

AMERICAN CRYOSTEM Corp  
Form 10-Q  
May 15, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

For the six month period ended March 31, 2015

Commission file number: 000-54672

**AMERICAN CRYOSTEM CORPORATION**

(Name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

26-4574088

(I.R.S. Employer Identification No.)

1 Meridian Road, Eatontown, NJ 07724

(Address of principal executive offices)(Zip Code)

(732) 747-1007

(Registrant's telephone number, including area code)

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 x No o

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

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).

Yes  No

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes  No

As of May 10, 2015, there were 32,913,150 shares of common stock outstanding.

**TABLE OF CONTENTS**

	Page No.
<b><u>PART I. - FINANCIAL INFORMATION</u></b>	3
<u>Item 1. Financial Statements.</u>	3
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Plan of Operations.</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk.</u>	30
<u>Item 4. Controls and Procedures.</u>	30
 <b><u>PART II - OTHER INFORMATION</u></b>	 31
<u>Item 1. Legal Proceedings.</u>	31
<u>Item 1A. Risk Factors.</u>	31
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.</u>	31
<u>Item 3. Defaults Upon Senior Securities.</u>	31
<u>Item 4. Mine Safety Disclosures</u>	31
<u>Item 5. Other Information.</u>	31
<u>Item 6. Exhibits.</u>	31

**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements****American CryoStem Corporation****Interim Balance Sheets****As of March 31, 2015 and September 30, 2014**

	March 31, 2015	Sept 30, 2014
<b>ASSETS</b>		
Current assets:		
Cash	\$ 5,508	\$ 21,471
Deferred Contract Expense	31,000	54,250
Accounts Receivable	19,296	6,074
Prepaid Expenses	250	—
Total current assets	56,054	81,795
Other Assets		
Other Deposit	—	550
Investment in joint venture	1,000	1,000
Security deposits	5,950	5,800
Patents and Trademarks	221,751	200,767
Equipment – net	230,561	250,182
Total Assets	\$ 515,316	\$ 540,094
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable & accrued expenses	\$ 803,711	\$ 698,105
Bridge notes payable	596,000	596,000
Convertible notes payable	159,500	173,000
Deferred Revenue	17,568	17,768
Capital Lease Payable	—	10,898
Total current liabilities	1,576,779	1,495,771
Long-Term Liabilities		
Convertible Notes payable	327,500	30,000
Payable to Shareholder	132,947	134,947

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Total Long-Term Liabilities	460,447	164,947
Shareholders' equity:		
Common stock (\$.001 par value, 32,915,500 shares issued and outstanding at March 31, 2015, and 32,890,864 shares issued and outstanding at September 30, 2014; 300,000,000 shares authorized)	32,916	32,286
Additional paid in capital	7,018,502	5,990,623
Accumulated deficit	(8,573,328 )	(6,075,393 )
Total shareholders' equity	(1,521,910 )	(52,484 )
Total Liabilities & Shareholders' Equity	\$ 515,316	\$ 569,032

See Notes to Financial Statements

**American CryoStem Corporation****Interim Statements of Operations****For the Three Months Ended March 31, 2015 and 2014****and the Six Months Ended March 31, 2015 and 2014**

	Three Months Ended March 31,		Six Months Ended March 31,	
	2015	2014	2015	2014
Sales	\$58,511	\$4,480	\$94,555	\$10,619
Operating Expenses:				
Professional Fees	22,107	146,890	32,452	214,801
Research & Development	83,634	116,364	179,668	179,198
Administration	100,047	210,315	247,984	392,318
Total Operating Expenses	205,788	473,569	460,104	786,317
Net Loss from Operations	(147,277 )	(469,089 )	(365,549 )	(775,698 )
Other Income (Expense)	(20,382 )	(8,396 )	(44,237 )	(14,410 )
Net Loss	\$(167,659 )	\$(477,485 )	\$(409,786 )	\$(790,108 )
Basic & fully diluted net earnings (loss) per common share	\$(.005 )	\$(.015 )	\$(.012 )	\$(.024 )
Weighted average of common shares outstanding: Basic & fully diluted	32,915,150	32,640,721	32,911,414	32,584,031

See Notes to Financial Statements

**American CryoStem Corporation****Interim Statements of Cash Flows****For the Six Months Ended March 31, 2015 and 2014**

	2015	2014
Operating Activities:		
Net loss	\$(409,786)	\$(790,108)
Adjustments to reconcile net income items not requiring the use of cash:		
Depreciation & amortization expense	20,619	20,149
Accrued Interest	44,237	13,048
Changes in other operating assets and liabilities		
Accounts Receivable	(13,222 )	(2,017 )
Deferred Contract Expense	23,250	(54,500 )
Prepaid Expenses	(250 )	(250 )
Other Deposit	550	—
Security Deposit	(150 )	—
Accounts Payable and accrued expenses	61,369	185,133
Contract Payable	—	45,000
Deferred Revenue	(200 )	1,100
Net cash used by operations	(273,583)	(582,445)
Investing activities:		
Purchase of equipment	—	(8,149 )
Investment of other assets	(21,982 )	(23,465 )
Net cash used by investing activities	(21,982 )	(31,614 )
Financing activities:		
Issuance of convertible notes	284,000	5,250
Payment to Shareholder	(2,000 )	(2,000 )
Issuance of notes payable	—	426,000
Issuance of common stock	8,500	124,250
Capital Lease	(10,898 )	(9,873 )
Net cash provided by financing activities	279,602	543,627
Net increase (decrease) in cash during the period	(15,963 )	(70,432 )
Cash Balance, Beginning of Period	21,471	115,932
Cash balance, End of Period	\$5,508	\$45,500
Supplemental disclosures of cash flow information:		
Interest Paid	\$324	\$1,361
Income Taxes Paid	\$—	\$—

See Notes to Financial Statements

5



**American CryoStem Corporation**

**Statement of Changes in Shareholders' Equity**

**For the Six Months Ended March 31, 2015**

**Prices & shares adjusted for stock splits**

	Common Stock Shares	Par Value	Additional Paid in Capital	Accumulated Deficit	Total Shareholders' Equity
Balance at September 30, 2014	32,890,864	\$32,892	\$7,010,026	\$(8,163,542 )	\$(1,120,624 )
Exercises of Convertible Notes	24,286	24	8,476		8,500
Net Loss				(409,786 )	(409,786 )
Balance at March 31, 2015	32,915,150	\$32,916	\$7,018,502	\$(8,573,328 )	\$(1,521,910 )

See Notes to Financial Statements

## American CryoStem Corporation

### Notes to the Financial Statements

March 31, 2015

#### NOTE 1. Organization of the Company and Significant Accounting Policies

American CryoStem Corporation (the “Company”) is a publicly held corporation formed on March 13, 2009 in the state of Nevada as R&A Productions Inc. (R&A).

In April 2011, R&A purchased substantially all the assets and liabilities of American CryoStem Corporation (ACS) a company formed in 1987, for 21 million shares of common stock. ACS was deemed to be the accounting acquirer. At the date of the purchase, the former operations of R&A were discontinued and the name of the Company was changed to American CryoStem Corporation.

The Company is in the business of collecting adipose tissue and processing and storing the adult stem cells extracted for future use. The process allows individuals to preserve their stem cells for future personal use in cellular therapy. The adipose derived stem cells are prepared and stored in their raw form without manipulation, bio-generation or the addition of biomarkers or other materials, making them suitable for current and future cellular treatments and therapies offered by existing and planned treatment centers worldwide. Individualized collection and storage of adult stem cells provides personalized medical solutions by providing the patient’s own preserved stem cells for future cellular therapies. The Company has devoted a significant amount of its time and resources to develop its technologies and intellectual property. These efforts have resulted in the development of cell lines, cell culture medium and other laboratory products which the Company believes are suitable for licensing and distribution by third parties. Additionally the Company has initiated a licensing program to license its technologies to laboratories currently processing other types of biologic materials including cord blood and general blood banks. The Company closed its first licensing agreement in 2014 and intends to pursue additional licensing partners in the future.

*Use of Estimates* - The preparation of the financial statements in conformity with United States generally accepted accounting principles (“GAAP”) uniformly applied requires management to make reasonable estimates and assumptions that affect the reported amounts of the assets and liabilities and disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses at the date of the financial statements and for the period they include. Actual results may differ from these estimates.

*Cash* - For the purpose of calculating changes in cash flows, cash includes all cash balances and highly liquid short-term investments with an original maturity of three months or less.

*Revenue Recognition* – The Company recognizes revenue from the processing of adipose tissue into usable stem cells once all the procedures have been performed and the client sample has been stored in the Company’ cryogenic storage tank. Storage revenues for stored client samples are recognized on an annual basis on the anniversary date of the storage.

Royalties from the licensing of the Company’s assets are recognized when earned and collection of the royalty is reasonably assured.

*Long Lived Assets* - The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount.

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

*Equipment* - Equipment is stated at cost. Depreciation expense is computed using the straight-line method over the estimated useful life of the assets, which is estimated as follows:

Office equipment	5 years
Lab equipment & Furniture	7 years
Lab software	5 years
Leasehold improvements	15 years

7

**American CryoStem Corporation**

**Notes to the Financial Statements**

**March 31, 2015**

**NOTE 1. Organization of the Company and Significant Accounting Policies (continued)**

*Income taxes* - The Company accounts for income taxes in accordance with generally accepted accounting principles which require an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for differences between financial statement and income tax bases of assets and liabilities that will result in taxable income or deductible expenses in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets and liabilities to the amount expected to be realized. Income tax expense is the tax payable or refundable for the period adjusted for the change during the period in deferred tax assets and liabilities.

The Company follows the accounting requirements associated with uncertainty in income taxes using the provisions of Financial Accounting Standards Board (FASB) ASC 740, *Income Taxes*. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not the positions will be sustained upon examination by the tax authorities. It also provides guidance for derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of March 31, 2015, the Company has no uncertain tax positions that qualify for either recognition or disclosure in the financial statements. All tax returns from fiscal years 2009 to 2012 are subject to IRS audit.

