

AMERICAN CRYOSTEM Corp  
Form 10-Q  
May 20, 2014

**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, 2014

Commission file number: 000-54672

**AMERICAN CRYOSTEM CORPORATION**  
(Name of registrant as specified in its charter)

Nevada      26-4574088  
(State or other (I.R.S.  
jurisdiction of Employer  
incorporation Identification  
or No.)  
organization)

1 Meridian Road, Eatontown, NJ 07724  
(Address of principal executive offices)(Zip Code)

(732) 747-1007  
(Registrant's  
telephone  
number,  
including area  
code)

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically 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

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

Accelerated filer

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 15, 2014 there were 32,685,721 shares of common stock outstanding.

**TABLE OF CONTENTS**

	Page No.
<b><u>PART I. - FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements.</u>	3
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Plan of Operations.</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk.</u>	26
<u>Item 4. Controls and Procedures.</u>	26
<b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings.</u>	27
<u>Item 1A. Risk Factors.</u>	27
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.</u>	27
<u>Item 3. Defaults Upon Senior Securities.</u>	27
<u>Item 4. Mine Safety Disclosures</u>	27
<u>Item 5. Other Information.</u>	27
<u>Item 6. Exhibits.</u>	27

**PART I – FINANCIAL INFORMATION****Item 1. Financial Statement****American CryoStem Corporation****Interim Balance Sheets****As of March 31, 2014 and September 30, 2013**

	<b>March 31, 2014</b>	<b>Sept 30, 2013</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 45,500	\$ 115,932
Accounts Receivable	4,020	2,003
Deferred Contract Expense	54,500	0
Prepaid Expenses	250	0
Total current assets	104,270	117,935
Other Assets		
Security deposits	5,800	5,800
Patents and Trademarks	186,400	163,935
Equipment – net	270,362	281,362
Total Assets	\$ 566,832	\$ 569,032
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable & accrued expenses	\$ 458,310	\$ 260,129
Contract payable	45,000	0
Convertible notes payable	196,050	0
Notes Payable	426,000	0
Capital Lease Payable	21,267	20,239
Total current liabilities	1,146,627	280,368
Long-Term Liabilities		
Deferred Revenue	1,100	0
Convertible notes payable	0	190,800
Capital Lease Payable	0	10,901
Payable to Shareholder	137,447	139,447

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Total Long-Term Liabilities	138,547	341,148
Shareholders' equity:		
Common stock (\$.001 par value, 32,640,721 shares issued and outstanding at March 31, 2014, and 32,285,721 shares issued and outstanding at September 30, 2013; 300,000,000 shares authorized)	32,641	32,286
Additional paid in capital	6,114,518	5,990,623
Accumulated deficit	(6,865,501 )	(6,075,393 )
Total shareholders' equity	(718,342 )	(52,484 )
Total Liabilities & Shareholders' Equity	\$ 566,832	\$ 569,032

See Notes to Financial Statements

**American CryoStem Corporation****Interim Statements of Operations****For the Three Months Ended March 31, 2014 and 2013****and the Six Months Ended March 31, 2014 and 2013**

	Three Months Ended March 31,		Six Months Ended March 31,	
	2014	2013	2014	2013
Sales	\$4,480	\$1,354	\$10,619	\$1,228
Operating Expenses:				
Professional Fees	146,890	41,760	214,801	59,286
Research & Development	116,364	76,403	179,198	125,577
Administration	210,315	191,014	392,318	336,483
Total Operating Expenses	473,569	309,177	786,317	521,346
Net Loss from Operations	(469,089 )	(307,823 )	(775,698 )	(520,118 )
Other Income (Expense)	(8,396 )	(6,404 )	(14,410 )	(9,865 )
Net Loss	\$(477,485 )	\$(314,227 )	\$(790,108 )	\$(529,983 )
Basic & fully diluted net earnings (loss) per common share	\$(.015 )	\$(.011 )	\$(.024 )	\$(.019 )
Weighted average of common shares outstanding: Basic & fully diluted	32,640,721	28,659,711	32,584,031	28,440,067
See Notes to Financial Statements				

