

AMERICAN CRYOSTEM Corp  
Form 10-Q  
February 21, 2017

**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 three month period ended December 31, 2016

Commission file number: 000-54672

**AMERICAN CRYOSTEM CORPORATION**

(Name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

26-4574088

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

1 Meridian Road, Eatontown, NJ 07724

(Address of principal executive offices)(Zip Code)

(732) 747-1007

(Registrant's telephone number, including area code)

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

Yes  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

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 February 13, 2017, there were 37,682,066 shares of common stock outstanding.

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**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements**

American CryoStem Corporation

**Balance Sheets**

	December 31, 2016	September 30, 2016
<b>ASSETS</b>		
Current assets:		
Cash	\$ 34,247	\$ 37,251
Accounts receivable	99,085	65,335
Inventory	24,696	24,698
Total current assets	158,028	127,284
Property and Equipment (Net of Accumulated Depreciation)	173,501	182,701
Other assets	289,510	281,936
Total assets	\$ 621,039	\$ 591,921
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable & accrued expenses	\$ 839,500	\$ 831,577
Bridge notes payable	226,500	226,500
Convertible notes payable	186,400	186,400
Deferred revenues	23,641	28,514
Total current liabilities	1,276,041	1,272,991
Long-Term Liabilities:		
Convertible notes payable	1,148,500	1,148,500
Payable to shareholder	114,357	117,184
Deferred Revenue	1,639	—
Total Long-Term Liabilities	1,264,496	1,265,684
Shareholders' equity:		
Common stock- \$.001 par value, authorized 300,000,000 shares authorized, issued and outstanding, 37,121,709 shares at September 30, 2016 and 37,657,513 at December 31, 2016	37,658	37,122
Additional paid in capital	9,561,753	9,440,282

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Accumulated deficit	(11,518,909 )	(11,424,158 )
Total shareholders' deficit	(1,919,498 )	(1,946,754 )
Total Liabilities & Shareholders' Deficit	\$ 621,039	\$ 591,921

**See the notes to the financial statements.**

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American CryoStem Corporation

**Statements of Operations****For the Three Months Ended December 31, 2016 and 2015**

	December 31, 2016		December 31, 2015
Revenues	\$ 320,471		\$ 139,114
Cost of Revenues	122,775		77,728
Gross Profit	197,696		61,386
Operating Expenses			
Laboratory Expenses	41,589		22,931
Professional Fees	16,436		1,810
Administration	136,696		84,974
Consulting Fees - Stock Issued	66,000		—
Total Operating Expenses	260,721		109,715
Net loss from operations	(63,025	)	(48,329
Other income (expenses):			
Interest Income	—		36
Interest expense	(31,726	)	(24,186
Net loss	\$ (94,751	)	\$ (72,479
Basic & fully diluted net loss per common share:			
Net loss	\$ (0.0025	)	\$ (0.0021
Weighted average of common shares outstanding:			
Basic & fully diluted	37,343,961		34,757,429

**See the notes to the financial statements.**

American CryoStem Corporation

**Statements of Cash Flows****For the Three Months Ended December 31, 2016 and 2015**

	December 31, 2016	December 31, 2015
Operating Activities:		
Net loss	\$ (94,751 )	\$ (72,479 )
Adjustments to reconcile net loss items not requiring the use of cash:		
Bad Debt Expense	5,122	10,043
Interest expense	31,726	24,186
Professional Fees	66,000	—
Depreciation & Amortization	9,698	—
Changes in other operating assets and liabilities :		
Accounts receivable	(38,872 )	47,900
Deferred charge	—	7,750
Inventory	2	—
Other Deposit	—	(7,500 )
Accounts payable and accrued expenses	(23,803 )	(19,516 )
Deferred revenue	(3,234 )	(17,942 )
Net cash used by operations	(48,112 )	(27,558 )
Investing activities:		
Patents development	(8,072 )	(6,750 )
Net cash used by investing activities	(8,072 )	(6,750 )
Financing activities:		
Payable to shareholder	(2,827 )	8,600
Issuance of convertible notes	—	—
Issuance of common shares	56,007	20,500
Options exercised	—	—
Net cash provided by financing activities	53,180	29,100
Net increase (decrease) in cash	(3,004 )	(5,208 )
Cash balance Beginning of Period	37,251	9,059
Cash balance at End of Period	\$ 34,247	\$ 3,851
Supplemental disclosures of cash flow information:		
Interest paid during the period	\$ —	\$ —
Income taxes paid during the period	\$ —	\$ —