*Recent Accounting Pronouncements:*

There are no recently issued accounting pronouncements that have a material impact on the Company's financial statements.

**NOTE 2. Going Concern**

The accompanying financial statements have been presented in accordance with GAAP, which assumes the continuity of the Company as a going concern. However, the Company has incurred significant losses since its inception and has no material revenues to date and continues to rely on financing to fund its business operations. Management's plans with regard to this matter are as follows:

The Company plans to continue to fund its operations through fundraising activities in fiscal 2015 until it generates sufficient revenue to support its operations. The Company has entered into an advisory agreement to assist in raising additional capital from institutional and strategic investors to fund the marketing and distribution of its products.

**NOTE 3. Loss per Share**

The Company applies ASC 260, “*Earnings per Share*” to calculate loss per share. In accordance with ASC 260, basic net loss per share has been computed based on the weighted average of common shares outstanding during the periods reported. The effects of the options and notes convertible into shares of common stock are not included in the calculation of loss per share since their inclusion would be anti-dilutive.

Net loss per share is computed as follows:

	For the Three Months Ended		For the Six Months Ended	
	March 31,		March 31,	
	2015	2014	2015	2014
Net Loss	\$(167,659 )	\$(477,485 )	\$(409,786 )	\$(790,108 )
Weighted average shares outstanding	32,915,150	32,640,721	32,911,414	32,584,031
Basic & fully diluted net earnings (loss) per common share	\$(.005 )	\$(.015 )	\$(.012 )	\$(0.024 )

8

**American CryoStem Corporation****Notes to the Financial Statements****March 31, 2015****NOTE 4. Equipment**

Equipment is comprised of the following:

	March 31, 2015	Sept 30, 2014
Office Equipment	\$ 26,637	\$ 26,637
Lab Furniture	642	642
Office Furniture	999	999
Lab Equipment	254,054	254,054
Lab Software	123,000	123,000
Less: Accumulated Depreciation	(174,771 )	(155,150 )
Equipment - net	\$ 230,561	\$ 250,182

**NOTE 5. Patents**

The patent and patents development are recorded at cost and are being amortized on a straight line basis over a period of seventeen years. The following is a description of the Company's patent assets.

On August 2, 2011, the Company was awarded U.S. Patent No. US 7,989,205 B2, titled Cell Culture Media, Kits, and Methods of Use. The Patent is for cell culture media kits for the support of primary culture of normal non-hematopoietic cells of mesodermal origin suitable for both research and clinical applications. The Company filed and maintains a continuation (U.S. Serial No. 13/194,900) with additional claims pending.

The Company has filed the following additional patents to extend its intellectual property to encompass additional aspects of the Company's platform processing technologies. To date the following patent filings have been made:

A Business Method for Collection Cryogenic Storage and Distribution of a Biologic Sample Material  
PCT/US2011/39260 filed June 6, 2011 with a priority date of June 6, 2010.

Systems and Methods for the Digestion of Adipose Tissue Samples Obtained from a Client for Cryopreservation  
U.S. Serial No. 13/646,647 filed October 5, 2012 with a priority date of October 6, 2011.

Compositions and Methods for Collecting, Washing, Cryopreserving, Recovering and Return of Lipospirates to  
Physician for Autologous Adipose Transfer Procedures PCT/US13/44621 filed June 6, 2013 with a priority date of June 7, 2013.

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Human Albumin Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells. US Serial No. 62/098799 filed December 31, 2014

Autologous Serum for Transport of Isolated Stromal Vascular Fraction or Adipose Derived Stem Cells 61/810,970 Filed in 2014 with a priority date of April 11, 2013.

Cell Culture Media, Kits and Methods of Use, US Serial No. 13/1-94/900 continuation of US Serial No. 11/542,863.

9

**American CryoStem Corporation****Notes to the Financial Statements****March 31, 2015****NOTE 6. Debt**

As of March 31, 2015, the Company had \$487,000 of convertible notes outstanding. Of those convertible notes \$159,500 had come due on September 30, 2014. Of the \$159,500, \$17,500 have been extended to September 30, 2015. The Company is currently in negotiations with the rest of these note holders to convert their notes or to extend their maturity dates. These notes are convertible into common stock at \$0.35 per share.

Convertible notes of \$327,500 come due at the end of fiscal year 2016 and are exercisable into common stock at \$0.30 per share.

During fiscal year 2014, the company issued “bridge notes” and received proceeds of \$596,000. The notes are due in fiscal year 2015 at 8% interest. Holders of the notes received options to purchase 596,000 shares of common stock at \$0.05 per share. The notes are unsecured.

The following table describes the Company’s debt outstanding as of March 31, 2015:

Debt	Carrying Value	Maturity	Rate
Convertible notes	\$142,500	Demand	8.00%
Convertible notes	\$17,000	Fiscal 2015	8.00%
Convertible notes	\$327,500	Fiscal 2015	8.00%
Bridge Notes	\$596,000	Fiscal 2015	8.00%
Due to shareholder	\$132,947	Demand	0.00%

**NOTE 7. Common Stock Issuances**

During fiscal year 2014, option holders exercised 170,000 options and the Company issued 170,000 shares of common stock and received proceeds of \$24,500.

During fiscal year 2014, holders of convertible notes converted \$152,300 of convertible notes and the Company issued 435,143 shares of common stock.

During the six months ended March 31, 2015, holders of convertible notes converted \$8,500 of convertible notes and the Company issued 24,286 shares of common stock.

**NOTE 8. Stock Options**

The Company applies ASC 718, “Accounting for Stock-Based Compensation” to account for its option issues. Accordingly, all options granted are recorded at fair value using a generally accepted option pricing model at the date



Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

of the grant. For purposes of determining the option value at issuance, the fair value of each option granted is measured at the date of the grant by the option pricing model with the following assumptions:

	2014	2013
Dividend yield	0.00 %	0.00 %
Risk free interest rate	0.25 %	0.25 %
Volatility	48.39%	16.60%

The fair values generated by option pricing model may not be indicative of the future values, if any, that may be received by the option holder.

**American CryoStem Corporation****Notes to the Financial Statements****March 31, 2015**

**NOTE 8. Stock Options (continued)** The following is a summary of common stock options outstanding at March 31, 2015:

	Options	Wgt'd Avg Exercise Price	Wgt'd Years to Maturity
Outstanding at September 30, 2014	10,556,000	\$ 0.21	3.74
Issues	0		
Exercises	0		
Expires	0		
Outstanding at March 31, 2015	10,556,000	\$ 0.21	3.24

**NOTE 9. Fair Values of Financial Instruments**

*Fair Value Measurements* under generally accepted accounting principles clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy as follows.

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs to the valuation methodology that are significant to the measurement of fair value of assets or liabilities.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is disclosed and is determined based on the lowest level input that is significant to the fair value measurement.

Cash, prepaid expense, security deposit, accounts payable and accrued expenses, capital lease payable, payable to shareholder, and note payable to shareholder in the balance sheet are estimated to approximate fair market value at March 31, 2015.

**NOTE 10. Commitments & Contingencies**

*Operating Leases* – The Company leases laboratory facilities at the Burlington County College Science Incubator in Burlington, New Jersey. The rent \$3,300 per month.

The Company leases office facilities in Eatontown, New Jersey. The rent is \$2,650 per month.

**NOTE 11. Reliance on Key Personnel**

The Company largely relies on the efforts of its Chief Operating Officer and its Chief Executive Officer and Chairman of its Board of Directors. A withdrawal of the efforts of these individuals would have a material adverse effect on the Company's ability to continue as a going concern.

**NOTE 12. Litigation**

The Company is not party to any litigation against it and is not aware of any litigation contemplated against it that would have a materially adverse effect on the Company as of March 31, 2015 and the date of these financial statements.

## ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF 2. OPERATIONS

### Forward-looking Statements

We and our representatives may from time to time make written or oral statements that are "forward-looking," including statements contained in this quarterly report and other filings with the Securities and Exchange Commission (the "SEC"), reports to our stockholders and news releases. All statements that express expectations, estimates, forecasts or projections are forward-looking statements. In addition, other written or oral statements which constitute forward-looking statements may be made by us or on our behalf. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "project," "forecast," "may," "should," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in or suggested by such forward-looking statements. We undertake no obligation to update or revise any of the forward-looking statements after the date of this quarterly report to conform forward-looking statements to actual results. Important factors on which such statements are based on assumptions concerning uncertainties, including but not limited to, uncertainties associated with the following:

- Inadequate capital and barriers to raising the additional capital or to obtaining the financing needed to implement our business plans;
- Our failure to earn revenues or profits;
- Inadequate capital to continue business;
- Volatility or decline of our stock price;
- Potential fluctuation in quarterly results;
- Rapid and significant changes in markets;
- Litigation with or legal claims and allegations by outside parties; and
- Insufficient revenues to cover operating costs.

The following discussion should be read in conjunction with the financial statements and the notes thereto which are included in this quarterly report. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ substantially from those anticipated in any forward-looking statements included in this discussion as a result of various factors.

### Background

American CryoStem Corporation was incorporated in the state of Nevada on March 13, 2009. On April 20, 2011, we acquired, through our wholly owned subsidiary American CryoStem Acquisition Corporation, substantially all of the assets from, and assumed substantially all of the liabilities of, ACS Global, Inc. ("**ACS**") in exchange for our issuance of 21,000,000 shares of Common Stock to ACS (the "**Asset Purchase**"). We filed a Current Report on Form 8-K with the Securities and Exchange Commission (SEC) on April 27, 2011 disclosing the Asset Purchase and certain related matters.

