

AMERICAN CRYOSTEM Corp  
Form 10-Q  
August 19, 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 nine month period ended June 30, 2014

Commission file number: 000-54672

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

Nevada 26-4574088  
(State or other jurisdiction of incorporation or organization) (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  No

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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 August 18, 2014 there were 32,882,364 shares of common stock outstanding.

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**PART I – FINANCIAL INFORMATION****Item 1. Financial Statement****American CryoStem Corporation****INTERIM FINANCIAL STATEMENTS****JUNE 30, 2014****American CryoStem Corporation****Balance Sheets****As of June 30, 2014 and 2013**

	June 30, 2014	June 30 2013
<b>ASSETS</b>		
Current assets:		
Cash	\$31,759	\$31,355
Trade Accounts Receivable	5,520	3,051
Other Receivable	—	710
Investment	1,000	—
Deferred Contract Expense	65,875	—
Prepaid Expenses	250	250
Total current assets	104,404	35,366
Property and Equipment (Net of Accumulated Depreciation)	137,505	167,927
Other Assets	325,311	291,400
Total Assets	\$567,220	\$494,693
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts Payable & Accrued Expenses	\$574,903	\$220,144
Contract Payable	68,000	—
Convertible Notes Payable	185,550	—
Notes Payable	506,000	—

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Capital Lease Payable	16,147	19,092
Total current liabilities	1,350,600	239,236
Long-Term Liabilities		
Deferred Revenue	1,100	—
Notes Payable	—	199,000
Capital Lease Payable	—	18,350
Payable to Shareholder	136,948	139,447
Total Long-Term Liabilities	138,048	356,797
Shareholders' equity:		
Common stock (\$.001 par value, 32,840,721 shares issued and outstanding at June 30, 2014, and 30,400,405 shares issued and outstanding at June 30, 2013; 300,000,000 shares authorized)	32,841	30,401
Additional paid in capital	6,149,318	4,395,840
Accumulated deficit	(7,103,587)	(4,527,581)
Total shareholders' equity	(921,428 )	(101,340 )
Total Liabilities & Shareholders' Equity	\$567,220	\$494,693
See accompanying notes to financial statements		

American CryoStem Corporation

**Statements of Operations****For the Three Months Ended June 30, 2014 and 2013****and the Nine Months Ended June 30, 2014 and 2013**

	Three Months Ended		Nine Months Ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Sales	\$63,760	\$ 5,761	\$74,379	\$ 7,257
Operating Expenses:				
Professional Fees	55,382	28,731	273,750	88,018
Research & Development	105,745	66,840	287,053	192,417
Administration	123,219	226,140	513,527	562,934
Total Operating Expenses	284,346	321,711	1,074,330	843,369
Net Loss from Operations	(220,586 )	(315,950 )	(999,951 )	(836,112 )
Other Income (Expense)	(13,833 )	(5,955 )	(28,243 )	(15,820 )
Net Loss	\$(234,419 )	\$(321,905 )	\$(1,028,194 )	\$(851,932 )
Basic & fully diluted net earnings (loss) per common share	\$(.007 )	\$(.011 )	\$(.032 )	\$(.029 )
Weighted average of common shares outstanding: Basic & fully diluted	32,683,908	29,856,282	32,617,324	28,902,802
See accompanying notes to financial statements				

