the application of management judgment in making estimates and assumptions which affect the amounts reported in the financial statements and disclosures made in the accompanying notes. Those estimates and assumptions are based on historical experience and various other factors deemed to be applicable and reasonable under the circumstances. The use of judgment in determining such estimates and assumptions is by nature, subject to a degree of uncertainty. Accordingly, actual results could differ from the estimates made.

### **Intangible Assets**

Intangible assets represents a patent acquired from a third party, which is recorded at cost and amortized over the remaining life of the patent. Intangible assets also include the purchase of Diakine Therapeutics, Inc. patent portfolio and know-how as in-process research and development. The intangible assets with estimable useful lives are amortized on a straight line basis over their respective estimated useful lives to their estimated residual values. This method of amortization approximates the expected future cash flow generated from their use. Definite lived intangibles are reviewed for impairment in accordance with FASB ASC 360, Property, Plant and Equipment.

### Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the identifiable assets acquired and liabilities assumed in business acquisitions. Goodwill is reviewed at least annually for impairment in the fourth quarter of the fiscal year, at the Company level, which is the sole reporting unit, and at any other time at which events occur or circumstances indicate that the carrying amount of goodwill may exceed its fair value. Such indicators would include a significant reduction in the Company's market capitalization, a decrease in operating results or a deterioration in the Company's financial position.

### Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, contract services and other outside expenses. Research and development costs are charged to operations when incurred.

### **Stock Based Compensation**

### Stock awards

FASB ASC 718, Compensation-Stock Compensation (FASB ASC 718), requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under FASB ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each stock award is estimated on the date of grant using the then available price of shares that have most recently been traded or sold through a private

offering and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period. The Company accounts for share-based payments to non-employees, with guidance provided by ASC 505-50, "Equity-Based Payments to Non-Employees". The Company currently has not issued any stock options.

### Warrants

Warrants granted to service providers are normally valued at the fair value of the instrument on the date of the grant (grant date) and are recognized in the statement of operations over the requisite service period or when they vest. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Black-Scholes Method. Warrants issued in connection with capital raises are normally valued at the fair value of the instrument on the date of the grant (grant date) and valued for disclosure purposes if they meet all the criteria under FASB ASC 718. The Company values these warrant using the Black-Scholes Method as well. As allowed by FASB ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average volatilities of a sampling of companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation.

### Off-Balance Sheet Arrangements

We do not have off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as "special purpose entities" (SPEs).

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Company's consolidated audited financial statements for the fiscal years ended April 30, 2013 and 2012, together with the report of the independent certified public accounting firm thereon and the notes thereto, are presented beginning at page F-1.

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

None.

### ITEM 9A. CONTROLS AND PROCEDURES

### Disclosure Controls and Procedures

The Securities and Exchange Commission defines the term "disclosure controls and procedures" to mean controls and other procedures of an issuer that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. The Company maintains such a system of controls and procedures in an effort to ensure that all information which it is required to disclose in the reports it files under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified under the SEC's rules and forms and that information required to be disclosed is accumulated and communicated to principal executive and principal financial officers to allow timely decisions regarding disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report.

### Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the (i) effectiveness and efficiency of operations, (ii) reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and (iii) compliance with applicable laws and regulations.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of the end of the period covered by this report. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. Based on our assessment, we determined that, as of the end of the period covered by this report, our internal control over financial reporting was not effective based on those criteria.

During our assessment of the effectiveness of internal control over financial reporting as of the end of the period covered by this report, management identified the following material weaknesses:

- 1. Lack of Internal Audit Function We lack qualified resources to perform the internal audit functions properly as well as oversight of recording and reporting of information. In addition, the scope and effectiveness of the internal audit function are yet to be developed.
- Review of Financial Information and Financial Reporting We do not have adequate levels of review of financial information necessary to ascertain the accounting for complex transactions as well as review of financial information presented.
- 3. Lack of Segregation of Duties We do not have segregation of duties between recording, authorizing and testing.

### Remediation Initiative

We are developing a plan to ensure that all information will be recorded, processed, summarized and reported accurately, and as of the date of this report, we have taken the following steps to address the above-referenced material weakness in our internal control over financial reporting:

- 1. We will continue to educate our management personnel to increase its ability to comply with the disclosure requirements and financial reporting controls; and
- 2. We will increase management oversight of accounting and reporting functions in the future; and
- 3. As soon as we can raise sufficient capital or our operations generate sufficient cash flow, we will hire additional personnel to handle our accounting and reporting functions.

While the first two steps of our remediation process are ongoing, we do not expect to remediate the weaknesses in our internal controls over financial reporting until the time when we start to commercialize our products (and, therefore, may have sufficient cash flow for hiring sufficient personnel to handle our accounting and reporting functions).

A material weakness (within the meaning of PCAOB Auditing Standard No. 5) is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of the company's financial reporting.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm because as a smaller reporting company we are not subject to Section 404(b) of the Sarbanes-Oxley Act of 2002.

### Changes in Internal Controls over Financial Reporting

No change in our system of internal control over financial reporting occurred during the fourth quarter of the fiscal year ended April 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### ITEM 9B. OTHER INFORMATION

Mr. John Steel has agreed to advance to the Company up to \$160,000 during any fiscal year. In May 2013, Mr. Steel increased his loan to the Company by \$17,500 for a total of \$27,500. The Company has issued promissory notes to the CEO in the aggregate principal amount of \$27,500.

### **PART III**

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth certain information as of August 12, 2013 concerning our directors and executive officers:

Name		Age	Position
Joel D. Perlin	67		Vice-President and Director
Richard Egan	61		Chief Financial Officer
John Steel	54		Director
Jonathan Lakey	49		Chief Scientific Officer, Director

John Steel was the Chairman and Chief Executive Officer of the Company at April 30, 2013. Effective July 9, 2013, Mr. Steel resigned as an officer and Chairman of the Company. On July 15, 2013, Mr. Michael Earley was appointed as the Chairman and Chief Executive Officer of the Company. On July 30, 2013, Mr. Earley resigned from his positions at the Company. Dr. Jerry Nadler was a director of the Company at April 30, 2013. He resigned on August 4, 2013.

Joel D. Perlin, age 67, has been the President of H.S. Perlin Co., Inc. since 2002. After his graduation from the San Diego State University in 1969, he began to pursue a career in the gold and rare coin industry. He has since become a renowned professional numismatist and a recognized expert in international gold trade and advisory. Mr. Perlin combines his coin expertise with a keen insight into factors affecting the precious metals trade, resulting in highly successful and lucrative gold investment market trading for his clients. For more than 40 years, he has been instrumental in developing personalized investment portfolios using both rare coins and U.S. gold coins for high net worth investors, corporate pension plans and financially private investors. Mr. Perlin receive his B.S. degree in marketing from the San Diego State University in 1969. We believe that Mr. Perlin's expertise in financial matters based on his extensive experience in international gold trade and advisory positions him well as our director.

Richard Egan, age 61, has been the Chief Financial Officer of Islet Sciences, Inc. since October 2011. Mr. Egan brings twenty five years of finance experience in the software and telecommunications industries. Mr. Egan held the following positions throughout his career: CFO of American Internet Services, LLC (business to business collocation facilities) from July 2008 to December 2009; CFO of QThink, Inc. (integrated circuit design firm) from February 2007 to July 2008; CFO of Global Wireless Entertainment, Inc., dba Skinit.com (internet commerce and licensed content company), from January 2006 to December 2006; CFO of Powernet Global Communications (telecommunications services), from May 2004 to December 2005; CFO and Vice-President of Digineer, Inc. (business intelligence software, custom software development), from 1987 to 2003. Mr. Egan received his B.S. degree in economics from the University of Cincinnati.

John Steel, age 54, was the President and CEO of Islet Sciences, Inc. from June 2010 until July 9, 2013. Mr. Steel brings over twenty years of senior management and investment experience in the healthcare services and biotechnology sector. In 1998, Mr. Steel founded MicroIslet, Inc., the firm that pioneered and developed the technology that comprises Islet Sciences, Inc., and served as its Chairman and Chief Executive Office from September 1998 to 2002. In 2002 MicroIslet, Inc. became public trough a merger with ALD Services, Inc. and Mr. Steel became Chairman and CEO of the public company, in which capacity he served until 2007. From January 1996 to December

1997, Mr. Steel was Chief Executive Officer of AKESIS Pharmaceuticals, Inc., a company that developed a patented treatment for insulin resistance for Type II diabetes. From 1996 to 2007 Mr. Steel served as a director of AKESIS Pharmaceuticals, Inc., which became a public company in December 2004 through a merger with Liberty Mint, Ltd. From January 1987 to June 1990, Mr. Steel served as the Vice President of Defined Benefit Inc., a company he founded in 1986 that provided financial services to health care professionals. After Defined Benefit Inc., Mr. Steel was an active investor and consultant within numerous areas including early-stage biotechnology and device companies through Steel Management. Mr. Steel himself is diagnosed with type 1 diabetes and is actively involved in fund raising for various diabetes research-related charities. Mr. Steel has recently chaired panels regarding the future of diabetes for the California Insurance Commissioner. Mr. Steel is also a noted speaker on the topic of diabetes - including its management, economics, and future opportunities for improvement in therapeutic modalities. Mr. Steel received his M.B.A. degree with an emphasis in finance from the University of Southern California and a Bachelor of Arts degree from Dartmouth College. We believe that Mr. Steel's qualifications and his extensive experience with biotechnology companies developing treatments for diabetes provide a unique perspective for our board.

Dr. Jonathan Lakey, age 49, has had a long history in cell and tissue transplantation with a focus on diabetes and islet transplantation. He has been an associate professor at the Department of Biomedical Engineering, Henry Samueli School of Engineering, University of California, Irvine since 2010, and associate professor at the Department of Surgery, University of California, Irvine since 2008. From 2006 to 2008, Dr. Lakey was the president and chief scientific officer of MicroIslet Inc., a publicly traded company engaged in the development of treatment for diabetes. He is a former Director of the Comprehensive Tissue Bank. His contributions and partnership with Dr. James Shapiro led towards the improvement of islet isolation techniques and the development of the "Edmonton Protocol" for patients with type 1 diabetes, a recognized major advancement in the treatment of diabetes. He has been awarded research grants and awards for diabetes and transplantation research from the Alberta Heritage Foundation for Medical Research (AHFMR), Canadian Diabetes Association and the Juvenile Diabetes Foundation International (JDFI). Dr. Lakey is widely sought after as a speaker in the field of diabetes islet transplantation and regulatory standards of cell and tissue transplantation. He has been widely published with over 250 referred scientific papers, 26 book chapters, submitted over 500 scientific abstracts, and has recently published a technical book on islet isolation. Among his proudest achievements, Dr. Lakey and his team have successfully trained over 40 islet transplant centers worldwide in replicating the Edmonton Protocol, resulting in diabetic patients being freed from exogenous insulin injections. He sits on editorial boards of several diabetes and transplantation journals, reviews manuscripts for several journals, and has served as a Counselor for Cell Transplant Society. He graduated from the University of Alberta (BSc, MSc, PhD) and received postdoctoral training in Indianapolis and Seattle before returning to establish his research program at the University of Alberta. We believe that Dr. Lakey's qualifications and his extensive scientific experience in the development of treatments for diabetes provide a unique perspective for our board.