## Overview

American CryoStem Corporation is a biotechnology pioneer in the field of Regenerative and Personalized Medicine and operates a state-of-the-art, FDA-registered, clinical laboratory dedicated to our standardized processing, bio-banking and development of cellular tools and applications using autologous adipose (fat) tissue and adipose derived stem cells (“**ADSCs**”). The Company has built a strong, strategic portfolio of intellectual property, patent applications, and proprietary operating processes that form its core standardized cellular platform which we believe supports and promotes a growing pipeline of biologic products and processes, clinical services and international licensing opportunities. Our FDA registered clinical laboratory which we believe to be in compliance with the FDA’s current Good Manufacturing Procedures (“**cGMP**”) for human tissue processing, cryo-storage and cell culture and differentiation media development is located in Mount Laurel, New Jersey at the Burlington County College Science Incubator.

12

The Company believes the reproducibility of scientific studies has become a substantial issue in life science research from drug discovery and development through clinical trials as researchers throughout the world continue to use different protocols for processes associated with sample preparation, cryopreservation and cold chain management. We believe the scientific community is becoming more aware of factors that affect sample integrity and experimental variability. By standardizing handling, storage, and transportation protocols we can substantially improve the quality and reproducibility of preclinical and clinical data will help to accelerate the transition from lab research to drug development and market launch.

Our business strategy is centered on marketing our standardized platform as a complete adipose stem cell solution and expanding our research and development through scientific collaborations. We intend to generate revenue through the sale and licensing of our patented products, laboratory tools, and services to attempt to capitalize on: (1) ADSC technologies; (2) scientific breakthroughs incorporating ADSCs that have been developing in the fast growing Regenerative and Personalized Medicine industries; (3) providing these growth industries with a standardized ADSC cell processing platform; (4) enhancing the delivery of healthcare through cellular-based therapies and applications which address disease treatment, wound and burn healing, joint repair and personalized health and beauty care; and (5) building a global network of physicians and affiliated laboratory facilities for the delivery of our products and services.

Our proprietary, patent pending clinical processing platform allows for the collection, preparation and cryo-preservation of adipose tissue without manipulation, bio-generation or the addition of animal-derived products or other chemical materials which require removal from the tissue sample upon retrieval or prior to use. Management believes this core process makes each tissue sample suitable for use in cosmetic grafting procedures or for further processing to adult stem cells for other types of stem cell therapies. Currently, we believe there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments identified or in use globally. As of May 1, 2015, a review of [clinicaltrials.gov](http://clinicaltrials.gov), operated by the US National Institutes of Health (NIH) indicates that there is a significant number of clinical trials registered or completed that are focused on adipose tissue (1583), adult stem cells (4820), adipose derived stem cells (137), mesenchymal stem cells (492), and stromal vascular fraction (31).

On February 10, 2015 the Company entered into an agreement to acquire the clients, physician network, all stored client samples and the cryo storage equipment of BioLife Cell Bank (“BioLife”) located in Dallas, Texas. BioLife Cell bank was one of the first private cell banks in the United States to store adipose tissue and adipose derived stem cells. We have received the samples and are currently undertaking a complete inventory and obtaining new storage agreements with the BioLife storage customers. The agreement also calls for us to collect all current and future storage fee’s associated with the transferred samples. The Company has begun the process of converting the BioLife clients to American CryoStem storage agreements, enrolling existing BioLife physicians in the American CryoStem network and performing inventory and integration processes on the received samples.

## **Products and Services**

American CryoStem is focused on multiple high margin business lines capable of generating sustainable, recurring revenue streams from each of our developed products and services. Our products and services are the result of more than seven years of scientific development. The Company also incorporates all of its proprietary and patented or patent pending laboratory products, such as our *ACSeperate*<sup>TM</sup> cell culture media, into our processing, product production and contract manufacturing services. Additionally, the Company requires licensee's of our tissue and cell processing technologies to purchase all the consumable products required in the collection, processing and storage of tissue/stem cells as part of the licensing agreement.

To date, we have generated minimal revenue; however, subject to, among other factors, obtaining the requisite financing, management believes that we are well positioned to leverage our developed products and services as the basis for international distribution through licensees of our technologies and a host of Regenerative Medicine uses and future applications.

The following products and services are designed to become the basis of, or an integral part of, numerous planned licensing, revenue generating, and cellular therapy development activities: Our products and services are:

- **CELLECT®**
  - Description: Tissue Collection methodology designed for participating physicians to facilitate the collection and overnight shipping of an individual's adipose tissue to our FDA registered laboratory;
  - Sales Channel: Manufacture and sale of our Collect collection boxes to licensees for our ATGRAFT™ and ATCELL™ technologies.
  
- **ATGRAFT™**
  - Description: Tissue processing at our Laboratory of a customer's received adipose tissue and preparation for long term storage in different configuration sizes allowing future retrieval for tissue grafting procedures or Regenerative Medicine applications
  - Sales Channel: US Plastic and Cosmetic surgeons, licensing of the ATGRAFT™ processing technology to international partners for utilizing our CELLECT™ collection boxes and ACSelerate mediums.
  
- **ATCELL™**
  - Description: Clinical Processing separating the component parts of an individual's adipose tissue, removing the adipocytes and red blood cells, and creating the ATCELL™ autologous stem cell lines for storage, expansion, or differentiation
  - Sales Channel Clinical and Research grade ATCELL™ (adipose Derived Stem Cells) lines for use with or sale to collaborative partners in research and application development and optimization, cell morphology and characterization assays, and growth analysis.
  
- **ACS Laboratories™**
  - Laboratory Division: Manufacturing and sale of our patented ACSelerate cell culture media products
  - Creation and sale of research grade ATCELL™
  - Participation and support of all collaborative research projects
  - Contract manufacturing, including Autokine-CM®
  - Provide testing services for physicians performing in-office procedures and tissue processing
  
- **International Licensing**
  - Standard Operating Procedures (SOPs) and all associated components and products
  - Consulting and Marketing Review and Assessment
  - CELLECT®
  - ATGRAFT™
  - ATCELL™
  - Adipose tissue processing, cellular expansion and product manufacture

**Our branded product and service offerings include:**

**CELLECT® Validated Collection, Transportation, and Storage System** – An unbreakable “chain of custody” clinical solution for physicians to collect and deliver tissue samples utilizing proprietary and patent pending methods and materials. The CELLECT® service is monitored in real-time and assures the highest cell viability upon laboratory receipt. The Collect system incorporates our ACSelerate–TR transport medium into all collection bags which supports the health of the tissue during transport. The CELLECT® kit is an integral part of our validated ATGRAFT™ and



ATCELL™ technology to be used by all licensees of these technologies. The CELLECT® service is included in our pending patent application U.S. Serial No. 13/702,304.

**ATGRAFT™ Adipose Tissue Storage Service** – A clinical fat storage solution allowing physicians to provide their patients with multiple tissue/stem cell storage options. The ATGRAFT™ service, through one liposuction procedure allows individuals the benefit of multiple cosmetic or regenerative procedures by using their own stored adipose tissue as a natural biocompatible filler or cellular therapy application without the trauma of further liposuctions. ATGRAFT™ procedures include breast reconstruction, layered augmentation, buttocks enhancement or volume corrections of the hands, feet, face and neck areas that experience significant adipose tissue (fat) volume reduction as we age. ATGRAFT™ is processed and stored utilizing our cGMP standards so that any stored fat tissue sample may be retrieved in the future and re-processed to create ATCELL™ our clinical grade stem cell product for use in Regenerative Medicine applications. The ATGRAFT™ service is included in our pending patent application U.S. Serial No. 13/646,647)

The Company's charges standardized fees for ATGRAFT™ tissue processing and initial storage ranges from \$985 to \$3,000, depending on the volume of tissue processed. The annual storage fee is \$200 for up to 100ml of tissue. Storage of tissue over 100ml is billed an additional \$1 per 1ml annually. These fees may be paid by the collecting/treating physician or the consumer. The Company earns additional fees ranging from \$100 to \$500 plus shipping costs, paid by the physician upon retrieval, for the thawing, packaging and shipment of the stored samples to the physician for immediate use upon receipt.

ATGRAFT™ Storage and Retrieval fees are determined by the storage configuration as follows:

- Small Sample package – for storages of 100ml of adipose tissue or less.
- Medium Sample package – for storage of 100ml to 300ml of adipose tissue.
- Large Storage package – for storage of over 300ml of adipose tissue.
- Custom Package – storage configuration for pre planned procedures.

The ATGRAFT™ service creates patient retention and significant revenue opportunities for the participating physician to promote additional procedures and generate additional fees from waste material collected during liposuction procedures. These additional fees can be generated with significantly lower physician costs by eliminating the overhead associated with performing a liposuction for each procedure. Physician cost savings may include: materials, supplies, equipment, and the expenses of utilizing a surgical center, hospital operating room or an in-office aseptic procedure room. The ATGRAFT™ service is designed to operate under the minimally manipulated regulations contained in both 21 CFR 1271.10 and PHS 361.

**ATCELL™ Adipose Derived Stem Cells (ADSCs)** – Clinically processed and characterized adipose derived stem cells (ADSCs) created using the Company's proprietary Standard Operating Procedures (SOPs) and patented cell culture media. ATCELL™ is the Company's trademarked name for its ADSC and differentiated cell products and processing. The Company can create multiple master and differentiated cell lines and labels them according to their characterization. (i.e. ATCELL™(adipose derived stem cells) ATCELL-SVF™ (stromal vascular fraction), ATCELL – CH™ (differentiated chondrocytes), etc.. Cell lines are custom created for patients desiring to store their cells for their own use in future Regenerative Medicine. The Company charges the client fees ranging from \$1,500 to \$10,000 to process a previously stored or newly collected ATGRAFT™ sample into the ATCELL™ product. Customer samples

submitted for processing must utilize the CELLECT® collection system to conform to our internal cGMP SOPs.

The Company believes it will also earn additional fees based upon the proposed storage configuration of the final ATCELL™ sample and for additional culturing in the ACSelerate™ cell culture and differentiation media. We believe cell culturing and differentiation can be performed upon receipt of the raw tissue sample or at any time on a previously processed and cryopreserved ATGRAFT™ or ATCELL™ sample. We believe ATCELL™ is ideally suited for expansion and differentiation into additional cell types utilizing the ACSelerate™ SFM (fetal bovine serum (FBS) free media), LSM (low 0.05% FBS media), or differentiation media. The ATCELL™ products and services are incorporated into our pending patent filing US Serial No. 13/646,647.