American CryoStem Corporation

**Statement of Cash Flows****For the Nine Months Ended June 30, 2014 and 2013**

	Nine Months Ended June 30,	
	2014	2013
<b>Operating Activities:</b>		
Net loss	\$ (1,028,194 )	\$ (851,932 )
Adjustments to reconcile net income items not requiring the use of cash:		
Depreciation expense	30,505	28,658
Accrued Interest	28,243	10,880
Common Stock Issued for Services	—	7,500
Changes in other operating assets and liabilities		
Accounts Receivable	(3,517 )	(3,051 )
Other Receivable	—	(710 )
Deferred Contract Expense	(65,875 )	—
Prepaid Expenses	(250 )	(250 )
Accounts Payable and accrued expenses	286,531	(31,266 )
Contract Payable	68,000	—
Deferred Revenue	1,100	—
Net cash used by operations	(683,457 )	(840,171 )
<b>Investing activities:</b>		
Investment	(1,000 )	—
Purchase of equipment	(8,149 )	(998 )
Investment in other assets	(34,075 )	(31,327 )
Net cash used by investing activities	(43,224 )	(32,325 )
<b>Financing activities:</b>		
Convertible notes	(5,250 )	126,525
Payment to Shareholder	(2,499 )	(365 )
Issuance of Notes Payable	506,000	
Issuance of common stock	159,250	767,350
Capital Lease	(14,993 )	6,302
Net cash provided by financing activities	642,508	899,812
Net increase (decrease) in cash during the period	(84,173 )	27,316
Cash Balance, Beginning of Period	115,932	4,039
Cash balance, End of Period	\$ 31,759	\$ 31,355
<b>Supplemental disclosures of cash flow information:</b>		
Interest Paid	\$ 1,361	\$ 405
Income Taxes Paid	\$ 0	\$ 0

See accompanying notes to financial statements

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American CryoStem Corporation

**Statement of Changes in Shareholders' Equity**

**For the Nine Months Ended June 30, 2014**

**Prices & shares adjusted for stock splits**

	Common Stock Shares	Par Value	Additional Paid in Capital	Accumulated Deficit	Total Shareholders' Equity
Balance at September 30, 2013	32,285,721	\$ 32,286	\$5,990,623	\$(6,075,393 )	\$(52,484 )
Issuance of Common Stock	555,000	555	158,695		159,250
Net Loss				(1,028,194 )	(1,028,194 )
Balance at June 30, 2014	32,840,721	\$ 32,841	\$6,149,318	\$(7,103,587 )	\$(921,428 )

See accompanying notes to financial statements

## American CryoStem Corporation

### Notes to the Financial Statements

June 30, 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>TM</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.

**American CryoStem Corporation**

**Notes to the Financial Statements**

**June 30, 2014**

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

*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

*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 June 30, 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 and the issuance of shares to raise capital 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****June 30, 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 June 30,		For the Nine Months Ended June 30,	
	2014	2013	2014	2013
Net Loss	\$ (234,419 )	\$ (321,905 )	\$ (1,028,194 )	\$ (851,932 )
Weighted average shares outstanding	32,683,908	28,659,711	32,617,324	28,902,802
Basic & fully diluted net earnings (loss) per common share	\$ (.007 )	\$ (.011 )	\$ (.032 )	\$ (0.029 )

**NOTE 4. Property and Equipment**

Property and Equipment is comprised of the following:

	June 30, 2014	June 30, 2013
Office Furniture and Equipment	\$ 24,986	\$ 24,986
Lab Furniture and Equipment	250,094	241,945
Leasehold Improvements	7,753	7,753
	282,833	274,684
Less: Accumulated Depreciation	(145,328 )	(106,757 )
Net Property and Equipment	\$ 137,505	\$ 167,927

**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.

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

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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)

**American CryoStem Corporation****Notes to the Financial Statements****June 30, 2014****NOTE 6. Debt**

During the nine months ended June 30, 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 nine months ended June 30, 2014, convertible notes of \$134,750 were converted to common stock.

During the nine months ended June 30, 2014, the Company raised \$506,000 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 June 30, 2014:

Debt	Carrying Value	Maturity	Rate
Capital lease	\$ 16,147	March 31, 2015	10.00 %
Convertible notes	\$ 185,550	September 30, 2014	8.00 %
Notes Payable (Bridge Notes)	\$ 506,000	Various – One year from inception	8.00 %
Due to shareholder	\$ 136,948	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.



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2014	5,610
2015	11,220
Total minimum lease payments	\$16,830
Less amounts representing interest	(683 )
Present value of net minimum lease payments	\$16,147

**American CryoStem Corporation**

**Notes to the Financial Statements**

**June 30, 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>™</sup> and *ACSelerate*<sup>™</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>™</sup> (adipose derived regenerative cells), and *ACSelerate*<sup>™</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 nine months ended June 30, 2014, the Company issued 385,000 shares of common stock in connection with the conversion by the holders of \$134,750 of principal amounts of its unsecured convertible notes, as referred in Note 6.