**See the notes to the financial statements.**





American CryoStem Corporation

**Statement of Changes in Shareholders' Equity****For the Three Months Ended December 31, 2016 and 2015**

	Common Shares	Par Value	Paid in Capital	Retained Deficit	Total Deficit
Balance at September 30, 2015	34,705,451	\$34,707	\$7,876,967	\$(9,543,022)	\$(1,631,348)
Exercises of options	10,000	10	490		500
Issuance of common shares	100,000	100	19,900		20,000
Net loss				(72,479)	(72,479)
Balance at December 31, 2015	34,815,451	\$34,817	\$7,897,357	\$(9,615,501)	\$(1,683,327)
Balance at September 30, 2016	37,121,709	\$37,122	\$9,440,282	\$(11,424,158)	\$(1,946,754)
Issuance of common shares	91,667	92	14,908		15,000
Shares issued for services	300,000	300	65,700		66,000
Shares issued to pay interest on debt	144,137	144	40,863		41,007
Net loss				(94,751)	(94,751)
Balance at December 31, 2016	37,657,513	\$37,658	\$9,561,753	\$(11,518,909)	\$(1,919,498)

**See the notes to the financial statements.**

## American CryoStem Corporation

### Notes to the Financial Statements

December 31, 2016 and 2015

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

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

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

The Company is in the business of collecting adipose tissue, processing it to separate the adult stem cells, and preparing such stem cells for long-term storage. The process allows individuals to preserve their stem cells for future personal use in cellular therapy. The adipose derived stem cells are prepared and stored in their raw form without manipulation, bio-generation or the addition of biomarkers or other materials, making them suitable for use in cellular treatments and therapies offered by existing and planned treatment centers worldwide. Individualized collection and storage of adult stem cells provides personalized medicine solutions by making the patient’s own preserved stem cells available for future cellular therapies.

The Company has devoted a significant amount of its time and resources to develop its technologies and intellectual property. These efforts have resulted in the development of cell lines, cell culture medium and other laboratory products which the Company believes are suitable for licensing and distribution by third parties. Additionally the Company has initiated a licensing program to license its technologies to laboratories currently processing other types of biologic materials including cord blood and general blood banks. The Company closed its first licensing agreement in 2014 and intends to pursue additional licensing partners in the future.

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

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

*Revenue Recognition* – The Company recognizes tissue processing 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. Royalties from the licensing of the Company’s assets are recognized when earned and collection of the royalty is reasonable assured. Revenue derived from the sales of collection kits and medium products to Licensees is recognized upon shipment of the products to the licensee.

*Inventory*- Inventory is valued at lower of cost or market using the last in, first out method. Inventory consists of the disposables and materials to produce production kits for the processing of adipose tissue and cellular samples, the manufacture of our medias used to prepare the samples and cryoprotectant for the storage of the samples.

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*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.

*Fixed Assets* – Fixed assets are 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

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**American CryoStem Corporation**

**Notes to the Financial Statements**

**December 31, 2016 and 2015**

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

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

The Company follows the accounting requirements associated with uncertainty in income taxes using the provisions of Financial Accounting Standards Board (FASB) ASC 740, Income Taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not the positions will be sustained upon examination by the tax authorities. It also provides guidance for derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of December 31, 2015 and December 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 2011 to 2015 are subject to IRS audit.