Our directors hold their positions on the board until our next annual meeting of the shareholders, and until their successors have been qualified after being elected or appointed. Officers serve at the discretion of the board of directors.

There are no family relationships among our directors and executive officers. There is no arrangement or understanding between or among our executive officers and directors pursuant to which any director or officer was or is to be selected as a director or officer, and there is no arrangement, plan or understanding as to whether non-management shareholders will exercise their voting rights to continue to elect the current board of directors.

Our directors and executive officers have not, during the past ten years:

had any bankruptcy petition filed by or against any business of which was a general partner or executive officer, either at the time of the bankruptcy or within two years prior to that time,

been convicted in a criminal proceeding and is not subject to a pending criminal proceeding,

been subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities, futures, commodities or banking activities; or

been found by a court of competent jurisdiction (in a civil action), the Securities Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacate

### **Board Committees**

We currently do not have standing audit, nominating or compensation committees. Currently, our entire board of directors is responsible for the functions that would otherwise be handled by these committees. We intend, however, to establish an audit committee, a nominating committee and a compensation committee of the board of directors as soon as practicable. We envision that the audit committee will be primarily responsible for reviewing the services performed by our independent auditors, evaluating our accounting policies and our system of internal controls. The nominating committee would be primarily responsible for nominating directors and setting policies and procedures for the nomination of directors. The nominating committee would also be responsible for overseeing the creation and implementation of our corporate governance policies and procedures. The compensation committee will be primarily responsible for reviewing and approving our salary and benefit policies (including stock options), including compensation of executive officers.

### Audit Committee Financial Expert

The Board of Directors has determined that Joel D. Perlin is our Audit Committee financial expert, as defined under Item 407(d)(5)(i) of Regulation S-K.

### Code of Ethics

We do not have a code of ethics but intend to adopt one in the near future.

### Section 16(a) Beneficial Reporting Compliance

Directors, executive officers and holders of more than 10% of our outstanding common stock are required to comply with Section 16(a) of the Securities Exchange Act of 1934, which requires generally that such persons file reports regarding ownership of transactions in securities of the Company on Forms 3, 4, and 5. Below is the information with respect to failures of directors, officers and/or beneficial owners of more than ten percent of any class of equity securities of the Company to timely file reports under Section 16(a):

		Date of	Required	
		Reporting	Filing	Date of
Name	Form	Event	Date	Filing
Charles	3	12/30/2011(1)	1/9/2012	Not filed
Dupont				
Charles	3	12/30/2011(1)	1/9/2012	Not filed
Rhodes				

(1) Date of issuance of shares of the Company's convertible preferred stock.

### ITEM 11. EXECUTIVE COMPENSATION

The following is a summary of the compensation we paid to our executive officers, for the two fiscal years ended April 30, 2013 and 2012.

# **Summary Compensation Table**

Name and		Salary	Stock Awards	All Other CompensationTotal	
Position	Year	(\$)	(\$)	(\$)	(\$)
John Steel, CEO	2013	212,500	1,074,149	15,274	1,301,923
	2012	128,880	205,667	10,132	344,679
Richard Egan, CFO	2013	122,990	280,000	-	402,990
	2012	43,469	5,000	-	48,469

- (1) Mr. Steel resigned as our Chief Executive Officer, President, and Secretary on July 9, 2013.
- (2) Mr. Egan was appointed as our Chief Financial Officer on December 30, 2011. During the fiscal year ended April 30, 2013, Mr. Egan was awarded a stock grant of 200,000 shares, all of which vested on January 31, 2013 valued at \$1.40 per share.

Compensation Discussion and Analysis

### Overview

We intend to provide our named executive officers (as defined in Item 402 of Regulation S-K) with a competitive base salary that is in line with their roles and responsibilities when compared to peer companies of comparable size in similar locations.

### **Employment Agreements**

### John Steel

On March 1, 2012, the Company and Mr. John Steel entered into an employment agreement (the "CEO Employment Agreement") for his service as the Company's Chief Executive Officer for a term of five years. The CEO Employment Agreement is automatically renewable for an additional year unless either party notifies the other at least 30 days prior to the end of the term of an intention to terminate. Under the CEO Employment Agreement, Mr. Steel is compensated with an annual salary of \$180,000, payable monthly in equal installments in arrears. He also received the following stock awards: (i) 866,668 shares of common stock which are not subject to any vesting conditions or subject to forfeiture, (ii) 866,668 shares of common stock, of which 433,334 shares shall be subject to forfeiture if Mr. Steel's employment is terminated before the first anniversary of the date of the agreement and 433,334 shares of which shall be subject to forfeiture if Mr. Steel's employment is terminated before the second anniversary of the date of the agreement, and (iii) 200,000 shares of common stock as a bonus for the closing of the acquisition of DiaKine Therapeutics, Inc., which shares vest upon issuance.

In the event that Mr. Steel's service as the Company's CEO is terminated, whether involuntarily or voluntarily, under certain circumstances, or following the occurrence of a Change of Control, as defined under the Employment Agreement (the "Separation from Service"), Mr. Steel shall receive: (i) a lump sum payment of fifteen times of Mr. Steel's annual salary; (ii) common stock equal to 3% of then outstanding common stock; and (iii) continuing health insurance benefits for two years after the occurrence of Change of Control. Additionally, all unvested options, restricted stock, performance shares and stock appreciation rights previously granted to Mr. Steel will immediately be fully vested upon his Separation from Service.

In the event that the above payments and benefits to Mr. Steel upon his Separation from Service following a Change of Control (the "Separation Parachute Payments") would (i) constitute a parachute payment within the meaning of Section 280G of the Internal Revenue Code of 1986 (the "Code") or any similar or successor provision to 280G; and (ii) be subject to the excise tax imposed by Section 4999 of the Code or any similar or successor provision to Section 4999 (the "Excise Tax"), then such Severance Parachute Payments shall be reduced to the largest amount which would result in no portion of the Severance Parachute Payments being subject to the Excise Tax, at the discretion of Mr. Steel.

Mr. Steel resigned as the Chief Executive Officer of the Company effective July 9, 2013.

### Richard Egan

On April 1, 2012, the Company and Richard Egan entered into a consulting agreement (the "CFO Agreement") for his service as the Company's Chief Financial Officer for a term of two years. Under the CFO Agreement, Mr. Egan is compensated on an hourly basis at the rate of \$150 per hour, payable monthly in equal installments in arrears. He also received a stock award of 200,000 shares of common stock of which 150,000 shares of common stock shall be subject to forfeiture if Mr. Egan's employment is terminated before January 31, 2013.

### Outstanding Equity Awards at Fiscal Year End

The following table reflects the unexercised options, stock that has not vested and equity incentive plan awards for each named executive officer outstanding as of the end of the fiscal year ended April 30, 2013:

	Stock Awards				
			Equity	Equity	
			Incentive	Incentive Plan	
			Plan	Awards:	
			Awards:	Market or	
			Number of	Payout Value	
			Unearned	of Unearned	
			Shares,	Shares, Units	
	Number of	Market Value of	Units or	or Other	
	Shares or Units	Shares of Units of	Other Rights	Rights That	
	of Stock That	Stock that Have Not	That Have	Have Not	
	Have Not Vested	Vested	Not Vested	Vested	
Name	(#)	(\$)	(#)	(\$)	
John Steel	433,334(1)	99,667	_	_	

(1) 433,334 shares are subject to forfeiture if Mr. Steel's employment with the Company is terminated before October 24, 2013. Mr. Steel's employment with the Company terminated on July 9, 2013 upon effectiveness of his resignation.

### Additional Narrative Disclosure

We have no plans that provide for the payment of retirement benefits, or benefits that will be paid primarily following retirement, including, but not limited to, tax qualified defined benefit plans, supplemental executive retirement plans, tax qualified defined contribution plans and non-qualified defined contribution plans.

### **Director Compensation**

The following table reflects the compensation of the directors (other than the named executive officers) including director fees, consulting fees and scientific advisory board fees for the Company's fiscal year ended April 30, 2013:

	Fees Earned			
	or Paid in	Stock	Option	
	Cash	Awards	Awards	Total
Name of Director	(\$)	(\$)(1)	(\$)(2)	(\$)
Joel D. Perlin(3)	10,000	187,481	-	197,481

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Jerry Nadler(3)	52,446	187,481	-	239,927
Jonathan Lakey(3)	198,700	537,481	-	736,181
Richard Franco(4)	5,250	-	70,000	75,250
George Todaro(5)	2,500	173,250	_	175,550

- (1) The amounts in these columns represent the compensation cost of stock awards granted during the fiscal year ended April 30, 2013, except that these amounts do not include any estimate of forfeitures. The amount recognized for these awards was calculated based on the value of the stock awards at the time of vesting.
- (2) The amounts in these columns represent the compensation cost of warrants to purchase common stock granted during the fiscal year ended April 30, 2013, except that these amounts do not include any estimate of forfeitures. The grant date fair value of option awards granted were determined in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 (formerly SFAS123(R) and are recognized as compensation cost over the requisite service period. The amount recognized for these awards was calculated using the Black-Scholes option-pricing model.
- (3) As of April 30, 2013, Messrs. Perlin, Nadler, and Lakey each earned stock awards of 185,625 shares of common stock.
- (4) Upon his appointment as a director of the Company on August 20, 2012, Mr. Franco was awarded warrants to purchase 300,000 shares of common stock at an exercise price of \$2.00 per share. Mr. Franco resigned as a director on March 3, 2013. Warrants to purchase 100,000 shares vested upon issuance and the remainder of the warrants remained unvested and expired upon Mr. Franco's resignation.
- (5) Dr. George Todaro resigned as a director of the Company on March 13, 2013. As of the date of his resignation, Dr. Todaro earned stock awards of 123,750 shares of common stock.

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

The following table sets forth information regarding beneficial ownership of our common stock as of the date of this report by (i) any person or group with more than 5% of any class of voting securities, (ii) each director, (iii) our chief executive officer and each other executive officer whose cash compensation for the most recent fiscal year exceeded \$100,000, and (iv) all such executive officers and directors as a group. Unless otherwise specified, the address of each of the officers and directors set forth below is in care of the Company, 641 Lexington Avenue, 6th Floor, New York, New York 10022. Except as indicated in the footnotes to this table and subject to applicable community property laws, the persons named in the table to our knowledge have sole voting and investment power with respect to all shares of securities shown as beneficially owned by them.