During the nine months ended June 30, 2014, the Company issued 170,000 shares of common stock in connection with the exercise of stock options for \$24,500.

**NOTE 9. Stock Options**

During the nine months ended June 30, 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.

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The following is a summary of common stock options outstanding at June 30, 2014:

	Options	Wgt'd Avg Exercise Price	Wgt'd Years to Maturity
Outstanding at September 30, 2013	6,600,000	\$ 0.18	4.16
Issues	506,000	\$ 0.05	1.85
Exercises	170,000	\$ 0.14	
Expires	0		
Outstanding at June 30, 2014	6,936,000	\$ 0.16	3.50

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**American CryoStem Corporation**

**Notes to the Financial Statements**

**June 30, 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 June 30, 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.

**American CryoStem Corporation**

**Notes to the Financial Statements**

**June 30, 2014 and 2013**

**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 fields of Regenerative and Personalized Medicine and operates a state-of-the-art, FDA-registered, clinical laboratory dedicated to our standardized processing platform, bio-banking and the 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, and proprietary operating processes that form the 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 we 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 affiliated laboratory facilities for the delivery of our products and services.

Our proprietary, patent pending clinical core 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, there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments identified or in use globally. As of August 4, 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 (1397) adult stem cells (4442) adipose derived stem cells (111), mesenchymal stem cells (414), and stromal vascular fraction (25).

## **Products and Services**

American CryoStem is focused on multiple business lines that we believe will 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. This modular configuration also permits the Company to customize the licensing of individual technologies so that the Licensee’s may quickly roll out the services that are permitted within their Licensed Territory. 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
- ATCELL™** Clinical Processing 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, characterization assays, and growth analysis;
- ACSelerate™** 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 all 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, neck and other areas of the body that experience significant adipose tissue (fat) volume reduction as we age. **ATGRAFT™**

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*<sup>™</sup> our clinical grade stem cell product for use in Regenerative Medicine applications.

The fees we charge for *ATGRAFT*<sup>™</sup> 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 *AGRAFT*<sup>™</sup> products and services are incorporated into our pending patent application PCT/US13/44621.

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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 – CH™ (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 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™		ATCELL™ – CH	

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	ACSelerate™ – (Chondrocytes) CH		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 <sup>M</sup>	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 enhances 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;

*ACSeperate-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-CP<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.

*ACSelerate-TR<sup>TM</sup>* 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.

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**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>®</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. Physicians can submit adipose tissue and cellular samples to ACS laboratory for ATGRAFT<sup>™</sup> 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, other biotech companies, wellness clinics and spa’s. Under an agreement with Personal Cell Sciences (“PCS”), we manufacture the key ingredient *Autokine-CM* (autologous adipose derived conditioned medium) for PCS’ *U-Autologous*<sup>™</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>®</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 the 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 an ongoing 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<sup>™</sup> and ATCELL<sup>™</sup> 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 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. 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 for further development and establishing a global footprint of American CryoStem's laboratory services and patented products. The platform allows for 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™ 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™ 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™ 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 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 standardized, clinically harvested and processed adipose tissue and ADSCs (ATCELL)<sup>SM</sup>, which we believe will be a significant step toward accelerating the development and approval of new treatments.

## **Collaboration and Partnering Opportunities**

### ***UHV Technologies, nanoRANCH***

On May 1<sup>st</sup>, 2014, the Company entered into a Material Transfer Agreement with the nanoRANCH division of UHV Technologies under which we delivered research grade ATCELLS and ACSelerate – SFM cell culture medium for scientific study and use in a novel technology for delivering cancer and other drugs utilizing adipose derived stem cells. The project is being managed jointly by Dr. Michael Moeller our Chief Scientist and Dr. Dan Dimitrijevic from nanoRANCH. The Company believes that new intellectual property, scientific publications and ultimately commercial applications may result from the ongoing scientific collaboration.

***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>SM</sup> and our patented cell culture mediums (ACSelerate)<sup>SM</sup> for testing with PGen’s patented products designed for the wound healing market. 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 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.