The Company's ATCELL™ cell lines are cGMP processed and cultured in our patented ACSelerate™ – SFM animal product free cell culture media. All tissue, cells, and research materials that are made available for sale to research institutions are tested for sterility, disease, lifespan, and population doubling rate (PDL). Additionally, we believe these cells are suited for any type of cellular therapy or regenerative medicine research. Cell morphology is confirmed by (i) flow cytometry and (ii) differentiation analysis using ACSelerate™ differentiation media. The Company's research program makes donor demographics, processing, and testing data available to the clinical researcher. Each ATCELL™ line can be further cultured and differentiated allowing the Company to provide genetically matched clinical grade cell types. We believe this research methodology provides opportunities for the Company's ATCELL™ and ACSelerate™ products to become building blocks of final developed commercial applications.

Additional information on stem cell research can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.nih.gov](http://www.nih.gov) (see adipose tissue, adipose derived stem cells and mesenchymal stem cells)

**ACSelerate™ Cell Culture Media Products** – Manufactured patented cell culture media products for growing human stromal cells (including all cells found in human skin, fat and other connective tissue). Certain ACSelerate™ cell culture media lines are available in animal serum free, which is suitable for human clinical and therapeutic uses; and a low serum version for application development and research purposes is also available.

On August 2, 2011, the Company was issued US patent number 7,989,205 for “Cell Culture Media, Kits and Methods of Use.” The granted claims include media variations for cellular differentiation of ADSCs into osteoblasts (bone), chondrocytes (cartilage), adipocytes (fat), neural cells, and smooth muscles cells in both clinical grade and research grade, the complete line of ACSelerate™ products we manufacture is listed below. This patent covers both non-GMP research grades and GMP clinical grades suitable for cell culture of adipose-derived stem cells intended for use in humans. Additionally, in 2014 the Company filed a continuation of this granted patent with additional claims and improvements.

Currently, we believe our media products are being utilized by our research partners engaged in developing novel new cellular applications and treatments. The Company supports these efforts by also making ATCELL™ samples available for research purposes and for internal product development through our research programs. We believe these cell lines are highly sought after by private researchers and universities for use in pre-clinical trial studies and in-vitro research. We also believe that the Company’s ability to provide clinical grade materials for these research and development collaborators, partners and other third parties extends the Company’s ability to become a primary source of clinical grade materials and services to support approved applications and treatments.

The Company manufactures several versions of its *ACSelerate™* cell culture media including:

*ACSelerate-SFM™* our flagship clinical grade, cGMP manufactured animal serum free cell culture media, which is ideally suited for the rapid expansion of adipose-derived cell samples for direct use or further culturing into other cell types;

*ACSelerate-LSM™* our flagship research grade, cGMP manufactured low FBS (0.05%) cell culture media, which is ideally suited for the rapid expansion of adipose-derived cell samples for research and cellular application development or further culturing into other research grade cell types;

*ACSelerate-CY™* for differentiation of ATCELL™ into chondrocytes (*ATCELL-CY™*), which are suitable for use in cartilage repair applications in knees and other joints for patients suffering from joint injury, osteoarthritis and other diseases that cause degeneration of joint cartilage;

*ACSelerate-OB™* for differentiation of ATCELL™ into osteoblasts (*ATCELL-OB™*) for the repair of bone injuries resulting from traumatic injury and musculoskeletal diseases;

*ACSelerate-AD™* for differentiation of ATCELL™ into adipocytes (*ATCELL-AD™*) for the repair of adipose tissue defects resulting from injury or surgical procedures and is designed for those patients without an appropriate amount of body fat for corrective tissue transfer procedures;

*ACSelerate-MY™* for differentiation of ATCELL™ into myocytes (*ATCELL-MY™*) for the repair of muscle tissue defects and loss as the result of traumatic injury, surgery or systemic disease;

*ACSelerate-CR<sup>TM</sup>* a clinical grade, non-DMSO (Dimethyl Sulfoxide) cellular cryopreservation media designed to conform to certain FDA and PHS 361 exemptions available for marketing our *ATGRAFT<sup>TM</sup>* service.

16

The Company continues to optimize additional versions of *ACSelerate*<sup>™</sup> media through further research and testing, to develop versions for differentiation of *ATCELL*<sup>™</sup>ADSCs into neural, lung and other specific cell types that may be necessary for use in future clinical applications. On December 31, 2014 the Company filed a new patent application for an advanced medium formulation titled Human Albumin Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells representing the most recent results of this ongoing optimization program. The new growth medium is designed to provide enhanced cell growth allowing for reduced culture times and management believes that it can produce the new media with 60% less materials costs. Internal growth studies have indicated a general increase in overall cell growth of up to 200% greater than other cell culture medium.

**ACS Laboratories<sup>™</sup> Laboratory Product Sales, Contract Manufacturing and Professional Services** – ACS Laboratories is an unincorporated subsidiary of American CryoStem Corporation, responsible for the sale and licensing of all the Company's patented and patent pending cellular, cell culture, processing and testing products to professional, institutional and commercial clients. The Company operates a separate website (*acslaboratories.com*) to distinguish the sale of commercial and research products from its consumer products and services, which are marketed on its main website (*americancryostem.com*). ACS Laboratories manufactures a full line of *ACSelerate*<sup>™</sup> cell culture media and *ATCELL*<sup>™</sup> products; and provides these products to our collaborative partners as further discussed below.

**Contract Manufacturing, Autokine-CM<sup>®</sup> Anti-Aging, Autologous Skin Care Product Line** – Under agreement with Personal Cell Sciences (PCS), we manufacture the key ingredient Autokine-CM<sup>®</sup> (autologous adipose derived stem cell conditioned medium) for PCS' U-Autologous<sup>™</sup> anti-aging topical formulation. Each product is genetically unique to the patient and custom blended, deriving its key ingredients from the individual client's own stem cells. The Company provides its CELLECT<sup>®</sup> Tissue Collection service to collect the required tissue to manufacture the U-Autologous product and processes it under the same cGMP standard operating procedures that it developed for the *ATGRAFT*<sup>™</sup> and *ATCELL*<sup>™</sup> cell processing services utilizing *ACSelerate*<sup>™</sup> cell culture media. The Company receives collection, processing and long term storage fees and earns a royalty on all U-Autologous product sales. The utilization of the Company's core services in its contract manufacturing relationships provides opportunities for the Company to promote *ATGRAFT*<sup>™</sup> and *ATCELL*<sup>™</sup> products.

Our Company's contract manufacturing services can be extended to develop custom and/or white label products and services for both local and global cosmetic and regenerative medicine companies, physicians, wellness clinics and med spas. The Company intends to expand its relationships and contract manufacturing regionally through its physician networks and globally through its International Licensing Program.

**International Licensing Program** – The Company believes that globally, many jurisdictions outside the US currently permit use of cellular therapies and regenerative medicine applications. The Company has received numerous inquiries concerning the sale or licensing of our SOPs, products and services in international jurisdictions to service the Regenerative Medicine and Medical Tourism Markets. The Company believes that the inquiries to date are a result of the global boom in Medical Tourism and the slow pace of approval of cellular therapies and regenerative medicine applications in the US. To attempt to expand the Company's sales, marketing and branding opportunities globally, the Company has created an international licensing program.

Significant to our international development activities is the proposed global expansion of the American CryoStem branded services and patented products, as well as the proposed expansion of the Company's services, technology and products as the core platform to implement cellular therapies and regenerative medicine globally.

The Company believes it can take advantage of the significant growth of the global cellular therapy market through its international licensing and marketing efforts. A recently published study by Transparency Market Research predicts that the Stem Cell market will grow at a CAGR of 24.2% upon its value of US \$26.23 billion in 2013 and will reach an approximate value of US \$119.52 billion by 2019. The report, titled "Stem Cells Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2012 - 2018", can be found at:

<http://globenewswire.com/news-release/2014/12/22/693419/10113247/en/Global-Stem-Cells-Market-to-grow-at-a-CAGR-of->

The Company has designed the program to permit the licensing of the Company's products and services to organizations that meet the Company's criteria. The Company believes that the proposed licensing program will allow for a variety of international business relationship including franchising, partnering and joint venturing.

Our licensing program is broken down into four operating modules corresponding to our CELLECT<sup>®</sup>, ATGRAFT<sup>™</sup>, ATCELL<sup>™</sup> and Contract Manufacturing services. Our proposed international development program offers the opportunity to develop and establish a global footprint of American CryoStem's laboratory services and patented products. The platform allows the Company's laboratory services, technology and products to become the core platform to implement cellular therapies and regenerative medicine in licensed territories globally.

On June 25, 2014, the Company entered into an agreement with Health Innovative Technology Corporation Limited, Hong Kong ("HIT") for the licensing of our ATGRAFT tissue storage product. Pursuant to the terms of the Agreement, American CryoStem has licensed to HIT the exclusive rights to utilize the Company's Standard Operating Procedures (SOP's) to create and market the Company's ATGRAFT<sup>™</sup> tissue storage service in Hong Kong. The financial terms call for annual minimum licensing payments for a period of three years as well as additional royalty payments based on gross revenue. HIT will also purchase CRYO's ACSelerate<sup>™</sup> storage media and other products necessary for clinical collection, processing and storage of Adipose Tissue. Upon execution CRYO received the initial payment of the minimum annual licensing fee with the balance of first year licensing payments due prior to full commercial launch of the ATGRAFT<sup>™</sup> service in Hong Kong. HIT currently operates a cord blood, cellular processing and banking platform and, offers comprehensive healthcare solutions to clients in Hong Kong.