Name		Office	Shares Beneficially Owned(1)	Percent of Class(2)
Officers and Directors				
Richard Egan		CFO	250,000	0.4%
John Steel(4)		Director	8,495,002	15.0%
Joel D. Perlin(3)(4)		Vice-President and Director	4,555,000	8.0%
Jonathan Lakey(4)(5)		Director	2,845,000	5.0%
All officers and directors as a group (4 persons named above)			16,145,002	28.4%
5% Securities Holders				
Charles Dupont 13740 Nob Avenue Belmar, California 92014			5,710,000	10.1%
Sand Dollar LLC 600 E. Speedway Tucson, Arizona 85705			3,591,729	6.3%
(1)	Beneficial ownership is degenerally includes voting or			
(2)	Based on 56,715,117 shar August 12, 2013.	es of the Company	's common stock of	outstanding as of

<sup>(3)</sup> Includes shares and warrants held by entities affiliated with or controlled by Mr. Perlin as follows:

- 2,000,000 shares held by H.S. Perlin Co., Inc., Defined Benefit Pension Plan 2,001,875 shares of common stock and 120,000 warrants held by The Perlin Family Trust (DTD 12/27/95)
- (4) Includes a stock grant of 495,000 shares of common stock vesting over two years in equal quarterly installments of 61,875 shares at the end of each 90-day period from June 26, 2012 of which a stock grant of 247,500 shares has vested as of the date of this report.
- (5) Includes a stock grant of 300,000 shares of common stock vesting over two years in equal annual installments of 150,000 shares at each anniversary from June 26, 2012 of which a stock grant of 150,000 shares has vested as of the date of this report.

#### Change in Control

As of the date of this report, there were no arrangements which may result in a change in control of the Company.

Securities Authorized for Issuance under Equity Compensation Plan

None.

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

Transactions with related persons

Mr. John Steel, our Director and Chief Executive Officer at April 30, 2013, loaned to ISI an aggregate amount of \$27,500 interest free and payable on demand.

Other than the above transactions or as otherwise set forth in this report or in any reports filed by the Company with the SEC, there have been no related party transactions, or any other transactions or relationships required to be disclosed pursuant to Item 404 of Regulation S-K. The Company is currently not a subsidiary of any company.

The Company's Board conducts an appropriate review of and oversees all related party transactions on a continuing basis and reviews potential conflict of interest situations where appropriate. The Board has not adopted formal standards to apply when it reviews, approves or ratifies any related party transaction. However, the Board believes that the related party transactions are fair and reasonable to the Company and on terms comparable to those reasonably expected to be agreed to with independent third parties for the same goods and/or services at the time they are authorized by the Board.

#### Director Independence

No member of the Company's board of directors qualifies as an independent director pursuant to the definition of "independent director" under the Rules of NASDAQ, Marketplace Rule 5605(a)(2).

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following lists fees billed by the auditors for the Company, for the years ended April 30, 2013 and 2012:

	2	2013(1)	 012(1)
Audit Fees	\$	45,750	\$ 30,500
Audit Related Fees		-	-
Tax Fees		14,061	2,667
All Other Fees		8,859	-

(1) These services were provided by PKF, Certified Public Accountants who were engaged January 26, 2012.

Audit Fees. Represents fees for professional services provided for the audit of the Company's annual financial statements and review of its quarterly financial statements, and for audit services provided in connection with other statutory or regulatory filings.

2013(1)

2012(1)

Audit-Related Fees. Represents fees for assurance and other services related to the audit of Company's financial statements.

Tax Fees. Represents fees for professional services provided primarily for tax compliance and advice. These fees include the tax returns for Islet Sciences, Inc., One E-Commerce Corporation and DiaKine Therapeutics, Inc. for multiple periods.

All Other Fees. Represents fees for products and services not otherwise included in the categories above.

In the event that we should require substantial non-audit services, the audit committee would pre-approve such services and fees.

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# PART IV

# ITEM 15. EXHIBITS

Number	Description
2.1	Certificate of Merger (1)
2.2	Agreement and Plan of Merger (1)
3.1	Articles of Incorporation of the Company
3.2	Certificate of Amendment to Articles of Incorporation of the Company dated March 30, 1999
3.3	Certificate of Amendment to Articles of Incorporation of the Company dated February 16, 2012
3.4	Amended and Restated By-laws of the Company
4.1	Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (1)
4.2	Certificate of Designations of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (1)
4.3	Certificate of Designations of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (2)
4.4	Form of Warrant (3)
4.5	Form of Warrant issued to NeoStem Inc.
4.6	Specimen of Common Stock Certificate
10.1	Stock Purchase Agreement by and between Islet Sciences, Inc. and John Welch (1)
10.2	Agreement dated January 10, 2012 by and between ISI and Progenitor Cell Therapy (4)
10.3	Share Exchange Agreement dated February 23, 2012 by and among the Company, ISI and DiaKine Therapeutics, Inc. (5)
10.4	Form of Lock-Up Agreement (5)
10.5	Employment Agreement dated March 1, 2012 by and between the Company and John Steel
10.6	Consulting Agreement dated April 1, 2012 by and between the Company and Richard Egan
10.7	Form of Subscription Agreement (3)
10.8	Long-Term Supply Agreement with Spring Point Project (6)

Separation Agreement and Release dated July 1, 2013 by and between the Company and John Steel (7)
Consulting Agreement dated July 1, 2013 by and between the Company and John Steel (7)

# List of Subsidiaries Certifications of Joel Perlin pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 Certifications of Richard Egan pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Interactive data files pursuant to Rule 405 of Regulation S-T

#### Footnotes:

- (1) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on January 6, 2012.
- (2) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on March 16, 2012.
- (3) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on March 21, 2012.
- (4) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on January 13, 2012.
- (5) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on February 29, 2012.
- (6) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on July 27, 2012.
- (7) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on July 16, 2013.

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#### **SIGNATURES**

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

Islet Sciences, Inc.

Date: August 13, 2013 By: /s/ Joel Perlin

Joel Perlin

Vice-President, Director (principal executive officer)

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name and Title Date

/s/ Joel Perlin August 13, 2013

Joel Perlin

Vice-President and Director (Principal Executive officer)

/s/ Richard Egan August 13, 2013

Richard Egan

Chief Financial Officer

(Principal Financial Officer and Principal

Accounting Officer)

/s/ John Steel August 13, 2012

John Steel, Director

/s/ Jonathan Lakey August 13, 2013

Jonathan Lakey, Director

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#### Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of Islet Sciences, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Islet Sciences, Inc. and Subsidiaries (A Development Stage Company) (the "Company") as of April 30, 2013 and 2012 and the related consolidated statements of operations, stockholders' equity/(deficit), and cash flows for each of the two years then ended, and for the period from May 4, 2010 (Inception) through April 30, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We have conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal controls over financial reporting. Our audit includes consideration of internal controls over financial reporting as a basis for designing audit procedures that are appropriate in the circumstance, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Islet Sciences, Inc. and Subsidiaries (A Development Stage Company) as of April 30, 2013 and 2012, and the results of its operations and cash flows for each of the two years then ended, and for the period from May 4, 2010 (Inception) through April 30, 2013, in conformity with accounting principles generally accepted in the United States of America.

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 financial statements, the Company has incurred losses since inception resulting in an accumulated deficit of \$17.4 million as of April 30, 2013 and further losses are anticipated in the development of its business 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

August 12, 2013 San Diego, California /s/ PKF PKF Certified Public Accountants A Professional Corporation

### Islet Sciences, Inc. and Subsidiaries (A Development Stage Company) Consolidated Balance Sheets

	April 30, 2013	April 30, 2012
ASSETS		
CURRENT ASSETS	<b></b>	<b>4.000.700</b>
Cash	\$3,589	\$1,908,532
Prepaid expenses	50,000	-
Advance to related party	2,405	-
Total current assets	55,994	1,908,532
OTHER ASSETS	1 475 700	1.506.100
Intangible assets, net (Note 3)	1,475,788	1,506,192
Goodwill (Note 3)	2,111,107	2,111,107
Total other assets	3,586,895	3,617,299
TOTAL ASSETS	\$3,642,889	\$5,525,831
LIABILITIES & STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$2,233,314	\$168,578
Accounts payable - related party	-	14,228
Subscribed shares - not issued	96,600	1,124,265
Accrued stock compensation expenses (Note 5)	63,702	1,135,365
Notes payable - related party	11,880	1,442
Derivative liability (Note 4)	58,588	824,875
Total current liabilities	2,464,084	3,268,753
Total Carrent nuclinies	2,101,001	3,200,733
Deferred tax	547,000	547,000
Total liabilities	3,011,084	3,815,753
2011 1110 11110	2,011,001	2,010,700
Commitments and Contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; no shares		
issued and outstanding at April 30, 2013 and April 30, 2012	-	-
Common stock, \$0.001 par value, 100,000,000 shares authorized;		
56,715,117 and 44,584,855 shares issued and outstanding at April 30, 2013 and April		
30, 2012, respectively	56,716	44,585
Additional paid-in capital	18,017,392	7,405,197
Deficit accumulated during the developments stage	(17,442,303)	(5,739,704)
Total stockholders' equity	631,805	1,710,078
TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	\$3,642,889	\$5,525,831

See accompanying notes to the consolidated financial statements

Islet Sciences, Inc. and Subsidiaries (A Development Stage Company) Consolidated Statements of Operations

	Year endec	l April 30	period from May 4, 2010 (Inception) through April 30,
	2013	2012	2013
REVENUE	\$-	\$-	\$-
OPERATING EXPENSES			
General and administrative	8,058,684	1,888,136	10,366,937
Research and development	4,063,790	1,803,671	6,148,910
Total operating expenses	12,122,474	3,691,807	16,515,847
LOSS FROM OPERATIONS	(12,122,474)	(3,691,807)	(16,515,847)
OTHER INCOME (EXPENSE)			
Other income	430,000	-	430,000
Other expenses	-	(1,345,710)	(1,345,710)
Interest expense	(10,125)	(621)	(10,746)
Total other income (expense)	419,875	(1,346,331)	(926,456)
LOSS BEFORE INCOME TAXES	(11,702,599)	(5,038,138)	(17,442,303)
INCOME TAX EXPENSE	-	-	-
NET LOSS	\$(11,702,599)	\$(5,038,138)	\$(17,442,303)
NET LOSS PER COMMON SHARE,			
BASIC AND DILUTED	\$(0.21)	\$(0.15)	
WEIGHTED AVERAGE NUMBER OF			
COMMON SHARES OUTSTANDING BASIC AND DILUTED	54,511,585	33,956,094	

See accompanying notes to the consolidated financial statements

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For the

# Islet Sciences, Inc. and Subsidiaries (A Development Stage Company) Consolidated Statements of Stockholders' Equity/(Deficit)

									Deficit	
	Series A Preferred Number	d Prefe Number	r	Serie Prefe Number	erred	Common Number	Stock	Additional Paid-In	Accumulate During the	e
	of Shares Am	of nount Shares		of Shares	Amount	of Amount Shares		Paid-In Capital	Developme: Stage	nt
Balance, May 4, 2010	¢	S	\$-		\$-		\$-	\$-	<b>\$</b> -	
Issuance of	- ψ	,	Ψ-	_	Ψ-	_	ψ-	Ψ-	Ψ-	
founders'						12 120 000	12.120	(12.120		
common stock	-		-	-	-	13,430,000	13,430	(13,430	) -	
Issuance of common stock										
in exchange for										
intangible asset			_	_	_	3,000,000	3,000	197,000	_	
Issuance of						2,000,000	2,000			
common stock										
to reduce										
accounts										
payable – relate	d									
party	-		-	-	-	100,000	100	9,900	-	
Conversion of										
debt and										
accrued interest										
into common						2 501 520	2.502	252 400		
stock	-		-	-	-	3,591,729	3,592	353,408	-	
Stock-based								7.021		
compensation Issuance of	-		-	-	-	-	-	7,031	-	
common stock										
for services	_		_	_	_	1,200,000	1,200	118,800	_	
Net loss	-		-	_	_	-	-	-	(701,566	)
Balance, April									(, , , , , ,	
30, 2011	-		-	-	-	21,321,729	21,322	672,709	(701,566	)
Sale of										
common stock										
at \$0.10/share	-		-	-	-	8,090,000	8,090	780,910	-	
Issuance of										
common stock										
for services	-		-	-	-	4,931,668	4,932	488,236	-	
Sale of										
common stock						2 474 007	2.475	207 525		
at \$0.12/share	-		-	-	-	2,474,997 1,187,476	2,475 1,187	287,525 533,178	-	
	-		-	-	-	1,107,470	1,107	333,176	-	