## American CryoStem Corporation

## Interim Statements of Cash Flows

## For the Six Months Ended March 31, 2014 and 2013

	<b>2014</b>	<b>2013</b>
Operating Activities:		
Net loss	\$(790,108)	\$(529,983)
Adjustments to reconcile net income items not requiring the use of cash:		
Depreciation & amortization expense	20,149	19,086
Accrued Interest	13,048	0
Changes in other operating assets and liabilities		
Accounts Receivable	(2,017 )	(1,496 )
Other Receivable	0	(710 )
Deferred Contract Expense	(54,500 )	0
Prepaid Expenses	(250 )	(3,000 )
Accounts Payable and accrued expenses	185,133	(11,702 )
Contract Payable	45,000	
Deferred Revenue	1,100	0
Net cash used by operations	(582,445)	(527,805)
Investing activities:		
Purchase of equipment	(8,149 )	(998 )
Investment of other assets	(23,465 )	(21,233 )
Net cash used by investing activities	(31,614 )	(22,231 )
Financing activities:		
Issuance of convertible notes	5,250	186,525
Payment to Shareholder	(2,000 )	(365 )
Issuance of notes payable	426,000	0
Issuance of common stock	124,250	374,850
Capital Lease	(9,873 )	10,899
Net cash provided by financing activities	543,627	571,909
Net increase (decrease) in cash during the period	(70,432 )	21,873
Cash Balance, Beginning of Period	115,932	4,039
Cash balance, End of Period	\$45,500	\$25,912
Supplemental disclosures of cash flow information:		
Interest Paid	\$1,361	\$223
Income Taxes Paid	\$0	\$0

See Notes to Financial Statements

5



**American CryoStem Corporation**

**Statement of Changes in Shareholders' Equity**

**For the Six Months Ended March 31, 2014**

**Prices & shares adjusted for stock splits**

	<b>Common Stock</b>	<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	Shares	Par Value	Capital	Shareholders' Equity
			Deficit	
Balance at September 30, 2013	32,285,721	\$32,286	\$ 5,990,623	\$ (6,075,393 ) \$ (52,484 )
Issuance of Common Stock	355,000	355	123,895	124,250
Net Loss			(790,108 )	(790,108 )
Balance at March 31, 2014	32,640,721	\$32,641	\$ 6,114,518	\$ (6,865,501 ) \$ (718,342 )

See Notes to Financial Statements

## American CryoStem Corporation

### Notes to the Financial Statements

March 31, 2014

#### 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) for 21 million shares of common stock. ACS was deemed to be the accounting acquirer. At that time, the former operations of R&A were discontinued and the name of the Company was changed to American CryoStem Corporation.

The Company operates within the Regenerative Medicine sector of the Life Sciences industry which aims to repair, replace or regenerate organs and tissue that have been damaged or diseased, to provide its consumers and institutions with a standardized, patented cellular platform and clinical grade solutions using adipose derived adult stem cells (ADSCs).

The Company maintains a state-of-the-art, FDA-registered, clinical laboratory dedicated to processing, bio-banking and manufacturing of cellular applications using autologous adipose (fat) tissue and ADSCs. Through its scientific efforts, the Company has built a strong, strategic portfolio of intellectual property, patent applications, and proprietary operating procedural processes that form its core cellular platform.

The Company has received Institutional Review Board (IRB) approval of its protocols for isolating Stromal Vascular Fraction (SVF) and culturing of ADSCs from a patient’s adipose tissue. These protocols provide validated testing methods necessary to move the clinical investigative process towards uniform disease treatments, and the collection of cGMP data necessary for approval of regenerative cellular therapies.

The Company’s lead product, *ATCELL*<sup>™</sup> is currently being combined with university research and product development partners and collaborators such as Rutgers University and Autogenesis Corporation to create new cellular therapy applications.

*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 and interest bearing deposits* - 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’s cryogenic storage tank. Storage revenues for stored client samples are recognized on an annual basis on the anniversary date of the

storage.

*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.

*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, 2014**

**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, 2014, 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:

On August 26, 2013, the Company entered into an Agreement with an investment banker as the exclusive financial advisor and placement agent in connection with a private offering of the Company's securities. The Company is completing the due diligence and expects to begin the offering in the third quarter of fiscal 2014.

The Company plans to continue to fund its operations through fundraising activities in 2014 until the new commercial facilities generate sufficient revenue to support its operations.

**American CryoStem Corporation****Notes to the Financial Statements****March 31, 2014****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 March 31,		For the Six Months Ended March 31,	
	2014	2013	2014	2013
Net Loss	\$(477,485 )	\$(314,227 )	\$(790,107 )	\$(529,983 )
Weighted average shares outstanding	32,640,721	28,659,711	32,584,031	28,440,067
Basic & fully diluted net earnings (loss) per common share	\$(.015 )	\$(.011 )	\$(.024 )	\$(0.019 )

**NOTE 4. Equipment**

Equipment is comprised of the following:

	March 31, 2014	Sept 30, 2013
Office Equipment	\$ 26,637	\$ 26,637
Lab Furniture	642	642
Office Furniture	999	999
Lab Equipment	254,555	246,407
Lab Software	123,000	123,000
Less: Accumulated Depreciation	(135,471 )	(116,323 )
Equipment - net	\$ 270,362	\$ 281,362

**NOTE 5. Patents**

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.