## **Product Development**

Our strategic approach to product development is to design, develop and launch new products and services that utilize our existing products and services. Management believes that this approach will provide the Company with opportunities to produce near term cash flow, strong recurring revenue streams, strong international licensing partners and complementary scientific data. We focus on developing products, services and applications that require tissue collection and processing as the initial requirement to produce cellular therapies and products. These products and services may include adipose tissue and stem cell sample processing and storage as a form of personal "bio-insurance", adipose tissue (fat) storage for cosmetic fat engraftment procedures, and the creation and production of topical applications and ingredients used by other companies in the wound care and cosmetic industries as well as cellular applications and bio-materials development.

We intend to focus our efforts on expanding our product and services pipelines based upon our intellectual property portfolio, collaborative development relationships, product sales and distribution, and international licensing and partnering opportunities. Our current activities include supporting our university and industry collaborations by providing our products and services with the expectation that our products and services become the basis for new adipose tissue and stem cell based Regenerative Medicine and cellular therapy applications. We believe this strategy allows our proposed research partners and their application development teams to begin with clinically harvested and processed adipose tissue and ADSCs (ATCELL<sup>™</sup>), which may be a significant step toward accelerating the development and approval of new treatments.

## **Collaboration and Partnering Opportunities**

### ***Protein Genomics and Formation of Autogenesis Corporation***



In 2012, American CryoStem entered into a Memorandum of Understanding (MOU) outlining our initial collaborative efforts with Protein Genomics, Inc. (PGEN) to test and develop new products by combining certain components of our respective intellectual property and patented products. We have provided PGEN and its research partner, Development Engineering Sciences (DES), with Adipose Derived Stem Cells (ATCELL™) and our patented cell culture mediums (ACSelerate™) for testing with PGEN's patented products designed for the wound healing market. Research and development has been ongoing since late 2012 and notable progress has been achieved. In October of 2014, the early results of this initiative was the subject of local media coverage in Arizona showcasing the groundwork laid by PGEN, DES and American CryoStem in providing assistance in what we believe is a quicker way to heal skin injuries using a patient's stem cells.

As a result of the success realized in the early stage of this research collaboration, in fiscal 2013 we entered into a formal joint venture with Protein Genomics through the incorporation of Autogenesis, Corp. as required by the 2012 MOU. Each company (CRYO and PGen) initially have an equal ownership interest. All products capable of being commercialized, as well as any new intellectual property, resulting from the ongoing scientific collaboration will be wholly-owned by Autogenesis. This is representative of how we believe additional research collaborations utilizing our Company's technology may evolve in the future.

During 2013 and 2014, the collaborative efforts resulted in successful initial “proof of concept” combining PGEN’s unique biomaterial and the Company’s ATCELL™ product. Management believes the publication of the preliminary results showed successful healing of full depth wounds on the backs of immune deficient mice. Following this publication the partnership agreed to file grant applications to fund the additional research. The grant applications were prepared and filed in 2014.

Our collaborative research has established that membrane scaffolds fabricated from human proteins can be cultivated with ATCELL cells causing the scaffolds to rapidly, completely become covered by the cells. We believe the cells then secrete their own extracellular matrix, creating a structure with layers of matrix, cells and scaffold. This living structure, when introduced into a mouse wound model, localizes the stem cells in the wound, protects the cells within the wound environment, promotes cell growth and causes a statistically significant increase in the rate of wound closure and healing compared to the standard of care. Further evaluation will measure the performance of these scaffolds in accelerating the rate of wound closure, healed scar thickness, growth of new blood vessels and production of key wound healing factors. Our objective is to show that these constructs can stimulate the growth of new tissue and promote wound closure and healing. The next step in developing this remarkable result is preclinical and clinical studies in humans.

### *Rutgers University*

In May of 2012, American CryoStem entered into Material Transfer Agreements with three research scientists at Rutgers University allowing them to utilize the Company’s autologous Adipose-Derived Stem Cells (ATCELL™) and patented, serum free, GMP grade cell culture and differentiation mediums (ACSelerate™) for evaluation with the anticipation to implement additional agreements to research, develop and commercialize innovative new cellular therapies targeting incurable diseases, neurological disorders and the \$5 billion global wound care market.

In December of 2012, American CryoStem and Rutgers University executed a Collaboration and Research Agreement involving stem cell differentiation molecules and molecular biological reagents under the direction and supervision of Dr. KiBum Lee, the PRINCIPAL INVESTIGATOR (PI). Our collaborative efforts have advanced rapidly and new intellectual property resulted from this work. Based on the collaborative efforts under the Collaboration and Research Agreement, our Company’s patent counsel prepared patent applications based upon earlier developments which are now optioned to American CryoStem. In addition, American CryoStem’s agreement with Rutgers University allows us the use of intellectual property and biomaterials developed by Dr. Lee and his team in combination with our ATCELL™ and ACSelerate™ products for the development of new cellular therapies and regenerative medicine applications. To support the new discoveries, Dr. Lee and our professionals will develop, file and publish patent applications, research papers, government and private grant funding applications to support future clinical studies as appropriate.

During 2013 and 2014 the Company and Dr. Lee’s team investigated various combinations of NanoScript and ATCELL™ focused on the regeneration of neural, cartilage and muscle cells. This research led to filing a new patent jointly owned by Rutgers and the Company entitled “Nanoparticle-Mediated Synthetic Transcription Factor from Enhanced Gene Expression and Cell Differentiation” and the publication of papers and posters by Dr. Lee’s team. Dr. Lee’s team also received an initial seed grant to Dr. Lee from Rutgers neural engineering group. The team is continuing its research, the creation of scientific papers and in 2014 filed for a new grant with the National Institute of Health.

### *Additional Collaborations*

The Company is in the early stages of developing collaborations with additional industry and university partners. These developing relationships in their earliest stages are covered by Confidential Disclosure Agreements and those that are more advanced also include Material Transfer Agreements under which the Company supplies either

ATCELL or ACSelerate™ medium products for evaluation, testing, and the development of new cellular therapy applications.

To Date the Company has advanced to a Material Transfer Agreement with the University of Miami, University of Washington, UHV Technologies, and STEMCELL Technologies and has provided both ATCELL™ and ACSelerate™ products to these entities under Agreement. No assurance can be given that these relationships will progress to full collaborative agreements or ultimately result in new technology for future commercialization.

## **Institutional Review Board Approval of Protocols**

In 2013 we obtained approval from the Institutional Review Board (IRB) of the International Cell Surgical Society (ICSS) of our protocols for the processing of SVF and culturing of mesenchymal stem cells from autologous adipose tissue. The two protocols were, titled: *Autologous Adipose Tissue-Derived Stromal Vascular Fraction (SVF) Containing Adult Stem Cells with Isolation of SVF*, and *Culturing of Adipose Derived Stem Cells (ADSCs) For Use in Institutional Review Board Studies*. On June 30, 2013, the ICSS IRB approved the protocols until June 30, 2014.

Additionally, the Company obtained approval for a new study, entitled “*Comparative Viability Assessment of Human Adipose Tissue Before and After Cryopreservation* (ICSS -2013-010), the Study was approved on November 22, 2013 and is valid until November 22, 2014

In June of 2014 the Company submitted its IRB Studies to another Institutional Review Board; The Institute of Regenerative Cellular Medicine (the “IRCM”) and on July 23, 2014 the ICEM IRB approved the following studies:

*Isolation of SVF: Autologous Adipose Derived Stromal Vascular Fraction Containing Adult Stem Cells* (IRCM 2014-024) until July 23, 2015

*Comparative Viability Assessment of Human Adipose Tissue Before and After Cryopreservation* (IRCM 2014-025) until July 23, 2015

*Isolation of SCF and Culturing Adipose Derived Stem Cells for Use in Investigational Review Board Studies* (IRCM 2014-023) until July 23, 2015

The Company is currently making its processing services available to physicians and clinical researchers utilizing the IRB-approved protocols for inclusion in their studies. By adopting these standardized and repeatable protocols utilizing our laboratory services, researchers are able to focus their resources on application development rather than creating, validating and managing a clinical laboratory for processing tissue and cellular samples.

In 2014, the Company created and is the Sponsor of a new IRB study with The DaVinci Center, Dr. Louis Cona, Principal Investigator, in George Town, Grand Cayman Island entitled *Impact and Safety of Cultured Expanded Autologous, Adipose-Derived Stem Cells deployed via Intravenous Injection for the Treatment of Multiple Sclerosis Protocol: CRYO-MS-ADSC-006*.

On July 23, 2014 the study was approved for 100 patients and the first patient was treated by Dr. Lou Cona, Principal Investigator, at the DaVinci on November 1, 2014. The IRB filing can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), (ClinicalTrials.gov Identifier NCT02326935).

Management intends to pursue additional collaborative and partnering opportunities as a strategic method to enhance awareness of and expand the distribution of our patented products, services, technologies and expertise in the IRB-approved clinical processing of adult adipose tissue and ADSCs for autologous (self) use. We believe that as the pace of clinical trials and result reporting increase and scientific and peer reviewed papers are published, new opportunities to market our existing products, services and Intellectual Property portfolio may also emerge.

Moreover, we believe that the combination of our validated cellular processing capabilities and patented products give us an economical platform to develop and produce cellular therapy applications for injection or intravenous therapy, topical applications, burn and wound healing, joint repair, disease treatments and cosmeticeuticals. The clinical methods and products we have developed are designed to permit a variety of treatments for any patient with their own genetically matched raw materials ATCELL™ and ATGRAFT™ prepared with our patent pending line of ACSelerate cell culture mediums. Autologous cellular therapies have shown promising results for safety and efficacy in a variety of applications in published early stage clinical trial results and application studies.