*Recently Issued 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 generally accepted accounting principles in the United States, 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, the issuance of debt and equity to raise capital to fund its business operations. Management's plans with regard to this matter are as follows:

The Company plans to continue to fund its operations through capital fundraising activities through the sale of its debt and equity securities in fiscal 2017 until it generates sufficient revenue to support its operations.

**NOTE 3. Loss per Share**

The Company applies ASC 260, "Earnings *per Share*" to calculate loss per share. In accordance with ASC 260, basic and fully diluted net loss per share has been computed based on the weighted average of common shares outstanding during the years. The dilutive effects of the convertible notes and the options outstanding 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:

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	Dec 31, 2016	Dec 31, 2015
Net Loss	\$(94,751 )	\$(72,479 )
Weighted average shares outstanding	37,343,761	34,757,429
Basic & fully diluted net earnings (loss) per common share	\$(0.0025 )	\$(0.0021 )

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**American CryoStem Corporation****Notes to the Financial Statements****December 31, 2016 and 2015****NOTE 4. Fixed Assets**

Fixed Assets owned by the Company are comprised of the following:

	December 31, 2016	September 30, 2016
Office Equipment	\$ 26,637	\$ 26,637
Lab Furniture	642	642
Office Furniture	999	999
Lab Equipment	261,364	261,365
Lab Software	123,000	123,000
	412,642	405,332
Less: Accumulated Depreciation	(239,141 )	(229,942 )
Net Property and Equipment	\$ 173,501	\$ 182,701

**NOTE 5. Patents & Patents Filings**

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

On August 2, 2011, the Company was awarded U.S. Patent No. US 7,989,205 B2, titled Cell Culture Media, Kits, and Methods of Use. The Patent is for cell culture media kits for the support of primary culture of normal non-hematopoietic cells of mesodermal origin suitable for both research and clinical applications. The Company filed and maintains a continuation (U.S. Serial No. 13/194,900) and additional claims were granted on October 19, 2016. The Company filed an additional continuation on November 7, 2016 as part of our overall patent strategy and to cover expanded modifications of the original patent grant.

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

A business method for Collection, Cryogenic Storage and Distribution of a Biologic Sample Material US Serial No. 13/702,304 filed June 6, 2011 with a priority date of June 6, 2010

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

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

Stem Cell Based Therapeutic Devices and Methods U.S. Serial No. 14/196,616 filed March 4, 2014 with a priority dated of March 10, 2013

Autologous Serum for Transport of Isolated Stromal Vascular Fraction or Adipose Derived Stem Cells US Serial No. 14,250,338 filed in 2014 with a priority date of April 11, 2013

Human Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells, International PCT filing PCT/US/68350 filed December 31, 2015 with a priority date of December 31, 2014

Systems and Methods to Isolate and Expand Stem Cells from Urine Provisional Application Number 62/335,426 Filed May 12, 2016

**American CryoStem Corporation****Notes to the Financial Statements****December 31, 2016 and 2015****Note 6. Debt**

The following table describes the Company's debt outstanding at December 31, 2016:

Debt	Carrying Value	Fair Value	Maturity	Rate
Bridge Notes	\$226,500	\$226,500	Demand	8.00% In default
Convertible Notes 35 cents	\$133,900	\$139,500	Demand	8.00% In default
Convertible Notes 30 cents	\$52,500	\$52,500	Demand	8.00%
Convertible Notes 20 cents	\$783,000	\$783,000	Fiscal 2018	8.00%
Convertible Notes 15 cents	\$365,500	\$365,500	Fiscal 2018	8.00%

The convertible notes are exercisable at any time and have exercise prices ranging from \$0.15 to \$0.35 with the amount of shares exercisable based on the face value of the convertible note. The holders of the bridge notes were granted an option to purchase common shares of the Company at \$0.05 per share with the number of shares dependent upon the face value of the bridge note. As of the date of this report 26,500 of these options remain outstanding.