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

The Company has filed the following additional patents to extend its intellectual property to encompass additional aspects of the Company's platform processing technologies:

A Business Method for Collection Cryogenic Storage and Distribution of a Biologic Sample Material  
PCT/US2011/39260

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

Compositions and Methods for Collecting, Washing, Cryopreserving, Recovering and Return of Lipaspirates to  
Physician for Autologous Adipose Transfer Procedures PCT/US13/44621 filed June 6, 2013

Stem Cell-Based Therapeutic Devices and Methods U.S. Serial No. 14/196,414 Filed March 10, 2013

Autologous Serum for Transport of Isolated Stromal Vascular Fraction or Adipose Derived Stem Cells 61/810,970  
Filed April 11, 2013

Cell Culture Media, Kits and Methods of Use US Serial No. 13/194,900 Continuation of US Serial No. 11/542,863

Nanoparticle Mediated Synthetic Transcription Factor for Enhanced Gene Expression and Cell Differentiation  
61/947,898 Filed March 28, 2014 (Jointly Owned with Rutgers University)

9

**American CryoStem Corporation****Notes to the Financial Statements****March 31, 2014****NOTE 6. Debt**

During the six months ended March 31, 2014, the Company issued \$129,500 of convertible notes. The convertible notes have an exercise price of \$0.35 per share of common stock and mature in September 2014. During the six months ended March 31, 2014, convertible notes of \$124,250 were converted to common stock.

During the six months ended March 31, 2014, the Company raised \$426,000 in an 8% Note Offering with principal and interest to be repaid one year from the date of issuance or from the proceeds of a future offering of Company securities (the "Bridge Notes"). Additionally, the Company granted each note holder an option to purchase one share of the Company's common stock for each dollar of the principal amount of the note at \$0.05 per share. The options expire one year from the date on which the note is repaid.

The following table describes the Company's debt outstanding as of March 31, 2014:

Debt	Carrying Value	Maturity	Rate
Capital lease	\$ 21,267	March 31, 2015	10.00%
Convertible notes	\$ 196,050	September 30, 2014	8.00 %
Notes Payable (Bridge Notes)	\$ 426,000	Various – One year from inception	8.00 %
Due to shareholder	\$ 137,447	Demand	0.00 %

**NOTE 7. Commitments & Contingencies**

*Operating Leases* – The Company has two operating leases for its laboratory facilities at the Burlington County College Science Incubator in Burlington, New Jersey. Each lease is for a term of three years with a monthly rent of \$1,650 per laboratory. The term of the leases is from February 1, 2014 through January 31, 2017.

The Company has an operating lease for its office facilities in Eatontown, New Jersey. The lease is for a term of three years with a monthly rent of \$2,650. The term of the lease is from May 1, 2012 through April 30, 2015.

*Capital Lease* – The Company has a capital lease for laboratory equipment. The minimum lease payments due on the capital lease are as follows.

2014	11,220
2015	11,220
Total minimum lease payments	\$22,440



Less amounts representing interest (1,173 )

Present value of net minimum lease payments \$21,267

10

**American CryoStem Corporation**

**Notes to the Financial Statements**

**March 31, 2014**

**NOTE 7. Commitments & Contingencies (continued)**

*Research & Development* – On December 1, 2013, the Company executed two additional agreements (1) the Cooperative Research Agreement and (2) the Research Evaluation and License Option Agreement, with Rutgers University for further collaboration and intellectual property development with Dr. Kibum Lee. The Cooperative Research Agreement calls for the Company to provide Dr. Lee’s laboratory and staff with additional materials to continue their research utilizing the Company’s *ATCELL*<sup>TM</sup> and *ACSelerate*<sup>TM</sup> products. The Agreement also provides for the Company to have exclusive access to certain identified Rutgers intellectual property and for the joint ownership of any additional intellectual property developed. The Research Evaluation and License Option Agreement provides a platform for the Company to be the exclusive developer and licensor of any new intellectual property and patent rights. The Company will be managing all patent application and prosecution for any technologies developed under the Agreements. The Company has agreed to pay Rutgers University \$93,000 for this research project.

On October 18, 2013, the Company formed Autogenesis Corporation (“Autogenesis”) as part of its collaborative agreement to develop wound healing products and other cellular therapies with privately-held Protein Genomics (PGen). The Company is jointly owned by American CryoStem and Protein Genomics. Autogenesis will be separately funded and will serve as the dedicated business unit focused on continuing and accelerating the research and development of innovative new products and biotechnologies that combine American CryoStem’s *ATCELL*<sup>TM</sup> (adipose derived regenerative cells), and *ACSelerate*<sup>TM</sup> cell media culture products with PGen’s *Elastatropin*<sup>®</sup> human-based protein materials.