Our Company has multiple patent applications for our products and methods to be used in the IRB studies, which include:

- *ACSeperate-SF*<sup>TM</sup> (animal serum free) adipose stromal cell culture and differentiation medium in clinical and research grades;
- The *CELLECT*<sup>®</sup> collection and tracking system for collecting tissue and cellular samples;
- Adipose tissue, stromal vascular fraction (SVF) and adipose-derived mesenchymal cell processing, expansion and differentiation;
- Storage preparation methods for adipose tissue, stromal vascular fraction (SVF) and adipose derived cellular samples;
- Testing and quality management methods, systems, data collection and maintenance;
- Cryoprotectant for the storage of adipose tissue samples; and
- The *ATGRAFT*<sup>TM</sup> service for the collection, preparation, storage and retrieval of adipose tissue for cosmetic and plastic surgery biocompatible fillers.

## Regulatory Information

The Company has spent years developing processing methodologies and laboratory facilities which are designed to be in compliance with all current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) as defined by the United States Public Health Service Act (“PHS” or the “PHS Act”) and the Food and Drug Administration (FDA) regulations as they relate to the operation of a tissue processing and storage facility.

The Company’s Mount Laurel facility is registered with the FDA (FEI 3008307548) as a processing and storage facility for Human Cells, Tissues and Cellular and Tissue Based Products (HCT/Ps) since 2010. In 2013, we registered the facility with the State of New York (CP169TP136) and the State of California (CNC80948) the only states in the U.S. requiring registration. We renew the registrations as required. These state registrations required the submission of our SOPs for review by the respective State Health Departments, and annual updates to maintain the registrations are required. Our New Jersey Medical Waste Generator registration number is 036439.

The Company is also subject to complying with a significant body of FDA and PHS regulation; the regulations governing our business are mainly contained within 21 CFR 1271.10, 800, 600, 200, 210 and 211. The forgoing regulations govern all aspects of the Company’s SOPs, which we periodically review with our FDA consultants.

Our SOPs are the key to properly operating our clinical tissue processing facility. To ensure delivery of the highest quality services, we incorporate these SOPs, which are designed to provide a basis for accreditation by the American Association of Blood Banks (AABB), the American Association of Tissue Banks (AATB) and the Foundation for the Accreditation of Cellular Therapy (FACT-JACIE). We have consistently endeavored to ensure that our processes, methodologies and procedures are and remain among the highest standards in the global tissue collection, processing and storage market. To this end, we have equipped ourselves with state-of-the-art quality processing and testing

equipment, which help to ensure that every sample that is collected and processed is sterile (free from adventitious agents), viable and capable of significant growth and expansion. While published studies generally report total viable cells, our assessment testing also reports each sample's growth capabilities.

## **Quality Management**

The Company's quality management program ensures that during processing and testing of each adipose tissue or SVF sample, the appropriate quality management tests and processing methodologies are performed and the data is collected, recorded and reviewed by the laboratory management team.

### ***Chain of Custody Control***

Central to the individual sample testing is an unbroken chain of custody and tracking. Sample tracking begins with the creation of each collection box. All samples, processing, quality management, batch, and storage documents and records, are coded with this unique number. All records and testing samples are cross referenced and verified as required by the standard operating procedures.

**Testing Design and Standard Operating Procedures**

Testing methods are standardized and operate under a complete set of validated SOPs and Quality Management (QM) processes. All SOPs are designed to be in compliance with the US Food and Drug Administration's cGMP/cGTP regulations and guidance for aseptic processing. Strict QM is enforced to avoid and/or record any process deviations.

**Intellectual Property**

From the Company's formation, our strategy has been to invest time and capital in intellectual property protection. This strategy is intended to strengthen our Company's foundation in any defensive or offensive legal challenge. In addition, we are developing our IP portfolio to ensure and enhance our business flexibility and allow us to gain favorable terms in potential future collaborative partnerships with third parties. Our intellectual property portfolio currently includes one issued U.S. patent (No. 7989205, *Cell Culture Media Kits and Methods of Use*); and seven pending patent applications, one joint patent filing with Rutgers University, and 8 in-licensed patents which are detailed in the following charts:

**American CryoStem Patents:**

<b>PATENT TITLE</b>	<b>USE OF PATENT</b>	<b>APPLICATION #</b>
A Business Method for "Collection, Cryogenic Storage and Distribution of a Biological Sample Material"	Company Core Tissue Collection Processing and Storage Methodology	U.S. Serial No. 13/702,304 filed June 6, 2011, and claiming a priority date of June 7, 2010 from provisional application 61/352,217
Systems and Methods for "The Digestion of Adipose Tissue Samples Obtained From a Client for Cryopreservation"	Adipose Tissue Digestion Laboratory Processing Methods	U.S. Serial No. 13/646,647 filed October 5, 2012, and claiming a priority date of October 6, 2011 from provisional application 61/544,103
Compositions and Methods for "Collecting, Washing, Cyroprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures"	Company Adipose Tissue Storage Platform for Cosmetic Procedures	PCT/US13/44621 Filed June 6, 2013 and claiming a priority date of June 7, 2012
Autologous Serum for Transport of Isolated Stromal Vascular Fraction or Adipose Derived Stem Cells	Utilization of Autologous Blood Components for the Transport of Adipose Derived Cells to a Patient	U.S. Serial No. 14,250,338 and claiming a priority date from provisional application 61/810,970 filed April 11, 2013
Cell Culture Media, Kits, and Methods of Use	Continuation of U.S. Serial No. 11/542,863, includes Optimized and improvements to Media Formulations	U.S. Serial No. 13/194,900



Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Human Albumin Serum for Cell Culture  
Medium for Clinical Growth of Human  
Adipose Stromal Cells.

New formulation for an  
advanced animal product  
free medium formulation

US Serial No. 62/098799  
filed December 31, 2014

22

**Jointly Owned and in licensed Patents;**

<b>PATENT TITLE</b>	<b>USE OF PATENT</b>	<b>APPLICATION #</b>
Nanoparticle-Mediated Synthetic Transcription Factor from Enhanced Gene Expression and Cell Differentiation	Rutgers collaboration and R&D	Rutgers Docket Number 20113-013  USPTO Provisional Filing No. 61/947,898
Direct Stamping-Assisted Graphene Oxide Patterned Substrates for Controlling Adipose Derived Adult Stem Cell Differentiation	Rutgers collaboration and R&D	Rutgers Docket Number 2014-024
Single Vehicular Delivery of siRNA and Small Molecules to Control Stem Cell Differentiation	Rutgers collaboration and R&D	Docket Number 2014-034
Devices and Methods to Guide Stem Cell Differentiation Using Graphene Nanofiber Hybrid Scaffold	Rutgers collaboration and R&D	US Provisional Filing No. 61/978,177
Cosmetic compositions including tropoelastin isomorphs	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #5,726,040
Cosmetic compositions	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #6,451,326
Recombinant hair treatment compositions	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #6,572,845
Wound healing compositions and methods using tropoelastin and lysyl oxidase	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO: #6,808,707
Business methods, processes and systems for collection, cryogenic storage and distribution of cosmetic formulations from an obtained stem cell based biological	Personal Cell Sciences and American CryoStem collaboration	USPTO application #61/588,841

**Trademarks**

In addition to patents, the Company has registered the following trademarks with the U.S. Patent and Trademark Office: *American CryoStem*<sup>®</sup>, *CELLECT*<sup>®</sup> and *ATGRAFT*<sup>™</sup>. We plan to obtain additional registered trademarks for our future products, slogans and themes to be used in our marketing initiatives, including, for example, *ACSelerate-SFM*<sup>™</sup>, *ACSelerate-LSM*<sup>™</sup> and *ATCELL*<sup>™</sup>.

The Company has also secured a number of online domain names relevant to its business, including [www.americancryostem.com](http://www.americancryostem.com) and [www.acslaboratories.com](http://www.acslaboratories.com).

**Marketing and Distribution**

The key objective of our marketing strategy is to position American CryoStem in the market as the “Gold Standard” for adipose tissue collection, cell processing and cryogenic storage, - therapeutic applications, and research/commercial uses of adipose tissue. The combination of a traditional sales approach, supported by continuous internal and external marketing programs, are/will be closely coordinated with the expansion of our laboratory processing capabilities. Our initial marketing efforts intend to disseminate current and future uses of adipose tissue and adult stem cells which support our business model, products and services. In 2015, we intend to continue to employ both print advertising and social media sales campaigns. In addition, we plan to continue to utilize key leaders, and early adopters in the medical community as a marketing resource to enhance awareness of our proprietary, patented products and services and to increase the number of surgeons who join our network, university and private collaboration and consumers who use our products and services.

We plan to continue direct marketing programs focused on reaching plastic and cosmetic surgeons to join the initial group of providers that began to offer our services to their patients in 2013. This marketing initiative has been implemented using a traditional sales approach common to the pharmaceutical and biotechnology industries. This fundamental sales approach at the core of our marketing activities is being strategically and tactically expanded using a combination of in-house sales personnel and outside independent channels.

Our plan, capital permitting, provides for a comprehensive integrated marketing approach using various traditional and new media, such as the Internet, social media/blogging, video, print, TV, radio and trade shows to reach targeted potential consumers and promote awareness of our Company and our branded products and services. The essence of this targeted strategy is to reach the end-users as quickly as possible and to accelerate the adoption curve of our products and services. We also plan to utilize outside marketing resources and trade groups to increase the number of surgeons willing to offer our products and services to their patients.

### **Market Size and Opportunities**

By leveraging and capitalizing on our proprietary Adipose Tissue Processing Platform, our Company is working to address multiple high growth, multi-billion dollar market opportunities, including those prevailing within the Regenerative Medicine, Cosmeceuticals, Medical Tourism and Cell Culture Media markets. The Company regularly reviews independent market research to gauge the market dynamics of its intended domestic and international markets and to identify additional areas within these markets where the Company's cell culture medium, laboratory products, and tissue and cellular processing services, can be marketed, sold and/or licensed.

A recent report published by Markets and Markets Research in July 2014 titled "Cell Culture Market by Equipment (Bioreactor, Incubator, Centrifuge), by Reagent (Media, Sera, Growth Factors, Serum Free Media), by Application (Cancer Research, Gene Therapy, Drug Development, Vaccine Production, Toxicity Testing) - Global Forecast to 2018" July 2014.