Issuance of common stock for purchase consideration in reverse merger										
Conversion of shares during merger	_	_	38,006	38	_	-	(38,005,870)	(38,006)	37,968	-
Assumption of One E Commerce										
Shares upon reverse merger	_	_	_	_	_	_	187,063	187	(187 )	_
Sale of							107,003	107	(107	
preferred A										
shares at	1 172								464.620	
\$450/share Purchase of	1,173	1	-	-	-	-	-	-	464,638	-
Diakine with										
shares	_	_	_	_	200,000	200	100,000	100	2,829,523	_
Conversion of					200,000	200	100,000	100	2,027,323	
shares upon										
completion of										
merger with										
One E										
Commerce	(1,173)	(1)	(38,006)	(38)	-	-	39,178,870	39,179	(39,140)	-
Automatic										
conversion of					(200,000)	(200)				
shares							7 (//// ////	2 000	(1.000)	
	-	-	-	-	(200,000)	(200)	2,000,000	2,000	(1,800 )	-
Sale of	-	-	-	-	(200,000)	(200)	2,000,000	2,000	(1,800)	-
Sale of common stock	-	_	-	_	-	-				-
Sale of	-	_	-	-	-	-	2,000,000 3,118,922	2,000 3,119	(1,800 ) 1,346,876	-
Sale of common stock at \$0.45/share	-	-	-	-	-	-				-
Sale of common stock at \$0.45/share Stock-based compensation Net loss	- - -	-	- -	- - -	- -				1,346,876	-
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April	- - -	-	- -	-	-		3,118,922	3,119	1,346,876 4,761	- (5,038,138
Sale of common stock at \$0.45/share Stock-based compensation Net loss	- - -	- - -	-	-	- - -	- - -			1,346,876	-
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012	- - -	- - - -	- - -	-	- - -	-	3,118,922	3,119	1,346,876 4,761	- (5,038,138
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012	- - -	-	- - -	- - -	- - -	-	3,118,922	3,119	1,346,876 4,761	- (5,038,138
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012 Sale of common stock	- - -	-	-	-		-	3,118,922 - - 44,584,855	3,119 - - 44,585	1,346,876 4,761 7,405,197	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share	- - -	-	-	-		-	3,118,922	3,119	1,346,876 4,761	- (5,038,138
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012 Sale of common stock	- - -	-	-	-		-	3,118,922 - - 44,584,855	3,119 - - 44,585	1,346,876 4,761 7,405,197	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of	- - - -	-	- - - -	-		-	3,118,922 - - 44,584,855	3,119 - - 44,585	1,346,876 4,761 7,405,197	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of common shares	- - -	-	-	-		-	3,118,922 - - 44,584,855 7,041,667	3,119 - - 44,585 7,042	1,346,876 4,761 7,405,197 3,008,405	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of common shares for services Issuance for common stock	- - - -	-	- - - -	-		-	3,118,922 - - 44,584,855 7,041,667	3,119 - - 44,585 7,042	1,346,876 4,761 7,405,197 3,008,405	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of common shares for services Issuance for common stock for purchase	- - -	-	-	-	-	-	3,118,922 - - 44,584,855 7,041,667	3,119 - - 44,585 7,042	1,346,876 4,761 7,405,197 3,008,405	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of common shares for services Issuance for common stock for purchase consideration in	- - - -	-	-	-		-	3,118,922 - - 44,584,855 7,041,667	3,119 - - 44,585 7,042	1,346,876 4,761 7,405,197 3,008,405	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of common shares for services Issuance for common stock for purchase consideration in reverse merger	-	-	-	-		-	3,118,922 - - 44,584,855 7,041,667	3,119 - - 44,585 7,042	1,346,876 4,761 7,405,197 3,008,405	- (5,038,138) (5,739,704)
Sale of common stock at \$0.45/share Stock-based compensation Net loss Balance, April 30, 2012  Sale of common stock at \$0.45 a share Issuance of common shares for services Issuance for common stock for purchase consideration in	- -	-	- -	-	-	-	3,118,922 - - 44,584,855 7,041,667	3,119 - - 44,585 7,042	1,346,876 4,761 7,405,197 3,008,405	- (5,038,138) (5,739,704)

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Issuance of										
warrants for										
services	-	-	-	-	-	-			183,989	-
Net loss	-	-	-	-	-	-	-	-	-	(11,702,599)
Balance, April										
30, 2013	-	\$-	-	\$-	-	\$-	56,715,117	\$56,716	\$18,017,392	\$(17,442,303)

See accompanying notes to the consolidated financial statements

## Islet Sciences, Inc. and Subsidiaries (A Development Stage Company) Consolidated Statements of Cash Flows

	Year ended	April 30,	For the period from May 4, 2010 (Inception) through April 30,
Cash flows from operating activities:	2013	2012	2013
Net loss	\$(11.702.599)	\$(5.038.138)	\$(17,442,303)
Adjustments to reconcile net loss to net cash used in operating activities		ψ(ε,σεσ,1εσ)	ψ(17,1.1 <b>=</b> ,000)
Equity issued for acquisition of One E-Commerce Corporation	_	534,365	534,365
Equity issued for payment of accounts payable - related party	_	-	10,000
Stock based compensation for services and other	5,635,053	497,929	6,163,412
Derivative liabilities	72,174	824,875	897,049
Amortization of intangible asset	30,404	30,404	91,212
Accrued stock compensation expenses	63,702	1,135,365	1,199,067
Change in operating assets and liabilities:	00,702	1,100,000	1,1>>,007
Advances to related party	(2,405)	6,700	(2,405)
Prepaid expense	(50,000)	-	(50,000)
Accounts payable	2,064,736	53,433	2,153,762
Accounts payable - related party	(14,228)	(127,300 )	(20,000)
raced and purpose relative purey	(11,220)	(127,000)	(=0,000
Net cash used in operating activities	(3,903,163)	(2,082,367)	(6,465,841)
Cash flows from investing activities:			
Net cash provided by investing activities	-	-	-
Cash flows from financing activities:			
Proceeds from issuance of stock	1,891,182	2,893,633	4,597,416
Subscribed shares - not issued	96,600	1,124,265	1,504,865
Proceeds from notes payable - related party	13,500	-	400,500
Payments on notes payable - related party	(3,062)	(30,289)	(33,351)
Net cash provided by financing activities	1,998,220	3,987,609	6,469,430
Net (decrease) increase in cash	(1,904,943)	1,905,242	3,589
Thet (decrease) increase in cash	(1,501,515)	1,505,212	3,307
Cash at beginning period	1,908,532	3,290	-
Cash at end period	\$3,589	\$1,908,532	\$3,589
	. ,	. , .,	
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATIO	N:		
Cash paid during the period for:	_		_
Interest	\$-	\$-	\$-
Income taxes	\$-	\$-	\$-

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SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING												
INFORMATION:												
Shares issued for settlement of accrued expenses \$1,135,365 \$- \$1,13												
Shares issued for settlement of derivative liabilities	\$838,461	\$-	\$838,461									
Shares issued for issuance of subscribed shares – not issued \$1,124,265 \$- \$1,408,265												
Shares issued for acquisition of Diakine Therapeutics, Inc. \$-\$2,829,823\$\$2,829,823												
Net liabilities assumed in acquisition of Diakine Theapeutics, Inc.	\$-	\$101,284	\$101,284									
Deferred income tax liability and goodwill associated with the												
acquisition of Diakine Therapeutics, Inc.	\$-	\$547,000	\$547,000									
Common stock issued in exchange for convertible notes	\$-	\$-	\$357,000									
Common stock issued in exchange for intangible asset	\$-	\$-	\$200,000									
Common stock issued in exchange for accounts payable - related party	\$-	\$-	\$10,000									

See accompanying notes to the consolidated financial statements

# ISLET SCIENCES, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY) NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### NOTE 1. DESCRIPTION OF BUSINESS AND GOING CONCERN

#### **Description of Business**

Islet Sciences, Inc., a Nevada corporation ("Islet Sciences"), is a development stage company engaged in the research, development, and commercialization of patented technologies in the field of transplantation therapy for people with conditions requiring cell-based replacement treatments, with a focus on type 1, or insulin-dependent diabetes. Patented islet transplantation technology, along with our own developments, constitute methods for isolating, culturing, cryopreservation, and immuno-protection (microencapsulation) of islet cells. Islet Sciences intends to continue its research and development efforts and ultimately to introduce products to the market. Currently, Islet Sciences has no products for sale and are focused on research and development activities in preparation for clinical activities.

Islet Sciences was incorporated under the name One E-Commerce Corporation on September 14, 1994 in the State of Nevada. Effective February 23, 2012, the Company changed its name to Islet Sciences, Inc. On March 14, 2012, Islet Sciences acquired DiaKine Therapeutics, Inc., a Delaware corporation ("DTI"). Islet Sciences together with its subsidiaries, Islet Sciences Inc., a Delaware corporation ("ISI"), and DTI are referred to as the Company.

#### Going Concern

The consolidated financial statements have been prepared assuming the Company will continue as a going concern. This contemplates the continuity of operations, realization of assets, and liquidation of liabilities in the normal course of business. Since inception, the Company has incurred operating losses of \$17,442,303 and has had negative operating cash flows of \$6,465,841. As of April 30, 2013, the Company had cash of \$3,589. Further, the Company has incurred net losses of \$11,702,599 and negative operating cash flows of \$3,903,163 for the fiscal year ended April 30, 2013. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company's future cash requirements will depend on many factors, including continued scientific progress in its research and development programs, the scope and results of pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, and the cost of product commercialization. The Company does not expect to generate a positive cash flow from operations at least until the commercial launch of its first product and possibly later given the expected spending for research and development programs and the cost of commercializing product candidates. The Company's continued operations will depend on its ability to raise funds through various potential sources such as debt and equity financing. There can be no assurance that such capital will be available on favorable terms or at all. If the Company is unable to raise additional capital, the Company will likely be forced to curtail its desired development activities, which would delay the development of its product candidates.