The Company has entered into a number of Material Transfer Agreements (MTAs) with potential collaborative, licensing and product distribution partners. These potential partners are evaluating the company products and there can be no assurance that these evaluations will result in material product distribution, licensing or collaborative arrangements.

**NOTE 8. Common Stock Issuances**

During the six months ended March 31, 2014, the Company issued 355,000 shares of common stock in connection with the conversion by the holders of \$124,500 of principal amounts of its unsecured convertible notes, as referred in Note 6.

**NOTE 9. Stock Options**

During the six months ended March 31, 2014, the Company issued options to the holders of the Notes mentioned in Note 6. The Company has granted each note holder an option to purchase one share of the Company’s common stock for each dollar of the principal amount of the note at \$0.05 per share. The options expire one year from the date on which the note is repaid.

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

The following is a summary of common stock options outstanding at March 31, 2014:

	Options	Wgtd Avg Exercise Price	Wgtd Years to Maturity
Outstanding at September 30, 2013	6,600,000	\$ 0.18	4.16
Issues	426,000	\$ 0.05	1.85
Exercises	0		
Expires	0		
Outstanding at March 31, 2014	7,026,000	\$ 0.17	3.80

11

**American CryoStem Corporation**

**Notes to the Financial Statements**

**March 31, 2014**

**NOTE 10. 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, 2014.

**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 the Chief Operating Officer or the Chief Executive Officer and Chairman would have a material adverse effect on the Company's ability to continue as a going concern.

**NOTE 12. Litigation**

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.

**NOTE 13. Subsequent Events**

On *April 9, 2014* the Company filed its first jointly-owned patent application with its research partners at Rutgers University titled, “Nanoparticle-Mediated Synthetic Transcription Factor for Enhanced Gene Regulation and Cell Differentiation.”

12

**American CryoStem Corporation**

**Notes to the Financial Statements**

**March 31, 2014 and 2013**

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF 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 fields 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 applications using autologous adipose (fat) tissue and adipose derived stem cells (ADSCs). Through its scientific efforts, 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.

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

Our business strategy is centered on promoting our standardized platform as a complete adipose stem cell solution and expanding our research and development through scientific collaborations and plan to generate revenue through the sale and licensing of our patented products, laboratory tools, and services to attempt to capitalize on: (1) adipose tissue and adipose derived stem cell (“**ADSC**”) technologies; (2) scientific breakthroughs incorporating ADSCs that we believe have been rapidly 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 laboratory facilities for the delivery of our products and services.

Our proprietary, patent pending clinical core processing platform that 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, there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments identified or in use globally. As of January 31, 2014, 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 (1277) adult stem cells (4205) adipose derived stem cells (93), mesenchymal stem cells (376), and stromal vascular fraction (15).

## Products and Services

American CryoStem is focused on multiple business lines that we believe can generate sustainable, recurring revenue streams from each of our developed products and services. Our core platform is designed in a modular fashion so that each service or product we offer can be performed in connection with or as a precursor to another Company service. The Company also incorporates its proprietary and patented or patent pending laboratory products, such as our ACSelerate™ cell culture and differentiation medias in all product processing, production and contract manufacturing services.

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

Products and services we offer are:

**CELLECT®** Tissue collection system designed for participating physicians to facilitate the collection and overnight shipping of an individual’s adipose tissue to our FDA registered laboratory for processing into any cellular products for storage

**ATGRAFT™** Tissue processing at our laboratory of adipose tissue received from clients and prepared for long term storage in different configuration sizes allowing future retrieval for tissue grafting procedures or the



production of ATCELL™ products for Regenerative Medicine applications  
Clinical Processing of the adipose tissue which removes the adipocytes and red blood cells for storage, expansion, or differentiation;

ATCELL™ Clinical and Research grade donated ATCELL™ lines for use with collaborative partners in research and application development and optimization, cell morphology and characterization assays, and growth analysis;

Patented animal serum free cell culture media products for growing human stromal cells (including all cells found in human skin, fat and other connective tissue);

ACSelerate™ ACSelerate-SFM™ cell culture media is available animal free (Fetal Bovine Serum (FBS) free), which is designed for clinical grade cell culture;

ACSelerate-LSM™ is a low FBS (0.05%) version for application development and research purposes.