(<http://www.marketsandmarkets.com/Market-Reports/cell-culture-market-media-sera-reagents-559.html>)

*The report states that "The global cell culture market was valued at \$ 14,772 million in 2013 and is poised to grow at a CAGR of 10.71% between 2013 and 2018, to reach \$24,574 million in 2018. Rapid increase in biopharmaceutical production and increasing healthcare expenditure will be the two most important growth drivers for this market in the forecast period from 2013 to 2018. Biopharmaceutical production had the largest share of the cell culture market in 2013. According to IMS Health, biopharmaceutical is expected to one of the fastest growing pharmaceutical segment between 2012 and 2017. The increasing demand for biopharmaceutical products like vaccines and antibodies coupled with strong pipelines for biopharmaceuticals and increasing healthcare expenditure will drive the demand for cell culture products."*

The Report further states that *"The global cell culture market comprises of cell culture equipment and cell culture media, sera, and reagent markets. The cell culture equipment market consists of five equipment segments, namely, lab equipment, bio-safety cabinets, consumables, storage equipment, and sterilization equipment. On the other hand, the*

*cell culture media, sera, and reagents market consists of six segments, namely, serum, media, lab reagents, contamination detection kits, cryoprotective agents, and other reagents.*

*The application segments included in this report are biopharmaceutical production, tissue culture and engineering, vaccine production, drug screening and development, gene therapy, toxicity testing, cancer research, and other applications. The biopharmaceutical application segment had the largest share of the cell culture market in 2013, owing to the large demand for cell culture sera, media, and reagents for biopharmaceutical production.”*

Another report by Transparency Market Research titled “*Stem Cells Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2012 - 2018*” states “*The Global Stem Cells Market to grow at a CAGR of 24.2%, to Push US\$119.52 billion by 2019. The report analyzes the highly fragmented stem cells market by the type of stem cells, processes in the stem cell market, applications of stem cells, and geography. Regenerative medicine is by far the dominant application of stem cells, including uses in neurology, cardiology, and oncology. According to process, the market is divided into the stem cell acquisition, stem cell production, stem cell cryopreservation, and stem cell expansion segments. Due to the expected increase in demand, stem cell acquisition will retain its position as the major segment of the stem cell market. Geographically, North America and Europe will remain well ahead of the competition.”*

<http://globenewswire.com/news-release/2014/12/22/693419/10113247/en/Global-Stem-Cells-Market-to-grow-at-a-CAGR-of->

### ***Regenerative Medicine Market***

According to a leading research firm focused on the biotechnology, healthcare and life sciences industries, TriMark Publications categorizes the Regenerative Medicine market into three main categories:

- Tissue Engineering;
- Biomaterials; and
- Biomolecules (scaffolds, growth factors and stem cell therapy).

TriMark Publications.com cites in its “Regenerative Medicine Markets” report (March 2013) that the Regenerative Medicine market continues to witness significant advances in clinical efficacy, regulatory approval and product commercialization of cell based therapies which will catapult to over \$35 billion by 2019. Affirmative results produced from the application of adult stem cells have resulted in greater government and private sector investment in research and development of new cell therapies. Investment made into the regenerative medicine market include firms that harvest, process, purify, expand, cryopreserve, store or administer stem cells.<sup>1</sup>

According to BCC Research (January 2013), the market for Regenerative Medicine continues to grow worldwide. “*It is expected to accelerate at roughly 12% annually, from \$3.8 billion in 2011 to \$6.6 billion in 2016*”. BCC Research states “*the American market for stem cell products was \$1.3 billion in 2011. This sector is expected to rise at a CAGR of 11.5% and reach nearly \$2.3 billion by 2016. The European market for stem cell products was \$872 million in 2011 and is expected to reach nearly \$1.5 billion by 2016, a CAGR of 10.9.*”<sup>2</sup>

### ***Medical Tourism, Global Wellness Tourism***

As stated by the Global Wellness Institute; adding up all expenditures made by international/inbound and domestic, primary and secondary wellness tourists, we estimate the wellness tourism industry to be \$494 billion in 2013, a 12.7% increase over 2012. Wellness tourism accounts for 14.6% of all tourism expenditures and is growing much faster than the 7.3% growth rate for overall tourism expenditures from 2012-2013.

The \$494 billion in wellness tourism expenditures represent 586.5 million wellness trips taken in 2013, across 211 countries. Wellness tourism accounts for about 6.2% of all domestic and international tourism trips taken in 2013.

[http://www.globalwellnesssummit.com/images/stories/gsws2014/pdf/GWI Global Spa and Wellness Economy Monitor Full Report.pdf](http://www.globalwellnesssummit.com/images/stories/gsws2014/pdf/GWI%20Global%20Spa%20and%20Wellness%20Economy%20Monitor%20Full%20Report.pdf)

### ***Cell Culture Market***

The Company believes the reproducibility of scientific studies has become a substantial issue in life science research from drug discovery and development through clinical trials as researchers throughout the world continue to use different protocols for processes associated with sample preparation, cryopreservation and cold chain management. We believe the scientific community is becoming more aware of factors that affect sample integrity and experiment variability. By standardizing handling, storage, and transportation protocols we believe we can substantially improve the quality and reproducibility of preclinical and clinical data which we believe will help to accelerate the transition from lab research to drug development and market launch.

<sup>1</sup> <http://www.trimarkpublications.com/regenerative-medicine-markets/>

<sup>2</sup> <http://www.bccresearch.com/market-research/biotechnology/stem-cells-global-markets-bio035d.html>

25

### ***Cosmeceutical Market***

Many industry experts agree that Cosmeceuticals has become one of the fastest growing segment of the Cosmetics and Personal Care industry. Cosmeceutical products have a big emphasis on scientifically advanced formulations and often contain active ingredients that can also be found in pharmaceutical products. This continued emergence of increasingly sophisticated active ingredients is said to be the main driving force behind the growth of this segment, which is rapidly evolving into significant category of the personal care industry.

In a report titled *Global Cosmeceuticals Market Outlook 2016*, published February 2013, RNCOS reports that the worldwide market is estimated to be valued at \$30.5 billion and is likely to grow at a consistent CAGR of 7.7% during the period 2012 through 2016.<sup>3</sup> In a separate report, Transparency Market Research, a U.S. - based market intelligence firm states that the global facial care market is expected to report an approximate value of \$39.75 billion by 2019. The report, titled '*Facial Care Market (By Product Type - Skin Whitening/ Lightening and Anti-Ageing, Facial Creams, Face Wash, Cleansing Wipes, Serums and Masks and Others (fade creams, pore strips and toners)- Asia-Pacific Industry Analysis, Size, Share, Growth, Trends and Forecast 2013 – 2019*.' <http://globenewswire.com/news-release/2014/10/17/674123/10103135/en/Global-Facial-Care-Market-to-be-Worth-39-75-Billi>

### **Development of U.S. Markets**

#### ***Physician Network***

The Company continues to develop relationships to leverage our products and services through existing cosmetic surgery and regenerative medicine practices while at the same time growing its current efforts to develop and expand its network of individual physicians and surgeons seeking to adopt the Company's products and services. These efforts are currently focused on surgeons performing liposuction, tissue transfer or regenerative procedures involving the use of adipose tissue. The Company intends to expand its efforts to non-cosmetic medical professionals interested in Regenerative Medicine applications utilizing ADSCs to establish itself as a primary source of collection, processing and preparation of cellular therapies as they are developed and approved for patient use by the FDA.

#### ***The Stern Center***

During our first fiscal quarter ended December 31, 2012, we announced the initiation of adult stem cell and adipose tissue collection at the Stern Center for Aesthetic Surgery in Bellevue Washington. Dr. Frederick Stern, a member of the Company's Scientific and Medical Advisory Board, founded the Stern Center in 1997. The Stern Center offers state-of-the-art laser and cosmetic surgical techniques to patients throughout the western U.S., and is one of the premier laser-assisted liposuction centers in the Pacific Northwest.



*Development of International Markets*

**International Licensing Program** – Globally, many jurisdictions outside the US permit the use of adipose tissue, cellular therapies and regenerative medicine applications. The Company has received numerous inquiries concerning the sale or licensing of our products and services in these jurisdictions. The Company believes that the inquiries to date are a result of the global boom in Medical Tourism and the slow pace of approval of cellular therapies and regenerative medicine applications in the US. To address these inquiries and to expand the Company’s sales, marketing and branding opportunities the Company has designed and is offering an International Licensing Program.

<sup>3</sup> <http://www.researchandmarkets.com/research/mbmvbh/global>

26

The program is designed to permit the licensing of the company's products and services to organizations that meet the Company's financial and technical criteria. The licensing program allows for a variety of business relationship including franchising, partnering and joint venturing. Marketing efforts to date have been to clinics, physician and hospitals in foreign jurisdictions capable of rapidly building or committing the appropriate facilities and personnel to create the required laboratory facilities to operate the *CELLECT*<sup>®</sup>, *ATGRAFT*<sup>™</sup> and *ATCELL*<sup>™</sup> services in their local market. Strategically, the Company's international licensees will maintain the branding of the Company's services along the lines of the "Intel Inside" branding program.

Qualified Licensees can quickly take advantage of the rapidly expanding opportunity to collect, process, store and culture individual stem cell samples for their clients with the comfort and confidence that they are providing services that have been developed to US FDA standards. Core to the relationship is the developed proprietary and patent pending processing and laboratory operational methodologies contained in our Standard Operating Procedures, Training, and Continuous Quality Management, Testing Program, and Laboratory Operations manuals.

Licensing programs may be initiated through a letter of intent (LOI) agreement between the Company and the prospective licensee. This LOI agreement is designed for due diligence and facility qualifications purposes. The Company may receive an initial fee under the agreement which is credited toward future royalty payments. Following evaluation of the prospective licensee the Company will enter into a final Agreement which outlines all upfront fees, minimum royalties and consumable purchase obligations of the Licensee. The Company's first international licensing agreement was executed with Health Innovative Technology Company, LTD, a cord blood collection and storage company with operations in Hong Kong and Shenzhen China.