**NOTE 7. Common Stock Issuances**

During fiscal year 2016, the Company issued 687,500 shares of common stock and received proceeds of \$137,501.

During fiscal year 2016, a holder of a \$7,000 convertible note exercised and received 20,000 shares

During fiscal year 2016, option holders exercised their options and received 709,500 shares of common stock. The Company received proceeds of \$55,476 upon exercise.



During fiscal year 2016, the Company issued 425,000 shares of common stock to consultants for services rendered valued at \$95,750.

During fiscal year 2016, the Company issued 50,000 shares of common stock for a security deposit on its new lab location in Princeton, New Jersey. The value of the deposit is \$10,450.

During fiscal year 2016, the Company issued 557,591 shares of common stock to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid is \$168,763.

During the three months ended December 31, 2016, the Company issued 91,667 shares of common stock and received proceeds of \$15,000.

During the three months ended December 31, 2016, the Company issued 300,000 shares of common stock to consultants for services rendered valued at \$66,000.

During the three months ended December 31, 2016, the Company issued 144,137 shares of common stock to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid is \$41,007.

**American CryoStem Corporation****Notes to the Financial Statements****December 31, 2016 and 2015****NOTE 8. Stock Options**

The Company applies ASC 718, "Accounting for Stock-Based Compensation" to account for its option issues. Accordingly, all options granted are recorded at fair value using a generally accepted option pricing model at the date of the grant. The Company uses the Black-Sholes option pricing model to measure the fair values of its option grants. For purposes of determining the option values at issuance, the fair value of each option granted is measured at the date of the grant by the option pricing model using the parameters of the volatility of the Company's share prices and the risk free interest rate

The Company normally issues options to its key personnel at the end of each fiscal year. There were no options issued during the three months ended December 31, 2016.

	Options	Weighted Avg Exercise Price	Weighted Years to Maturity
Outstanding at September 30, 2016	14,671,500	\$ 0.22	3.17
Issues	0		
Exercises	0		
Expires	0		
Outstanding at December 31, 2016	14,671,500	\$ 0.22	2.92

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

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

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

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

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

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

The Company has no investments at December 31, 2016 and December 31, 2015 that would qualify for the above hierarchy.

**Note 10. Commitments & Contingencies**

The Company is committed to a non-cancelable lease for lab space in South Brunswick, New Jersey through fiscal year 2019. Minimum lease payments under this lease are as follows:

2017	\$29,304
2018	39,072
2019	13,024
Net minimum lease payments	\$81,400

**American CryoStem Corporation**

**Notes to the Financial Statements**

**December 31, 2016 and 2015**

**Note 10. Commitments & Contingencies (continued)**

The Company also leases office space in Eatontown, New Jersey. The lease is on a “month to month” basis and rents for \$2,650 per month.

The Company is not party to any litigation against it and is not aware of any litigation contemplated against it as of December 31, 2016.

**Note 11. Concentrations of Credit**

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

The Company received approximately 60% of its revenues during the three months ended December 31, 2016 from two clients; Cells on Ice, a network of physicians through which we market our services under the Cells on Ice brand, and Cell Source, our licensee located in Tokyo Japan.

**Note 12. Joint Venture**

During fiscal year 2014, the Company invested \$1,000 in a joint venture. The joint venture is called Autogenesis Corporation and was incorporated in the state of Florida. The Company and its two chief executives own 50% of Autogenesis. Autogenesis was formed for the purpose of developing a wound healing protocol. The Company has no further obligations to Autogenesis and the joint venture will be responsible for its own funding. Autogenesis has no material business operations as of December 31, 2016

**Note 13. Related Party Transactions**

At December 31, 2016, the Company has an advance receivable from Autogenesis, discussed in Note 12, for \$10,880. The advance receivable has no interest rate, is unsecured, and due on demand.

At December 31, 2016, the company was indebted to a Company that is the majority owner of the Company \$114,357. The advances are due on demand, are unsecured, and carry no interest rate.