Our branded product and service offerings include:

**CELLECT®- Validated Collection, Transportation, and Storage System** – A clinical solution allowing physicians to collect and ship tissue samples to our laboratory utilizing proprietary and patent-pending methods and materials. The CELLECT® service is monitored in real-time and we believe assures the highest cell viability in the tissue upon laboratory receipt. The CELLECT® service is included in our pending patent application US Serial No. 13/702,304.

We believe that American CryoStem is the first tissue bank to globally incorporate through its CELLECT® service the International Blood Banking identification and labeling and product identification coding system. The coding was developed in conjunction with the American Association of Blood Banks (AABB), the American Red Cross and the International Society of Blood Transfusion (ISBT). The Company intends to promote this standard in laboratories that license or utilize our technology.

**ATGRAFT™ Adipose Tissue Storage Service** – A clinical adipose tissue (fat) storage solution allowing physicians to provide their patients with multiple tissue/stem cell storage options. The ATGRAFT™ Service, is incorporated into one liposuction procedure, and permits the individual to access multiple cosmetic or regenerative procedures by using their own stored adipose tissue (from the initial ATGRAFT™ Storage). The stored ATGRAFT™ samples can be used as a natural biocompatible filler or processed to a cellular therapy application and allows the client to avoid the trauma of additional or multiple liposuction procedures. We believe that potential ATGRAFT™ uses and 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 may be retrieved from cryopreservation in the future and re-processed to create ATCELL™ our clinical grade stem cell product for use in Regenerative Medicine applications.

The fees we charge for ATGRAFT™ tissue processing and storage range from \$750 to \$2,500, depending upon the volume of tissue processed. The annual storage fees we charge are: (i) the minimum storage fee of \$200 for up to 100mL of tissue, or (ii) samples over 100mL are billed \$200 plus \$1 per mL for the amount over 100mL annually. These fees may be paid by the collecting/treating physician or the consumer. The Company believes it will earn additional fees from the physician of \$100 to \$500, for the thawing, packaging and shipment of the stored samples to the physician for immediate use. The ATGRAFT™ products and services are incorporated into our pending patent application PCT/US13/44621.

We believe the ATGRAFT™ Service creates a significant revenue opportunity for the participating physician to promote additional procedures and generate additional fees from adipose tissue (fat) collected during liposuction procedures. 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 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 may create multiple master and differentiated cell lines for an individual and labels them according to their characterization. (i.e. ATCELL™(adipose derived stem cells) ATCELL-SVF™ (stromal vascular fraction), ATCELL – CF™ (differentiated chondrocytes), etc.). The personalized stem cell lines are custom created for patients desiring to store their cells for their own use in future Regenerative Medicine applications and procedures. The Company intends to charge fees ranging from \$750 to \$10,000 to process a previously stored ATGRAFT™ sample or a minimum of \$1,500 for newly collected client tissue samples requesting ATCELL™ (cellular component) processing. Customer samples submitted for processing must utilize the CELLECT<sup>R</sup> collection system to conform to our internal cGMP SOPs.

The Company's ATCELL™ cell lines are adipose derived stem cells (ADSC), cGMP processed and cultured in our patented ACSelerate™ – SFM, and ACSelerate-LSM™ cell culture media. All tissue samples, cells, and research materials that are made available for sale to research institutions are tested for sterility, disease, lifespan, and population doubling rate (PDL). Cell morphology is confirmed by (i) flow cytometry and (ii) differentiation analysis using ACSelerate™ differentiation media. All ATCELL™ lines 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 the building blocks necessary for the final development of commercial applications.

The chart below illustrates the flexibility and capabilities of our products and how they are combined to create new and differentiated lines and their potential applications

Master Cell Product	Cell Media Used	Resulting Cell Type	Potential Applications *
ATCELL™	ACSelerate – SFM™ (animal product free)	Animal free clinical grade cultured adult stem cell lines in passages P0 to P4	Systemic and chronic disease, infusion therapy, regenerative tissue technologies focused on structural and stromal tissue loss from disease and injury throughout the body, wounds, ulcers, burns
ATCELL™	ACSelerate – LSM™ (contains 0.05% Fetal Bovine Serum)	Research grade cultured adult stem cell lines in passages P0 to P4	Research and Development of applications, Systemic and chronic disease, infusion therapy, regenerative tissue technologies focused on structural and stromal tissue throughout the body
ATCELL™	ACSelerate™ – CH	ATCELL™ – CH (Chondrocytes)	Cell Morphology Assays, repair and regeneration of cartilage damage and loss resulting from degenerative disease (rheumatoid and osteoarthritis) trauma, sports injury, etc.
ATCELL™	ACSelerate™ – OB	ATCELL™ – OB (Osteoblasts)	Cell Morphology Assays, repair and regeneration of bone damage and loss due to chronic or systemic disease, trauma and sports injury
ATCELL™	ACSelerate™ – AD	ATCELL™ – AD (Adipocytes)	Cell Morphology Assays, repair and regeneration of stromal and adipose tissue loss from disease, injury, trauma, surgical procedures, lumpectomy, mastectomy, radiation and chemotherapy
ATCELL™	ACSelerate™ – SFM	Autokine™ – CM	Topical wound healing, infusion therapies, Orthopedic, Dental and Cosmetic applications
ATCELL –SVF™	ACSelerate – SFM™	ATCELL™	Topical wound healing, infusion therapies, Orthopedic, Dental and Cosmetic applications
	ACSelerate – LSM™		