#### Merger Agreement

On September 15, 2011, Mr. John Welch, shareholder, director and Chief Executive Officer of One-E Commerce Corporation, entered into a stock purchase agreement, pursuant to which Mr. Welch sold to ISI, an aggregate of 9,902,180 shares of One E-Commerce Corporation common stock, which shares then represented approximately 54.06% of the issued and outstanding shares of common stock, and certain convertible promissory notes in the

aggregate principal amount of \$514,458 and accrued interest, previously issued by One E-Commerce Corporation, for an aggregate purchase price of \$250,000. Additionally, under the stock purchase agreement, ISI agreed to cause One E-Commerce Corporation to enter into a reverse merger transaction at a future date whereby the Company was to acquire all of the outstanding equity interests of ISI in consideration for the issuance of its shares to the shareholders of ISI ("Reverse Merger Transaction"). The closing that took place on September 22, 2011, resulted in the change of control of One E-Commerce Corporation. Immediately after the closing, the shares together with the notes, acquired by ISI comprised 54.06% of the then issued and outstanding common stock of the One-E Commence Corporation on a non-diluted basis and 82.8% on a fully-diluted basis.

On December 30, 2011, ONCE, Inc., a Delaware corporation wholly-owned by the Company (the "Merger Sub"), ISI and Islet Sciences consummated the Reverse Merger Transaction, whereby the Merger Sub was merged with and into ISI, and the holders of common stock of ISI received an aggregate of 38,005.87 shares of Islet Sciences' Series B preferred stock, \$0.001 par value per share ("Series B Preferred") in exchange for the cancellation of all of the shares of common stock of ISI formerly owned by them, and the holders of Series A preferred stock of ISI received an aggregate of 1,173 shares of the Series A preferred stock, \$0.001 par value per share ("Series A Preferred") in exchange for the cancellation of all of the shares of Series A preferred stock of ISI formerly owned by them. The issuance of Series A and B Preferred, with each share of preferred stock having voting rights equal to 1,000 shares of the Company's common stock, resulted in ISI's shareholders having obtained control of the combined Company. ISI is deemed to be the accounting acquirer (legal acquiree) and One E-Commerce Corporation to be the accounting acquiree (legal acquirer). The financial statements before the date of the Reverse Merger Transaction are those of ISI with the results of the Company being consolidated from the date of the Reverse Merger Transaction. The equity section and earnings per share have been retroactively restated to reflect the reverse acquisition. The merger of a private operating company into a non-operating public shell corporation with nominal net assets is considered to be a capital transaction, in substance, rather than a business combination, for accounting purposes. Accordingly, ISI treated this transaction as a capital transaction without recording goodwill or adjusting any of its other assets or liabilities. The consideration in the amount of \$1,345,710 for the Company, consisting of \$250,000 paid in cash and \$1,095,710 paid in the form of common stock, was recorded as another expense item in the accompanying consolidated statements of operations during the year ended April 30, 2012. Effective February 23, 2012, Islet Sciences completed a 1-for-45 reverse stock split of its issued and outstanding common stock. Upon effectiveness of the reverse stock split, all outstanding shares of Series A Preferred and Series B Preferred were converted into common shares based on their respective conversion ratios. In connection with the closing of the Reverse Merger Transaction, ISI agreed to cancel the shares and the outstanding notes of One E-Commerce Corporation purchased from Mr. Welch, and the interest accrued thereon effective upon the effectiveness of the reverse stock split.

#### NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Presentation**

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. All shares and per share amounts in these consolidated financial statements and notes thereto have been retroactively adjusted to give effect to the reverse stock split.

The accompanying consolidated financial statements include the accounts of Islet Sciences and its wholly-owned subsidiaries, ISI and DTI. All significant intercompany balances have been eliminated.

The Company's planned principal operations have not yet commenced. Accordingly, the Company's activities have been accounted for as those of a development stage enterprise in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 915-10, Accounting and Reporting by Development Stage Enterprises (FASB ASC 915-10). All losses since inception have been considered as part of the Company's development stage activities.

#### **Emerging Growth Company**

The Company is an "emerging growth company" and has elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies.

#### Reclassifications

Certain prior year balances and account groupings have been reclassified to conform to the current year presentation.

#### 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 reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include the recoverability of long-lived assets, the valuation of intangible assets and goodwill, the valuation of common stock, warrants and stock options and the valuation of deferred tax assets. Actual results could differ from those estimates.

#### Concentration of Credit Risk

The Company maintains its cash balances at a credit-worthy financial institution and management believes the risk of loss of cash balances to be low. All cash balances are fully insured.

#### **Intangible Assets**

Intangible assets represent a patent acquired from a third party, which is recorded at cost and amortized over the remaining life of the patent. Intangible assets also include the purchase of DiaKine Therapeutics, Inc. patent portfolio and know-how as in-process research and development ("IPR&D"). IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset. If the related project is not completed in a timely manner or the project is terminated or abandoned, the Company may have an impairment related to the IPR&D, calculated as the excess of the asset's carrying value over its fair value. The intangible assets with estimable useful lives are amortized on a straight line basis over their respective estimated useful lives to their estimated residual values. This method of amortization approximates the expected future cash flow generated from their use. Definite lived intangibles are reviewed for impairment in accordance with FASB ASC 360, Property, Plant and Equipment (FASB ASC 360).

#### Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the identifiable assets acquired and liabilities assumed in business acquisitions. Goodwill is reviewed at least annually for impairment in the fourth quarter of the fiscal year, at the Company level, which is the sole reporting unit, and at any other time at which events occur or circumstances indicate that the carrying amount of goodwill may exceed its fair value. Such indicators would include a significant reduction in the Company's market capitalization, a decrease in operating results or a deterioration in the Company's consolidated financial position.

#### Impairment of Long-Lived Assets

The Company applies the provisions of FASB ASC 360-10, Property, Plant and Equipment (FASB ASC 360-10), where applicable to all long lived assets. FASB ASC 360-10 addresses accounting and reporting for impairment and disposal of long-lived assets. The Company periodically evaluates the carrying value of long-lived assets to be held and used in accordance with FASB ASC 360-10. FASB ASC 360-10 requires impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amounts. In that event, a loss is recognized

based on the amount by which the carrying amount exceeds the fair market value of the long-lived assets. Loss on long-lived assets to be disposed of is determined in a similar manner, except that fair market values are reduced for the cost of disposal.

#### Loss Per Share Data

Basic loss per share is calculated based on the weighted average common shares outstanding during the period. Diluted earnings per share also give effect to the dilutive effect of restricted stock. The Company does not present diluted earnings per share for years in which it incurred net losses as the effect is anti-dilutive.

At April 30, 2013, 2,275,625 unvested shares of restricted common stock and warrants to exercise 6,366,794 shares of common stock were outstanding, but were not included in the computation of diluted earnings per share as their effect would be anti-dilutive. At April 30, 2012, 1,116,668 unvested shares of restricted common stock and warrants to exercise 2,145,961 shares of common stock were outstanding, but were not included in the computation of diluted earnings per share as their effect would be anti-dilutive

#### Fair Value of Financial Instruments

The Company adopted FASB ASC 820, Fair Value Measurements and Disclosures (FASB ASC 820), which provides a framework for measuring fair value under GAAP. 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 on the measurement date. The standard also expands disclosures about instruments measured at fair value and establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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

Level 2 — Quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 — Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

#### Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, contract services and other outside expenses. Research and development costs are charged to operations when incurred.

**Stock Based Compensation** 

#### Stock awards

FASB ASC 718, Compensation-Stock Compensation (FASB ASC 718), requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the consolidated statement of operations over the requisite service period. Under FASB ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each stock award is estimated on the date of grant using the then available price of shares that have most recently been traded or sold through a private offering and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period. The Company accounts for share-based payments to non-employees, with guidance provided by ASC 505-50, "Equity-Based Payments to Non-Employees". The Company has not issued any stock options.

#### Warrants

Warrants granted to service providers are normally valued at the fair value of the instrument on the date of the grant (grant date) and are recognized in the consolidated statement of operations over the requisite service period or when they vest. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Black-Scholes Method. Warrants issued in connection with capital raises are normally valued at the fair value of the instrument on the date of the grant (grant date) and valued for disclosure purposes if they meet all the criteria under FASB ASC 718. The Company values these warrant using the Black-Scholes Method as well. As allowed by FASB ASC 718, for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average volatilities of a sampling of three companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation.

The Company used the following assumptions in valuing the warrants issued:

	April 30,	April 30	,
	2013	2012	
	0.45 -	0.45 -	
Price per share of common stock	\$\$1.40	\$\$1.40	
	0.45 -		
Exercise price per share	\$\$2.00	\$1.00	
	80.0 -	80.0 -	
Expected volatility	102.7	% 90.0	%
	0.65 -	0.82 -	
Risk-free interest rate	1.30	% 1.12	%
Dividend yield	-	-	

#### Income Taxes

The Company accounts for income taxes under an asset and liability approach. This process involves calculating the temporary and permanent differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The temporary differences result in deferred tax assets and liabilities, which would be recorded on the Company's consolidated balance sheets in accordance with FASB ASC 740, Income Taxes, which established financial accounting and reporting standards for the effect of income taxes. The Company must assess the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent the Company believes that recovery is not likely, the Company must establish a valuation allowance. Changes in the Company's valuation allowance in a period are recorded through the income tax provision on the consolidated statements of operations.

FASB ASC 740 clarifies the accounting for uncertainty in income taxes recognized in an entity's consolidated financial statements and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FASB ASC 740-10, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FASB ASC 740 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As a result of the implementation of ASC 740, the Company recognized no material adjustment in the liability for unrecognized income tax benefits.

The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of April 30, 2013 and 2012, the Company has no accrued interest or penalties related to uncertain tax positions.

#### **Segment Reporting**

The Company currently operates in a single operating segment. In addition, financial results are prepared and reviewed by management as a single operating segment. The Company continually evaluates its operating activities and the method utilized by management to evaluate such activities and will report on a segment basis if and when appropriate to do so.

#### **Recent Pronouncements**

In June 2011, the FASB issued ASU 2011-05, "Comprehensive Income (Topic 220) – Presentation of Comprehensive Income." This update requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income in either a single continuous statement or two separate but consecutive statements. This guidance does not change the items that must be reported in other comprehensive income. Subsequently, in December 2011, the FASB issued ASU 2011-12 which deferred some aspects of the June guidance that relate to the presentation of reclassification adjustments. ASU 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company adopted this standard effective May 1, 2012. The adoption of this standard did not have a significant impact on the Company's consolidated financial position or results of operations.

In February 2013, the FASB issued ASU 2013-02, "Comprehensive Income (Topic 220) – Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income." This guidance adds new disclosure requirements for items reclassified out of accumulated other comprehensive income ("AOCI"), including changes in AOCI balances by component and significant items reclassified out of AOCI. This guidance does not amend any existing requirements for reporting net income or AOCI in the financial statements. The Company will adopt this standard in fiscal year 2014. The Company does not expect the adoption of this standard to have a significant impact on the Company's consolidated financial position or results of operations.

In March 2013, the FASB issued ASU 2013-05 "Foreign Currency Matters (Topic 830) – Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity." This guidance issued amendments to address the accounting for the cumulative translation adjustment when a parent entity sells or transfers either a subsidiary or group of assets within a foreign entity. The Company will adopt this standard in fiscal year 2015. The Company does not expect the adoption of this standard to have a significant impact on the Company's consolidated financial position or results of operations.