At December 31, 2016, the company was indebted to a Company that is majority owned by one Company's chief executive officers for \$14,316. The advances are due on demand, are unsecured, and carry no interest rate.

At December 31, 2016, the company was indebted to a Company that is majority owned by one Company's chief executive officers for \$2,237. The advances are due on demand, are unsecured, and carry no interest rate.

#### **Note 15. Subsequent Events**

The Company has made a review of material subsequent events from December 31, 2016 through the date of this report and found no material subsequent events reportable during this period.

## **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 field of Regenerative and Personalized Medicine and operates a state-of-the-art, FDA-registered, clinical laboratory dedicated to our standardized processing, bio-banking and development of cellular tools and applications using autologous adipose (fat) tissue and adipose derived stem cells (“**ADSCs**”). The Company has built a strong, strategic portfolio of intellectual property, patent applications, and proprietary operating processes that form its core standardized cellular platform which we believe supports and promotes a growing pipeline of biologic products and processes, clinical services and international licensing opportunities. Our FDA registered clinical laboratory which we believe to be in compliance with FDA regulations for human tissue processing, cryo-storage and cell culture and differentiation media development is located in Monmouth Junction, New Jersey.

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

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

Our proprietary, patent pending clinical processing platform allows for the collection, preparation and cryo-preservation of adipose tissue without manipulation, bio-generation or the addition of animal-derived products or other chemical materials which require removal from the tissue sample upon retrieval or prior to use. Management believes this core process makes each tissue sample suitable for use in cosmetic grafting procedures or for further processing to adult stem cells for other types of stem cell therapies. Currently, we believe there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments identified or in use globally. As of February 1, 2017, 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 (2136) stem cells (5778) adipose derived stem cells (201), mesenchymal stem cells (694), and stromal vascular fraction (69).

## **Products and Services**

American CryoStem is focused on multiple high margin business lines capable of generating sustainable, recurring revenue streams from each of our developed products and services. The Company also incorporates its proprietary and patented or patent pending laboratory products, such as our *ACSelerate*<sup>™</sup> cell culture media, into our processing product production and contract manufacturing services. Additionally, the Company requires licensees of our tissue and cell processing technologies to purchase our consumable products including our CELLECT<sup>®</sup> collection kit and ACSelerate – CP for the collection, processing, expansion and storage of tissue/stem cells.



We have generated initial revenues from our licensee's in Japan and Hong Kong and subject to, obtaining the requisite financing, management believes that we are well positioned to leverage our developed products and services as the basis for expansion of international distribution through licensees of our technologies for a host of Regenerative Medicine uses and future applications.

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

**CELLECT<sup>®</sup> Validated Collection, Transportation, and Storage System** – An unbreakable “chain of custody” clinical solution for physicians to collect and deliver tissue samples utilizing proprietary and patent pending methods and materials. The CELLECT<sup>®</sup> service is monitored in real-time and assures the highest cell viability upon laboratory receipt. The CELLECT<sup>®</sup> system incorporates our ACSelerate-TR<sup>®</sup> transport medium into all collection bags which supports the health of the tissue during transport. The CELLECT<sup>®</sup> kit is an integral part of our validated ATGRAFT<sup>™</sup> and ATCELL<sup>™</sup> technology platform to be used by all licensees of our technologies. The CELLECT<sup>®</sup> service is included in our patent application U.S. Serial No. 13/702,304.

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). These groups form the International Council for Commonality in Blood Banking Automation (ICCBBA) and developed the ISBT 128 Standard for machine readable labeling. This labeling system is an acceptable machine readable labeling standard, product description, and bar coding system for FDA Center for Biologics Evaluation and Research under 21 CFR 606.12(c) 13. American CryoStem conforms to this standard in its laboratory facility and all cellular and tissue products produced at the facility carry our W3750 ICCBBA facility identifier allowing any hospital, clinic, laboratory and regulator worldwide to identify the origin and obtain additional information on any sample produced at an American CryoStem facility. The Company will promote this standard in all laboratories that license or utilize our technology.