\* 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)

**ACSeperate™ 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). *ACSeperate™* cell culture media is available in animal serum (FBS) free, which is suitable for human clinical and therapeutic uses; and a low serum version (0.05% FBS) 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 HSA medium (clinical) grade and FBS (research) grade. 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. The Company has also filed a continuation of the media patent containing additional patent claims under US Serial No. 13/194,900.

The patented *ACSeperate™* cell culture media line was specifically developed to address increasing industry demand for animal serum-free cell culture products and for the acceleration of products from the laboratory to the patient.

We believe the ability of the Company to provide clinical grade materials for research and development collaborators, partners and other third parties extends the Company’s ability to become a primary source of standardized and validated clinical grade materials and services necessary to support approved applications and treatments.

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

*ACSeperate-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;

*ACSeperate-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;

*ACSeperate-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;

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

*ACSeperate-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-GY™* 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™* service.

*ACSelerate-TR™* a clinical grade transportation media designed for use with our CELLECT collection services to maintain tissue viability during transport from the collection site to the processing laboratory.

***ACS Laboratories:*** An unincorporated division of American CryoStem Corporation, intended to be responsible for (1) operating our Mount Laurel laboratory facility (2) the CELLECT<sup>R</sup> service (3) processing and storage of all ATGRAFT<sup>™</sup> and ATCELL<sup>™</sup> consumer samples, (4) manufacturing and distribution of all ACSelerate<sup>™</sup> media products (5) processing and testing products and services for professional, institutional and commercial clients and, contract manufacturing relationships. The Company operates the division and the website [www.acslaboratories.com](http://www.acslaboratories.com) to separate the proposed sale of commercial and research products from its consumer products, services and website [www.americancryostem.com](http://www.americancryostem.com).

ACS Laboratories also offers services to physicians and other medical professionals that perform tissue transfer and cellular therapy services in same day in-office procedures to develop specialized cosmetic procedures. Physicians can submit adipose tissue and cellular samples to the laboratory for ATGRAFT™ processing and storage or for sterility, viability, cellular density and growth assay analysis. The Company believes many physicians that provide their patients tissue transfer services do not have the facilities and equipment necessary to perform tissue testing. Large diagnostic and testing laboratories do not currently offer these specialized adipose tissue testing services.

**Contract Manufacturing:-** American CryoStem's contract manufacturing services are available for physician, corporate and biotech customers for custom and white label products and services for incorporation into their business. We believe the Company is positioned to develop, manufacture and license products for white label opportunities with physicians, wellness clinics and spa's. Under an agreement with Personal Cell Sciences ("PCS"), we manufacture the key ingredient *Autokine-CM*<sup>SM</sup> (autologous adipose derived conditioned medium) for PCS' *U-Autologous*<sup>TM</sup> and other anti-aging topical formulation products. 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>R</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™ and the ATCELL™ cell processing services utilizing ACSelerate™ 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 relationship provides opportunities for the Company to promote its ATGRAFT™ and ATCELL™ products for an individual's cosmetic purposes.

The Company intends to expand its relationships and contract manufacturing abilities through its physician network and globally through its proposed international licensing programs.

**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 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 attempt to expand the Company's believed sales, marketing and branding opportunities; the Company currently markets an international licensing program.

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

Our licensing program is broken down into four operating levels corresponding to our CELLECT<sup>R</sup>, ATGRAFT™, ATCELL™ and Contract Manufacturing services. Significant to our proposed international development activities is the opportunity for development and global expansion of the American CryoStem branded services and patented products footprint, for the Company's services, technology and products to become the core platform to implement cellular therapies and regenerative medicine in licensed territories.



## Product Development

Our strategic approach to product development is to design, develop and launch new products and services that utilize or incorporate 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 can 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 application and bio-materials development.