#### Other Income

In the year ended April 30, 2013, the Company received an indemnification payment of \$430,000 from a third party in connection with an agreement to indemnify the Company against litigation and other expenses incurred in connection with certain litigation.

#### NOTE 3. INTANGIBLE ASSETS AND GOODWILL

On May 4, 2010, the Company was assigned the intellectual property rights for a patent that was issued on December 1, 1999. The rights to this patent were purchased out of the bankruptcy proceedings of MicroIslet, Inc. for \$200,000 and then assigned to ISI in exchange for the issuance of 3,000,000 shares of common stock.

On March 14, 2012, the Company acquired the IPR&D from DiaKine Therapeutics, Inc. As of April 30, 2013, the \$1.3 million of acquired IPR&D is classified as indefinite life asset and is not being amortized. In conjunction with this acquisition, the Company recognized \$2.1 million of goodwill. Initially, the residual purchase price of \$1,564,107 was recorded as goodwill related to the acquisition of DTI. However, none of the goodwill recognized or amortization of the IPR&D acquired is expected to be deductible for income tax purposes. Accordingly, in conjunction with the valuation of intangible assets acquired, it was determined that a deferred income tax liability of \$547,000 was required to reflect the book to tax differences of the acquisition. This same amount was added to the goodwill balance. The Company performed its annual impairment test of goodwill during the fiscal fourth quarter using an analysis of the present value of future discounted cash flows for its valuation. The Company evaluated its goodwill for impairment during the year ended April 30, 2013 and determined that the fair value of the reporting unit is in excess of its carrying

value including goodwill.

The following is a summary of goodwill and intangible assets for the years ended April 30, 2013 and 2012:

	Gross	Ap	ril 30, 2013	Net	Gross	Ap	oril 30, 2012	Net
	Carrying Amount		ccumulated nortization	Carrying Amount	Carrying Amount		ccumulated mortization	Carrying Amount
Identifiable intangibles:								
Patents	\$ 200,000	\$	(91,212)	\$ 108,788	\$ 200,000	\$	(60,808)	\$ 139,192
In-process								
technology	1,367,000		-	1,367,000	1,367,000		-	1,367,000
Subtotal of identifiable								
intangibles	1,567,000	\$	(91,212)	1,475,788	1,567,000	\$	(60,808)	1,506,192
Goodwill	2,111,107		-	2,111,107	2,111,107		-	2,111,107
Total goodwill and								
intangibles	\$ 3,678,107	\$	(91,212)	\$ 3,586,895	\$ 3,678,107	\$	(60,808)	\$ 3,617,299

The patent is being amortized based on the remaining life of the patent, which was 6.5 years at May 4, 2010, the date of assignment. For the years ending April 30, 2013 and 2012, the amount amortized to expense was \$30,404 per year. The Company expects to amortize \$30,404 each of the next three fiscal years with the remaining balance amortized in 2017.

#### NOTE 4. DERIVATIVE LIABILITY

The Company has one agreement for which it accounts for in accordance with accounting guidance for derivatives. The accounting guidance provides a two-step model to be applied in determining whether a financial instrument is indexed to an entity's own stock that would qualify such financial instruments for a scope exception. This scope exception specifies that a contract that would otherwise meet the definition of a derivative financial instrument would not be considered as such if the contract is both (i) indexed to the entity's own stock and (ii) classified in the stockholders' equity section of the consolidated balance sheet. The Company determined that this agreement is ineligible for equity classification as a result of the anti-dilution provision.

The Company entered into a research and manufacturing contract with Progenitor Cell Therapy ("PCT"), a wholly owned subsidiary of NeoStem, Inc. ("NeoStem"), whereby the Company has committed to issue shares for no consideration so that PCT's ownership is not less than 1% of outstanding shares on a fully diluted basis through December 31, 2013. The derivative was valued at approximately \$264,000 at the time of issuance and recorded to the consolidated statement of operations. During the year ended April 30, 2013, the Company has issued 223,771 shares of common stock, valued at approximately \$313,000, to satisfy its obligation to PCT. During the year ended April 30, 2012, no shares were issued to satisfy its obligation to PCT. These costs are included in research and development expense in the accompanying consolidated statements of operations. The fair market value of the remaining derivative as of April 30, 2013, using the below assumptions, was approximately \$59,000.

The derivative liability was valued using the Monte Carlo Simulation method with the following assumptions:

	April 30,	April 30,	
	2013	2012	
Value price per share of common stock	\$0.23	\$1.40	
Expected volatility	60.0	% 80.0	%
Risk-free interest rate	0.09	% 0.24	%
Dividend yield	-	-	
Floor price	\$0.23	\$0.87	
Remaining expected term of underlying securities (years)	0.67	1.66	

In addition, as of the valuation dates, management assessed the probabilities of future financings assumptions in the Monte Carlo Simulation method, as well as the probability of the conditional exercise feature.

#### NOTE 5. STOCKHOLDERS' EQUITY

As of April 30, 2013, the Company had 10,000,000 authorized shares of preferred stock, par value \$0.001 per share; no shares were issued and outstanding at April 30, 2013 and 2012. Shares of Series A and Series B preferred stock issued at the closing of the Reverse Merger Transaction were automatically converted, upon the effectiveness of the reverse split on February 23, 2012, into common stock at a conversion rate of one thousands shares of common stock for one share of preferred stock. In February 2012, the Board of Directors of the Company adopted resolutions providing for the designation of Series C Preferred stock at \$0.001 par value. Shares of Series C preferred stock issued at the closing of the DTI acquisition were converted on April 26, 2012 into common stock at a conversion rate of ten shares of common stock for one share of preferred stock. At the conversion of all issued and outstanding shares of Series A, Series B and Series C preferred stock, designations of all three series of preferred stock were cancelled.

As of April 30, 2013, the Company had 100,000,000 authorized shares of common stock, par value \$0.001 per share. Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. Holders of common stock are entitled to receive dividends ratably, if any, as may be declared by the Board of Directors out of legally available funds, subject to any preferential dividend rights of any outstanding preferred stock. Upon liquidation, dissolution or winding up, the holders of common stock are entitled to receive ratably net assets available after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Holders of common stock have no preemptive, subscription, redemption or conversion rights. The outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of the common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock.

#### Grants

At the inception, the Company issued 13,430,000 founder shares of common stock for intellectual property assignments related to the Company's purpose, mission and contributions to the business plan and strategy for no consideration.

On May 4, 2010, the Company issued 3,000,000 shares of common stock for the assignment of the intellectual property rights purchased from a company in bankruptcy proceedings for \$200,000.

In May 2010, the Company issued a convertible note payable to an investor, in the amount of \$357,000. In September 2010, the note payable was converted to 3,591,729 shares of common stock.

In July 2010, a Scientific Advisor Board member, and in October 2010, the CFO, received a restricted stock grant of 100,000 shares of common stock for services provided to the Company. The shares vest 50% on the first anniversary of the date of the agreement and the remaining shares vest on the second anniversary of the date of the agreement. For the years ended April 30, 2012 and 2011, the Company recognized stock-based compensation expense of \$7,031, and \$4,761, respectively. The shares were issued during the year ended April 30, 2012. The share price of the shares issued was valued at \$0.10 per share, which equated to the then share price of common stock being sold to other investors.

In March 2011, as part of a consultant agreement for consulting services to be provided for a one year period, the Company issued 1,200,000 shares of common stock. The common shares were valued at \$120,000 at the grant date, and were fully expensed as stock-based compensation upon issuance as the shares were not subject to forfeiture. The share price of the shares issued was valued at \$0.10 per share, which equated to the then share price of common stock being sold to other investors.

In April 2011, the Company converted an accounts payable balance with a related party in the amount of \$10,000 into 100,000 shares of common stock.

From June to September of 2011, the Company consummated a private placement of its common stock to certain accredited investors whereby the Company issued 8,090,000 shares of common stock for cash at a purchase price of \$0.10 per share and 2,474,997 shares of common stock for a cash purchase price of \$0.12 per share for total gross proceeds of \$1,106,000. Originally, the shares sold were those of ISI's common stock, which were ultimately converted into common stock of Islet Sciences as a result of the Reverse Merger Transaction and following the reverse stock split of Islet Sciences' common stock.

In October 2011, the Company granted Mr. John Steel, the Company's CEO, 1,190,000 shares of common stock, for the services that he has provided in previous periods as part of his employment agreement; 866,668 shares of common stock, as a signing bonus as part of his employment agreement; and 866,668 shares of common stock, as a deferred stock compensation with a vesting schedule of 50% on the first anniversary date and 50% on the second anniversary date. The total number of shares issued was 2,056,668 and were valued at \$205,667 at the grant date, and was expensed ratably over the corresponding service period. The share price of the shares issued was valued at \$0.10 per share, which equated to the then share price of shares being sold to other investors. The Company has agreed to issue Mr. Steel and additional 200,000 of common shares upon the completion of the contemplated DiaKine Therapeutics, Inc. acquisition. For the year ending April 30, 2012, the Company accrued \$280,000 as a stock-based compensation expense related to the 200,000 shares which were to be granted as the result of the DiaKine Therapeutics, Inc. purchase. The shares were valued at \$1.40 per share based on the valuation performed at the acquisition date and were issued during the year ended April 30, 2013.

In October 2011, the Board of Directors granted certain consultants to the Company 2,775,000 shares of common stock as part of consultant agreements for services to be provided for multiple year periods. For the year ended April 30, 2012, the Company recognized \$277,542 of stock-based compensation expense related to these grants. The share price of the shares issued was valued at \$0.10 per share, which equated to the then share price of common stock being sold to other investors.

In October 2011, the Board of Directors allocated 400,000 shares of common stock for future issuance to members of the Company's Scientific Advisory Board once Scientific Advisory Board members have been selected, other than Dr. Lakey. The members of the Scientific Advisory Board will have a term of two years.

In December 2011, the Company consummated a private placement of its preferred stock to certain accredited investors whereby the Company issued 1,173 shares of Series A preferred stock for cash at a purchase price of \$450

per share for total net proceeds of \$464,640. Originally, the shares sold were those of ISI's Series A preferred stock, which were ultimately converted into common stock of Islet Sciences as a result of the Reverse Merger Transaction and following the reverse stock split of Islet Sciences' common stock. In conjunction with the issuance of preferred stock, each share of issued preferred stock included the right to receive a warrant to purchase 500 shares of common stock of Islet Sciences at a price of \$1.00 per share upon conversion of the preferred stock. The warrants were valued at approximately \$147,000 based on the assumptions used in Note 2.

As per the DTI acquisition agreement, the Company was required to issue to Mr. John Welch shares of common stock representing 3% of the outstanding shares, after giving effect to the issuance of shares of common stock in the financing. On December 30, 2011, the Company issued 1,187,476 shares of common stock valued at \$534,365 and was included in other expenses. During the year ended April 30, 2012, the Company computed the remaining number of shares issuable under the anti-dilutive provision of the contract in the amount of 375,398 shares, valued at \$525,557 and are included as derivative liabilities in the consolidated balance sheets. The shares were valued at \$1.40 per common share based on the stock valuation performed at the acquisition date. On June 6, 2012, the Company issued 375,398 shares of common stock to John Welch pursuant to the DTI acquisition.