We have committed extensive resources to establishing and perfecting our international shipping methodologies and protocols, ensuring that our processes meet the highest possible standards of regulatory compliance for shipment of biologic materials. As a result, our FDA registered laboratory and cryostorage facilities in New Jersey are now able to send and receive viable tissue samples to and from clients globally.

#### **Health Information Technology Company, LTD**

On June 30, 2014 the Company granted Health Information Technology Company, LTD ("HIT") exclusive rights to utilize the Company's Standard Operating Procedures (SOP's) to market the Company's *ATGRAFT*<sup>™</sup> tissue storage service in Hong Kong. The Agreement calls for upfront fees, royalties and the purchase by HIT of certain consumables manufactured by the Company. The Company and HIT have reached further agreement to extend their relationship on a non exclusive basis to include HIT's cord blood laboratory located in Shenzhen, Guangdong Province, one of China's most successful Special Economic Zones. The HIT agreement includes, initial upfront fees and royalty payments for predetermined gross revenue volumes. HIT will also purchase *CRYO ACSelerate*<sup>™</sup> storage media, *CELLECT*<sup>™</sup> collection and transportation kit as well as other American CryoStem products necessary for clinical adipose tissue processing and storage at the Shenzhen cord blood collection facility. The final master licensing agreement is for a period of 5 years with renewal options and was executed between the parties on September 24, 2014.

#### **BALS Institute**

On April 23, 2013, we announced receipt of our first commercial international shipment of adipose tissue for processing and long term cryostorage. The master sample was shipped to the Company by BALS (Biomedical and Life Sciences) Institute (BALS), a Hong Kong-based regenerative medicine company and client of Personal Cell Sciences Corp. (PCS), the developer of *U-Autologous* skin care products and formulations. In 2014 BALS and PCS mutually terminated their relationship.

### **Corporate Information**

Our principal executive offices are located at 1 Meridian Road, Eatontown, New Jersey 07724 and our telephone number is (732) 747-1007. Our website is [www.americancryostem.com](http://www.americancryostem.com). We also lease and operate a tissue processing laboratory in Mount Laurel, New Jersey at the Burlington County College Science Incubator located on the Burlington County College campus. Our laboratory website address is [www.acslaboratories.com](http://www.acslaboratories.com).

### ***Available information***

We file electronically with the U.S. Securities and Exchange Commission (SEC) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public can obtain materials that we file with the SEC through the SEC's website at <http://www.sec.gov> or at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 800-SEC-0330.

### **Going Concern**

As of the date of this quarterly report, there is substantial doubt regarding our ability to continue as a going concern as we have not generated sufficient cash flow to fund our business.

We have suffered recurring losses from operations since our inception. In addition, we have yet to generate sufficient internal cash flow from our business operations or successfully raise the financing required to fully develop our business. As a result of these and other factors, our independent auditor has expressed substantial doubt about our ability to continue as a going concern. Our future success and viability, therefore, are dependent upon our ability to generate capital financing. The failure to generate sufficient revenues or raise additional capital may have a material and adverse effect upon us and our shareholders.

Our plans with regard to these matters encompass the following actions: (i) obtaining funding from new investors to alleviate our working capital deficiency, and (ii) implementing a plan to generate sales of our proposed products and services. Our continued existence is dependent upon our ability to resolve our liquidity problems and increase profitability in our current business operations. However, the outcome of management's plans cannot be ascertained with any degree of certainty. Our financial statements do not include any adjustments that might result from the outcome of these risks and uncertainties.

### **Liquidity and Capital Resources**

We had a cash balance of \$5,508 as of the date of this quarterly report. Our principal source of funds has been sales of our securities. Should we be unable to raise sufficient funds, we will be required to curtail our operating plans if not cease them entirely. We cannot assure you that we will generate the necessary funding to operate or develop our business. Please see "*Cash Requirements*" above for our existing plans with respect to raising the capital we believe will be required.

In the event that we are able to obtain the necessary financing to move forward with our business plan, we expect that our expenses will increase significantly as we attempt to grow our business. Accordingly, the above estimates for the financing required may not be accurate and must be considered in light these circumstances.

### **Cash Requirements**

We will require additional capital to fund marketing, operational expansion, processing staff training, as well as for working capital. We are attempting to raise sufficient funds would enable us to satisfy our cash requirements for a period of the next twelve (12) to twenty-four (24) months. We have minimal long term debt and have been able to meet our past financial obligations.

In order to finance further market development with the associated expansion of operational capabilities for the time period discussed above we are planning additional fundraising through the sale of our equity and debt securities however we cannot assure you we can attract sufficient capital to enable us to fully fund our anticipated cash requirements during this period. In addition, we cannot assure you that the requisite financing, whether over the short or long term, will be raised within the necessary time frame or on terms acceptable to us, if at all. Should we be unable to raise sufficient funds we may be required to curtail our operating plans if not cease them entirely. As a result, we cannot assure you that we will be able to operate profitably on a consistent basis, or at all, in the future.

We expended \$22,107 during the six months ended March 31, 2015 in professional fees (legal, accounting and consultants) and \$ 83,634in Research and Development.

## **Commitments**

As of the date of this quarterly report, the Company's material capital commitments were (i) the continued funding of the expansion of our marketing efforts and laboratory processing capabilities; and (ii) the current two-year lease for the laboratory spaces at the Burlington County College Science Incubator, Laboratory 110 and 108, which was renewed for an additional three year period on February 1, 2014 and is subject to a monthly payment of \$3,300.

The Company has an operating lease for its main office facility located at 1 Meridian Road, Eatontown, New Jersey 07724. The lease is for a term of three years with a monthly rent of \$2,650. The total rent for office facilities for the three months ended March 31, 2015 was \$7,950.

The Company has unsecured liabilities without interest of \$132,947 due to ACS Global, the majority shareholder of the Company, for certain prepaid expenses made by ACS Global prior to the closing of the transaction. There is no due date associated with this liability.

We anticipate that any further capital commitments that may be incurred will be financed principally through the issuance of our securities. However, we cannot assure you that additional financing will be available to us on a timely basis, on acceptable terms, or at all.

## **Off Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

## **Critical Accounting Policies**

We prepare financial statements in conformity with U.S. generally accepted accounting principles ("GAAP"), which requires us to make estimates and assumptions that affect the amounts reported in our combined and consolidated financial statements and related notes. We periodically evaluate these estimates and assumptions based on the most recently available information, our own historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from those estimates. Some of our accounting

policies require higher degrees of judgment than others in their application. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

### **Basis of Presentation**

Our financial statements are presented on the accrual basis of accounting in accordance with generally accepted accounting principles in the United State of America, whereby revenues are recognized in the period earned and expenses when incurred.

### **Management's Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

### **Long-Lived Assets**

We review and evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, we compare the assets' carrying amounts against the estimated undiscounted cash flows to be generated by those assets over their estimated useful lives. If the carrying amounts are greater than the undiscounted cash flows, the fair values of those assets are estimated by discounting the projected cash flows. Any excess of the carrying amounts over the fair values are recorded as impairments in that fiscal period.

## **Statement of Cash Flows**

For purposes of the statement of cash flows, we consider all highly liquid investments (i.e., investments which, when purchased, have original maturities of three months or less) to be cash equivalents.

## **Fair Value of Financial Instruments**

Our financial instruments consist of cash and cash equivalents. The fair value of cash and cash equivalents approximates the recorded amounts because of the liquidity and short-term nature of these items.

## **Recent Accounting Pronouncements**

We have reviewed all recently issued, but not yet effective, accounting pronouncements and do not believe that any future adoption of such pronouncements will have a material impact on our financial condition or the results of our operations.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not Applicable

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Treasurer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.



As of March 31, 2015, our Chief Executive Officer and Treasurer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act). Based on such evaluation, our Chief Executive Officer and Treasurer concluded that our disclosure controls and procedures were effective as of March 31, 2015.

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

Our management has evaluated whether any change in our internal control over financial reporting occurred during the last fiscal quarter. Based on that evaluation, management concluded that there has been no change in our internal control over financial reporting during the relevant period that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

From time to time we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of business. We are not currently involved in legal proceedings that we believe could reasonably be expected to have a material adverse effect on our business, prospects, financial condition or results of operations.

### **ITEM 1A. RISK FACTORS**

Not applicable.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

During the six months ended March 31, 2015 the company issued \$327,500 of its 8% convertible notes due 9/30/2016. The notes are convertible into common shares of the Company at \$0.30

There are additional \$159,500 of convertible notes, all of which are convertible at \$0.35 per share, outstanding as of the date of this report.

The Company has outstanding \$596,000 of 8% Notes. The Notes are due one year from their date of issuance. In addition each purchaser of the Notes received an option to purchase one share of the Company's common stock at \$0.05 per share for each dollar of principal. The Company issued options to purchase 596,000 common shares to the note holders. The options expire one year from the date the note is repaid.

During the six months ended March 31, 2015, holders of the convertible debt converted \$8,500 of convertible debt and the Company issued 24,286 shares of common stock.

During fiscal year 2014, holders of the convertible debt converted \$152,300 of convertible debt and the Company issued 435,143 shares of common stock.

During fiscal year 2013, the Company issued 3,467,359 shares of common stock as a result of the convertible notes exercised.

During fiscal year 2013, the Company issued 660,000 shares of common stock to consultants for services rendered valued at \$236,000.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

(a) Exhibits furnished as Exhibits hereto:

**Exhibit No. Description**

31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
31	

**SIGNATURES**

Pursuant to the requirements 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.

**AMERICAN CRYOSTEM  
CORPORATION**

May 15, 2015 By: /s/ John Arnone  
John Arnone, Chief Executive Officer  
(Principal Executive Officer)

May 15, 2015 By: /s/ Anthony Dudzinski  
Anthony Dudzinski, Treasurer  
(Principal Financial Officer)

32