We intend to focus our efforts on the expansion of our product and service 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 for our current and proposed research partners and their application development to begin with clinically harvested and processed adipose tissue and ADSCs (ATCELL)<sup>™</sup>, which we believe can 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 into a new wound covering application, the “Living Bandage”. We have provided PGen and its research partner, Development Engineering Sciences (DES), with adipose derived stem cells (ATCELL)<sup>™</sup> and our patented cell culture mediums (ACSelerate)<sup>™</sup> for testing with PGen’s patented products designed for the wound healing market. We believe research and development has been ongoing since late 2012 and we believe notable progress has been achieved. As a result of the success realized in the early stage of this research collaboration, we entered into a formal joint venture with PGen through the incorporation of Autogenesis, Corp. as required in the 2012 MOU. Each company (CRYO and PGen) initially has an equal 50% ownership interest. The products being commercialized, utilizing the combined technology, as well as any new intellectual property resulting from the ongoing scientific collaboration will be wholly-owned by Autogenesis. Autogenesis has completed an initial proof of concept animal study to assess the safety and efficacy of the combined technologies. Autogenesis is planning additional animal studies designed to initiate the FDA application process for the wound covering products.

### ***Rutgers University***

In May of 2013, 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)<sup>™</sup> and patented, FBS serum free, cGMP grade cell culture and differentiation mediums (ACSelerate)<sup>™</sup> 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.

On April 9, 2014 the Company filed its first jointly-owned patent application with its research partners at Rutgers University titled, “Nanoparticle-Mediated Synthetic Transcription Factor for Enhanced Gene Regulation and Cell Differentiation.”

In December of 2013, 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) for the research. We believe our collaborative efforts have advanced rapidly and new intellectual property will result from this work. Based on the collaborative efforts under the Collaboration and Research Agreement, our Company’s patent counsel is preparing additional 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*<sup>™</sup> and *ACSelerate*<sup>™</sup> products for the development of new cellular therapies and regenerative medicine applications. To support the new discoveries, Dr. Lee and our professionals intends to develop file and publish patent applications, research papers, government and private grant funding applications to support future clinical studies as appropriate.

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

In an effort to make it easier for other physicians and researchers to study the safety of adipose derived stem cells ADSCs and stromal vascular fraction (SVF), we sought approval from the Institutional Review Board (“**IRB**”) of the International Cell Surgical Society (“**ICSS**”) of our protocols for the processing of ATCELL-SVF and culturing of stem cells from adipose tissue ATCELL.™ The two protocols, 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*, provide appropriate processing, storage and testing methods necessary to move the clinical investigative process towards uniform treatments. The collection of cGMP processing and outcome data from IRB approved protocols is required by prevailing FDA regulations and guidance for approval of regenerative cellular therapies including at a minimum, potency (cell count), contamination testing and cell viability data.

We believe the ICSS IRB thoroughly evaluated every step of our Standard Operating Procedures (“**SOPs**”), which serve to isolate the SVF or ADSCs from a patient’s adipose tissue. The objective of the IRB was to assess these protocols to ensure the highest patient safety possible and appropriate data reporting and collection and, to minimize the risks for individuals participating in innovative research and investigational studies. In 2013, the ICSS IRB approved protocols for an additional IRB reviewed study titled, “*Comparative Viability Assessment of Human Adipose Tissue Before and After Cryopreservation*”. The new study was developed and submitted to support a pending clinical study of our ATGRAFT™ products and services and the development of publications in support of our patented technologies and product marketing efforts.

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

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. We believe that as the pace of clinical trials result reporting increase and peer reviewed papers are published, new opportunities will be created to market our existing products, services and intellectual property portfolio.

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 Cosmeceuticals.

## **Regulatory Information**

The Company's methods, testing and facilities are designed to be and the Company believes are 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 The Company further registered the facility as a tissue bank with the State of New York (CP169TP136) and The State of California (CNC80948). These state registrations required the submission of our Standard Operating Procedures (SOPs) for review by the respective state Health Departments. Annual updates are required to maintain the tissue bank registrations. In addition we have discussed our operations with the State of New Jersey Health Department and Department of Environmental Protection (NJDEP) to ascertain whether we are subject to any special regulations thereunder. Based upon these discussions, and our use of a registered medical waste disposal company, we believe we do not at this time have any special requirements for compliance with the State of New Jersey regulations.

The Company also is required to comply with a significant body of FDA and PHS regulation, including, but not limited to, regulations governing our SOPs which we have developed and reviewed with our FDA consultants.

We believe our SOPs are the key to proper operation of a clinical tissue processing facility. To produce what the company believes are the highest quality products, processing tools and services we also incorporated into our SOPs portions of certain accreditation guidelines published 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).