On March 14, 2012, in exchange for all issued and outstanding stock of DTI, the Company issued to DTI shareholders 200,000 shares of Series C Preferred Stock with each share of preferred stock convertible into ten shares of the Company's common stock. The Company also issued 100,000 shares of its common stock as part of the acquisition. On April 24, 2012, the Company issued a total of 2,000,000 shares of common stock to holders of 200,000 shares Series C Preferred Stock upon conversion of Series C Preferred Stock.

In March and April of 2012, the Company consummated a private placement of its common stock at a per share price of \$0.45 pursuant to a series of subscription agreements with a number of accredited investors including one of the Company's directors. The investors in the private placement were also issued, for no additional consideration, warrants to purchase shares of the Company's common stock. The warrants granted the subscribers the right to purchase a number of shares of common stock, par value \$.001 per share, of the Company's common stock equal to fifty percent (50%) of the number of shares of common stock subscribed for. The warrants will have an initial exercise price equal to \$1.00 per share and shall be exercisable for a five year period. The warrants were valued at approximately \$392,000 based on the assumptions used in Note 2. As of April 30, 2012, 3,118,922 shares of common stock and 1,559,461 warrants were issued for total net proceeds of \$1,349,995. For the remaining shares of common stock and warrants which had not yet been issued, the Company recorded the proceeds, which amounted to \$1,124,265, as a subscribed shares not issued liability on the accompanying consolidated balance sheets at April 30, 2012. These shares were subsequently issued in May 2012 and were part of additional capital raises on May 2, 2012 and May 9, 2012 below.

On April 1, 2012, as compensation for future services, the CFO was awarded a grant 150,000 shares of the common stock which shall be subject to forfeiture if his consulting engagement is terminated before January 31, 2013. These shares vested during the year ended April 30, 2013 and were valued at \$210,000, which was based on a previous appraisal at a share price of \$1.40 and were included as general and administrative expenses in the consolidated statements of operations for the year ended April 30, 2013.

In May 2, 2012, the Company issued an aggregate of 4,552,222 shares of common stock at \$0.45 per share and warrants to purchase 2,276,111 shares of common stock at an exercise price of \$1.00 per share in connection with two closings of the private placement of its common stock of \$2,048,500 that occurred in April 2012. The warrants were valued at approximately \$492,000 based on the assumptions used in Note 2.

On May 9, 2012, the Company consummated a private placement of an aggregate of 1,711,667 shares its common stock at a per share price of \$0.45, for gross proceeds of \$770,250 pursuant to a series of subscription agreements with a number of accredited investors. The investors in the private placement were also issued for no additional consideration, warrants to purchase 855,833 shares of common stock at an exercise price of \$1.00 per share. The warrants were valued at approximately \$185,000 based on the assumptions used in Note 2.

In May 2012, the Company, entered into a license agreement with the Yale University ("Yale"). As part of this agreement, the Company issued 20,000 shares of its common stock valued at \$28,000 which is included in the consolidated statement of operations for the year ended April 30, 2013.

On May 23, 2012, the Company issued a total of 270,000 shares of common stock as compensation to its employee and consultants valued at \$378,000 of which 200,000 shares (or \$280,000) were accrued as of April 30, 2012. The shares issued were valued using a previous appraisal of \$1.40 per share.

On June 21, 2012, the Company consummated a private placement of an aggregate of 717,778 shares of common stock at a per share price of \$0.45, for gross proceeds of \$323,000 pursuant to a series of subscription agreements with a number of accredited investors. The investors in the private placement were also issued for no additional consideration warrants to purchase 358,889 shares of common stock at an exercise price of \$1.00 per share. The warrants were valued at approximately \$78,000 based on the assumptions used in Note 2.

During the year ended April 30, 2013, the Company initially issued 400,000 shares as part of its agreement with PCT along with a warrant to purchase 350,000 shares at an exercise price of \$1.00 per share. This initial issuance was valued at approximately \$855,000 and accrued at April 30, 2012. In addition and as part of the anti-dilution provision, the Company issued an additional 223,771 shares of common stock to maintain PCT's 1% ownership of the Company. These additional issuances were valued at an earlier appraisal of \$1.40 per share or approximately \$314,000.

In August 2012, the Company agreed to assume certain liabilities in connection with claims and liens on certain patents acquired for approximately \$17,000 in cash and issued 144,342 shares of its common stock. The shares issued were valued using a previous appraisal of \$1.40 per share or approximately \$202,000. These costs have been expensed to general and administrative expenses during the year ended April 30, 2013.

In August 2012, the Company issued 1,750,000 shares of its common stock to one of its placement agent pursuant to an agreement dated as of April 21, 2011, as amended on June 29, 2012. The initial performance conditions in the agreement were not met by the placement agent, however, both parties agreed to settle and amend the agreement by issuing a total of 1,750,000 shares of the Company's common stock to the placement agent. These shares were issued and the expense in the amount of \$2,450,000 during the year ended April 30, 2013, which was based on a share price of \$1.40 based on a stock valuation performed, is included as general and administrative expense in the consolidated statements of operations for the year ended April 30, 2013.

In August of 2012, the Company issued 3,000 shares of common stock to The Regents of the University of California as part of an exclusive licensing agreement. The Company valued these shares at approximately \$4,200 and included the cost as research and development expense within the consolidated statements of operations for the year ended April 30, 2013.

In August 2012, the Company issued 60,000 shares of common stock that were previously designated as subscribed shares – not issued. The Company initially received proceeds of approximately \$27,000 in December 2011. The investor was also issued for no additional consideration, a warrant to purchase 30,000 shares of common stock at an exercise price of \$1.00 per share. The warrant was valued at approximately \$6,000 based on the assumptions used in Note 2.

In September 2012, the Company issued an aggregate of 309,375 shares of its common stock to members of the Board of Directors which were considered to be vested. The Company valued these shares based on an earlier appraisal of \$1.40 per share or approximately \$433,000, and included the costs as general and administrative expenses within the consolidated statements of operations for the year ended April 30, 2013.

In October 15, 2012, the Board of Directors approved a grant of 250,000 shares of common stock to Dr. Jonathon Lakey for his role in the ongoing process with Yale University, PCT, and Spring Point Project which vested on January 31, 2013. These shares were issued and the expense in the amount of \$350,000, which was based on a previous appraisal at a share price of \$1.40, is included as research and development expenses in the consolidated

statements of operations for the year ended April 30, 2013.

On October 19, 2012, the Company issued 375,000 shares of its common stock to a consultant to provide financial services. The shares are not subject to any vesting conditions or forfeiture. These shares were issued in the amount of \$525,000, which was based on a previous appraisal at a share price of \$1.40 and is included as general and administrative expenses in the consolidated statements of operations for the year ended April 30, 2013.

On November 21, 2012, the Company issued 20,000 shares of common stock to Winthrop University Hospital as part of the agreement to license certain patents and technology. These shares were valued at an earlier appraisal of \$1.40 per share or \$28,000. The Company accounted for these costs as research and development expenses within the consolidated statements of operations for the year ended April 30, 2013.

On December 19, 2012, the Company issued a total of 433,334 shares of common stock as compensation to its CEO, John Steel, valued at \$606,667 based on a previous appraisal at a share price of \$1.40 and included in general and administrative expenses within the consolidated statements of operations for the year ended April 30, 2013.

On December 26, 2012, an aggregate of 309,375 shares of its common stock issuable to members of the Board of Directors fully vested. These shares were issued during the year ended April 30, 2013 in the amount of approximately \$433,000, which was based on a previous appraisal at a share price of \$1.40 and is included as general and administrative expenses in the consolidated statements of operations for the year ended April 30, 2013.

On January 25, 2013, the Company issued 30,000 shares to a consultant to provide investor relations services. The shares are not subject to any vesting conditions or forfeiture. These shares were expensed at a value of \$44,000. An additional \$4,000 was accrued for the balance of the amount due under this agreement. A total of \$48,000 is included in general and administrative expenses within the consolidated statements of operations for these services for the year ended April 30, 2013.

On January 28, 2013, the Company received net proceeds of \$96,600 for the sale of 70,000 shares of common stock at \$1.40 per share as part of a private offering. The Company has not issued these shares as of April 30, 2013, and has recorded these proceeds as subscribed shares not issued.

On February 5, 2013, the Company issued 20,000 shares of common stock to certain related parties (Jerry L. Nadler, David Taylor-Fishwick, Anca Dobrian and Swarup Chalrabarti - "12LO Licensors") as part of an exclusive licensing agreement. The Company valued these shares using a previous appraisal of \$1.40 per share or \$28,000 and included the cost as research and development expense within the consolidated statements of operations for the year ended April 30, 2013.

On March 19, 2013, an aggregate of 247,500 shares of its common stock issuable to members of the Board of Directors fully vested. The Company valued these shares based on the April 30, 2013 share price of \$0.23 per share, or \$56,925, and recorded it to accrued expense until the common stock is issued. The Company has included the costs as general and administrative expenses within the consolidated statements of operations for the year ended April 30, 2013.

On April 1, 2013, the Company issued 5,000 shares of common stock to Southridge Partners II. LLP as part of a settlement agreement dated April 1, 2013 regarding an investment made by Southridge Partners II, LLP in the Company. The Company valued these shares at \$7,000 which was based on a previous appraisal at a share price of \$1.40 and is included as general and administrative expenses in the consolidated statements of operations for the year ended April 30, 2013.

#### Warrants

In June 2012, the Company, as part of its agreement with third party consultants, issued warrants to purchase 150,000 shares of common stock at an exercise price of \$0.45 per share. These issuances were valued at approximately \$51,000 based on assumptions disclosed in Note 2 and they are included in general and administrative expense within the consolidated statements of operations for the year ended April 30, 2013.

In August 2012, the Company issued to one of its Directors a warrant to purchase 300,000 shares of its common stock at \$2.00 per share, of which, 100,000 shares can be purchased immediately upon issuance of this warrant with the balance of becoming exercisable in two equal installments at the first and second anniversary of the date of his election to the board. The Company valued the fully exercisable warrant at \$70,000 based on assumptions disclosed in Note 2 and are included in general and administrative expense within the consolidated statements of operations for the year ended April 30, 2013.

In November 2012, the Company, as part of its agreement with third party consultants, issued a warrant to purchase 65,000 shares of common stock at an exercise price of \$2.00 per share. The Company valued the fully exercisable warrant at approximately \$63,000 based on the assumptions disclosed in Note 2 which is included in general and administrative expense within the consolidated statements of operations for the year ended April 30, 2013.

The following table summarizes information regarding the warrants outstanding as of April 30, 2013 and 2012:

	Number of	Weighted Average Exercise	
	Warrants	Price	Expiry Dates
Warrants at April 30, 2011	-	\$-	n/a
Granted	2,145,961	\$1.00	February 2017 to March 2017
Expired	-	\$-	n/a
Warrants at April 30, 2012	2,145,961	\$1.00	February 2017 to March 2017
			April 2017 to January 30,
Granted	4,420,833	\$1.08	2018
Expired	(200,000)	\$2.00	August 20, 2017
			February 2017 to January 30,
Warrants at April 30, 2012	6,366,794	\$1.02	2018

#### NOTE 6. COMMITMENTS AND CONTINGENCIES

#### Contracts

On January 10, 2012, the Company entered into an agreement with PCT, which was amended by an agreement dated May 15, 2012 by and between the Company and NeoStem, PCT's parent company. Under the agreements, PCT will be providing the protocols, procedures, systems, equipment, testing, quality controls, and manufacturing and distribution services to support the development and commercialization of the Company's encapsulated porcine islet cells for the treatment of diabetes. As compensation for the services of PCT, the Company agreed to pay to PCT a non-refundable monthly fee of \$63,000 and a non-refundable monthly charge of between \$33,000 and \$54,000. NeoStem was entitled to receive shares and warrants of the Company's common stock (see Note 4), as well as additional shares for no consideration so that NeoStem's ownership is not less than 1% of outstanding shares on a fully diluted basis. PCT has the right for a period of ten years to be the exclusive manufacturer of any product involved in the services to be provided under the agreement. With respect to commercial production of such products, PCT will be entitled to a royalty of 2.85% of gross sales and 5% of any sublicensing fees, royalties, milestone fees or profit sharing payments. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations of approximately \$936,000 related to this contract.

On February 7, 2013, the Company sent to NeoStem a termination letter, terminating the agreement with Progenitor Cell Therapy, Inc. dated January 10, 2012. The Company and NeoStem are in negotiations on terms of the termination.

On July 23, 2012, the Company entered into a long-term supply agreement with Spring Point Project, a source animal facility to purchase pigs for use in the Company's xenotransplantation research. Regardless of the number of pigs supplied under this agreement, the Company is obligated to pay \$100,000 for each month of this agreement, plus an initial and one time facility setup fees of \$25,000, and to pay certain milestones royalties by issuing warrants exercisable into an aggregate of 300,000 shares of common stock. The initial term of the agreement is for two years with an automatic renewal for one additional year, unless terminated prior to the renewal period. It can be terminated by either party if either party defaults on its obligations under the agreement and fails to cure such default within 90 days. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations of approximately \$971,000 related to this contract.

The Company is currently in default regarding its payment obligations under the foregoing supply contracts.

#### Licenses

On May 2, 2012, the Company, entered into a license agreement with the Yale University. Under the agreement, the Company received exclusive license to the technology patented by Yale. In consideration of the license granted under the agreement, the Company paid Yale a license issue royalty of \$10,000 (plus a \$10,000 annual renewal fee) and issued 20,000 shares of its common stock, and agreed to pay certain milestones royalties by issuing an aggregate of 160,000 shares of common stock. The Company also agreed to pay to Yale a royalty of 5% of net sales. The agreement will expire automatically, on a country-by-country basis, on the date on which the last of the claims of the subject patents expires. The agreement can be terminated by Yale if the Company defaults on its obligations under the agreement and fails to cure such default within 60 days of a written notice by the university. The Company can terminate the agreement upon a six month notice subject to payment of all amounts due Yale under the agreement. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations of approximately \$144,000 related to this contract.

On July 23, 2012, the Company entered into a licensing agreement with the Winthrop University Hospital ("Winthrop") to license certain patents and technology. In consideration of the license granted under the agreement, the Company agreed to pay to Winthrop a license issue royalty of \$10,000 (plus a \$10,000 annual renewal fee) and issue 20,000 shares of its common stock, and to pay certain milestones royalties by issuing an aggregate of 160,000 shares of common stock. The Company also agreed to pay to Winthrop a royalty of 5% of net sales. The agreement will expire automatically, on a country-by-country basis, on the date on which the last of the claims of the subject patents expires. It can be terminated by Winthrop if the Company defaults on its obligations under the agreement and fails to cure such default within 60 days of a written notice by the university. The Company can terminate the agreement upon a six month notice subject to payment of all amounts due Winthrop under the agreement. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations of \$200,000 related to this contract.

In August 2012, the Company entered into an agreement with the Regents of the University of California ("UCI"), whereby UCI will provide work dealing with small molecule mediated porcine islet proliferation. Work under this agreement will be performed for a period of six months with an estimated cost of \$23,100. The Company has continued to work with UCI on a month to month basis. During the year ended April 30, 2013, the Company expensed as research and development expense within the consolidated statements of operations of \$276,000 related to this contract.

The Company is currently in default regarding its payment obligations under the foregoing license and research agreements.

On February 5, 2013, the Company entered into an exclusive license agreement with certain related parties, 12LO Licensors, to use screening inhibitors for a \$10,000, an non-refundable royalty payment (plus a \$10,000 annual renewal fee) and issuing 20,000 shares of the Company's common stock, and to pay certain milestones royalties by issuing an aggregate of 100,000 shares of the Company's common stock. The Company also agreed to pay to 12LO Licensors a royalty of 5% of net sales. The agreement can be terminated by the third party if the Company defaults on its obligations under the agreement and fails to cure such default within 60 days of a written notice by the third party. The Company can terminate the agreement upon a six month notice subject to payment of all amounts due under the agreement.

#### **Legal Proceedings**

In April 2012, Sand Dollar Partners, LLC, a shareholder of the Company filed a complaint in the Superior Court of Arizona, Pima County against, among other parties, ISI, DTI, John Steel, the Company's CEO and Director, and Jonathan Lakey, the Company's Director. In 2010 Sand Dollar invested \$357,000 in ISI through the purchase of a convertible promissory note which was converted into 3,591,729 shares of the Company's common stock. The plaintiff contends that it was entitled to issuance of additional shares and nomination of one board member. The plaintiff is seeking rescission of its investment and recovery of consideration paid, together with interest, attorneys' fees and costs, as well as damages incurred as a result. The complaint filed in Arizona court has been dismissed without prejudice. The plaintiff has re-filed the complaint with fewer claims in the U.S. District Court for the Southern District of California. Management believes the plaintiff's claims to be without merit and intend to vigorously defend against this action.

In July 2012, a complaint was filed against the Company and John Steel for infringement and misappropriation of MicroIslet patent in the United States District Court for the District of Utah, Central Division. The plaintiffs contend that they were the actual purchasers of the MicroIslet patent out of MicroIslet's bankruptcy proceedings in 2009 and that the respective intellectual property rights have been never assigned to either ISI or the Company. As a result, they allege that the Company's claim to the ownership of the MicroIslet patent based on the assignment of the patent by its founders are baseless. The complaint seeks monetary damages including punitive damages of at least \$12 million, costs, attorneys' fees, and declaratory judgment. The complaint filed in Utah has been dismissed without prejudice. On April 18, 2013, the Company, the plaintiffs and certain other parties thereto entered into a settlement agreement. Because of a subsequent failure of certain parties to the settlement agreement other than the Company to fulfill their obligations thereunder, the settlement has not been completed and as a result, the plaintiffs withdrew from it. On July 3, 2013, the plaintiffs filed an amended complaint in the United States District Court for the District of Utah, Central Division. Management believes the plaintiffs' claims to be without merit and intends to vigorously defend against this action.

#### NOTE 7. RELATED PARTY TRANSACTIONS NOT INCLUDED ELSEWHERE

The Company's CEO has agreed to advance to the Company up to \$160,000 during any fiscal year. During the year ended April 30, 2013, the Company borrowed \$10,000 from its CEO and issued a promissory note.

#### NOTE 8. INCOME TAXES

As of April 30, 2013 and 2012, the Company's net deferred tax assets were as follows:

	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	\$6,133,500	\$1,473,900
Derivative liability	23,300	328,600
Accrued expenses	44,500	452,300
Depreciation and amortization	19,600	15,700
Research and development credits	428,200	74,600
Total deferred tax assets	6,649,100	2,345,100
Valuation allowance	(6,649,100)	(2,345,100)
Deferred tax liabilities – intangible assets	(547,000)	(547,000)

Net deferred tax liability \$(547,000 ) \$(547,000 )

FASB ASC 740, Income Taxes, requires that a valuation allowance be established when it is more likely than not that its net deferred tax asset will not be realized. In determining whether a valuation allowance is required, a company must take into account all positive and negative evidence with regard to the utilization of a deferred tax asset. FASB ASC 740 further states that it is difficult to conclude that a valuation allowance is not needed when there is negative evidence such as cumulative losses in recent years.

The Company plans to continue to provide a full valuation allowance on future tax benefits until it can sustain an appropriate level of profitability and until such time, the Company would not expect to recognize any significant tax benefits in its future results of operations. The valuation allowance increased by \$4,304,000 and \$2,048,100 for the years ended April 30, 2013 and 2012, respectively.

As of April 30, 2013, the Company had net operating loss carry forwards for Federal and state income tax purposes of approximately \$15,368,000 and \$15,572,000, respectively. These Federal and state net operating loss carry forwards will begin to expire in 2031. The Company had research and development credits carry forwards for Federal and state income tax purposes of approximately \$318,000 and \$110,000, respectively. Pursuant to the Internal Revenue Code, Sections 382 and 383, use of the Company's net operating loss and credit carry forward could be limited if a cumulative change in ownership of more than 50% occurs within a three-year period. This analysis has not been performed as of April 30, 2013. Currently, the 2010 through 2012 tax years are open and subject to examination.

The provision for income taxes differs from the amount computed by applying the US statutory Federal income tax rate of 34% to income before income taxes. The reconciliation of statutory and effective taxes for the years ended April 30, 2013 and 2012 are presented below:

	2013	2012
Provision computed at statutory rate	\$(3,929,000)	\$(1,713,000)
State income tax, net of Federal tax benefit	(674,000)	(294,000)
Research and development credit	(325,000)	(50,000)
Change in valuation allowance	4,304,000	2,048,100
Permanent differences	625,000	5,000
Other	(1,000)	3,900
Income tax expense	\$-	\$-

#### NOTE 9. SUBSEQUENT EVENTS

In May 2013, the Company borrowed an additional \$17,500 from its CEO. Promissory notes were issued for these amounts.

In May 2013, the Company entered into a sales and services agreement with the Regents of the University of California to provide supplies consisting of isolated islets to be supplied to Spring Point Partners. The total amount of the agreement is \$312,014 and will terminate on December 31, 2013.

On June 18, 2013, one of the Company's Board Members loaned the Company \$4,430. A promissory note was issued for this amount.

Effective July 9, 2013, Mr. John Steel resigned as the Chairman, Chief Executive Officer, Treasurer and Secretary of the Company. Pursuant to the separation agreement, Mr. Steel forfeited an unvested stock grant of 433,334 shares of Company common stock, however, he is entitled to receive \$270,000 in cash or Company common stock at the

2012

2012

Company's discretion and a number of shares of common stock equal to 1.0% of the Company's total outstanding common stock if there is a change of control of the Company. In connection with the separation agreement, Mr. Steel and the Company entered into a consulting agreement dated as of July 1, 2013, whereby, Mr. Steel will provide business development services to the Company as may be directed by its newly appointed CEO. Under the consulting agreement, Mr. Steel will receive a monthly consulting fee of \$15,000. The consulting agreement expires on June 30, 2014 and may be extended by the parties.