## Intellectual Property

### Patents

From its very early stages, part of the Company's strategy has been to develop intellectual property and protect such intellectual property. One of the reasons we are developing our IP portfolio is to attempt to ensure and enhance our business flexibility and allow us to gain favorable terms in potential future collaborative efforts 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 the pending patent applications which are detailed in the following chart:

PATENT TITLE	USE OF PATENT	APPLICATION #
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
Stem Cell-Based Therapeutic Devices and Methods	Combining ADRCs with Biomaterials for healing and tissue growth	U. S. Serial No. 14/196,414 filed March 4, 2014 and claiming a priority date from provisional application 61/773,112 filed March 10, 2013
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 U.S. Serial No. 13/194,900  
improvements to Media Formulations

Additionally the Company has licensed the following intellectual property under its collaborations with Rutgers and Protein Genomics, Inc (Autogenesis Corporation).

21

<b>PATENT TITLE</b>	<b>USE OF PATENT</b>	<b>APPLICATION #</b> Rutgers Docket Number 20113-013
Nanoparticle-Mediated Synthetic Transcription Factor from Enhanced Gene Expression and Cell Differentiation	Rutgers collaboration and R&D	USPTO Provisional Filing# 61/947,898  (Jointly owned with Rutgers)
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 our patents, the Company has registered the following trademarks with the U.S. Patent and Trademark Office: *American CryoStem*<sup>®</sup> (Registration No. 4189056) and *CELLECT*<sup>®</sup> (Registration No. 4278333). We plan to file for registration trademarks for our future products, slogans and themes to be used in our marketing initiatives, including, for example, *ATGRAFT*<sup>™</sup>*ACSelerate SFM*<sup>™</sup>, *ACSelerate LSM*<sup>™</sup> and *ATCELL*<sup>™</sup>.

### **Marketing and Distribution**

A key objective of our marketing strategy is to position American CryoStem in the market as the “Gold Standard” for adipose tissue collection, cellular processing and cell storage, cellular expansion, therapeutic applications, and, research and commercial uses of adipose tissue within the current regulatory framework. The combination of a direct sales approach supported by continuous internal and external marketing programs the Company intends to be closely coordinated with the expansion of our laboratory processing capabilities. We intend to employ both print advertising and social media sales campaigns. In addition, we plan 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 and collaborate with us.

We have also initiated a direct marketing program focused on reaching plastic and cosmetic surgeons and have an initial group of providers that have begun to offer our services to their patients. This marketing initiative has been implemented using a direct sales approach. 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, when capital is available provides for a comprehensive marketing approach focused on identifying and supplying end users with samples of our cellular based products and services. The essence of this targeted strategy, capital permitting is to accelerate the adoption curve of our products and services within the academic and scientific communities. In the future we plan to utilize outside sales organizations to further increase the distribution of our products and services.

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

### ***Physician Network***

The Company continues to develop regional relationships to leverage its new products and services through existing cosmetic surgery and regenerative medicine practices along with 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 initially 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.

### ***Dr. Park Avenue***

In September 2013, we announced the opening of three new adipose tissue collection centers at Dr. Park Avenue's New Jersey locations. Dr. Park Avenue is a leading provider of aesthetic and cosmetic services in the Tri-State area with locations in Brick Township, Franklin Lakes and Hoboken, New Jersey. Dr. Park Avenue's newest center, located in Hoboken, held its grand opening in late September; in conjunction with the opening, Dr. Park Avenue formally

introduced our *ATGRAFT*<sup>™</sup> service for patients interested in fat grafting as an alternative to artificial fillers by using their own stored fat tissue to undergo transfer procedures to the face, hands, breast and buttocks.

### **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).

### **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 \$45,500 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 \$146,890 during the three months ended March 31, 2014 in professional fees (legal, accounting and consultants) and \$116,364 in 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; (ii) an equipment lease in the amount of \$21,267 for laboratory equipment with monthly payments of \$1,869.74 and the final payment due March 2015; and (iii) 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, 2014 was \$7,950.

The Company has unsecured liabilities without interest of \$137,447 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 2014, 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, 2014.



**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, 2014, the Company issued \$129,500 of convertible notes. The convertible notes have an exercise price of \$0.35 per share of common stock and mature in September 2014. During the six months ended March 31, 2014, convertible notes of \$124,250 were converted to common stock.

During the six months ended March 31, 2013, the Company issued a principal amount of \$426,000 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 \$0.5 per share for each dollar of principal. The Company issued options to purchase 426,000 to the note holders. The options expire one year from the date the note is repaid.

### **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

27

**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 20, 2014 By: /s/ John Arnone  
John Arnone, Chief Executive Officer  
(Principal Executive Officer)

May 20, 2014 By: /s/ Anthony Dudzinski  
Anthony Dudzinski, Treasurer  
(Principal Financial Officer)

28