**ATGRAFT™ Adipose Tissue Storage Service** – A clinical fat storage solution allowing physicians to provide their patients with multiple tissue and cell storage options. The ATGRAFT™ service, through one liposuction procedure allows individuals to prepare for future cosmetic or regenerative procedures by using their own stored adipose tissue as a natural biocompatible filler or the components for cellular therapy application without the trauma of further liposuctions. ATGRAFT™ procedures may 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 standards so that any stored fat tissue sample may be retrieved in the future and re-processed to create stem cells ATCELL™, our clinical grade cell product for use in Regenerative Medicine applications. The ATGRAFT™ service is included in our pending patent application U.S. Serial No. 13/646,647.

The Company charges standardized fees for ATGRAFT™ tissue processing and minimum annual storage fees depending on the volume of tissue processed. These processing and storage fees may be paid by the collecting/treating physician or the consumer. The Company earns additional fees upon sample retrieval, for the thawing, packaging and shipment of the stored samples to the physician or clinic for immediate use upon receipt. Additionally, physicians may request that any stored ATGRAFT™ tissue sample of 25ml or greater be reprocessed utilizing the Company's ATCELL™ and Autokine-CM™ processing. The Company charges fees for the reprocessing of a 25ml stored ATGRAFT™ sample and may charge additional fee's if expansion of the newly created ATCELL™ sample is also requested.

The Company believes the ATGRAFT™ service may create patient retention, and significant revenue opportunities for the participating physician. The ATGRAFT™ service lowers physician overall costs by eliminating additional liposuction procedures for each scheduled fat transfer or therapy procedure. Physician cost savings may include: materials, supplies, equipment, and the expenses of utilizing a surgical center, hospital operating room or an in-office aseptic procedure room. The ATGRAFT™ service is designed to operate under the minimally manipulated regulations contained in both 21 CFR 1271.10 and PHS 361.

**ATCELL™ Adipose Derived Stem Cells (ADSCs)** – Clinically processed and characterized adipose derived regenerative cells (ADRCs) created using the Company's proprietary Standard Operating Procedures (SOPs) and ACSelerate™ patented cell culture media. ATCELL™ is the Company's trademarked name for its ADRCs and

differentiated cell products and processing methodology. The Company maintains multiple master and differentiated cell lines and labels them according to their characterization. (i.e. ATCELL™(adipose derived stem cells) ATCELL-SVF™ (stromal vascular fraction), ATCELL – CH™ (differentiated chondrocytes) , etc. Cell lines are custom created for patients desiring to store their cells for their own use in future Regenerative Medicine procedures. The Company charges its customers fees to process a previously stored ATGRAFT™ sample and for newly collected client tissue samples to be processed. Customer samples submitted for processing must utilize the CELLECT® collection system and ACSelerate™ mediums to conform to our internal SOPs and quality control standards.

The Company believes it will earn additional fees based upon the proposed storage configuration of the final ATCELL™ sample and for future culturing in the ACSelerate™ cell culture and differentiation media. Cell culturing and differentiation can be performed upon receipt of the raw tissue sample or at any time on a previously processed and cryopreserved ATGRAFT™ or ATCELL™ sample. ATCELL™ has shown that it is ideally suited for expansion and differentiation into additional cell types utilizing the ACSelerate™ line of culture and differentiation mediums. The ATCELL™ products and services are incorporated into our pending patent filing US Serial No. 13/646,647.

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

The Company intends to support its cell therapy application research, development and collaborative efforts by making ATCELL™ and ATGRAFT™ samples available for research and product development purposes through joint ventures, and university and commercial collaborations. These adipose tissue and cell line samples, we believe will be highly sought after by private researchers and universities for use in pre-clinical trial studies and in-vitro research due to our clinical processing methodology, donor sample data and the ability to create multiple cell types that have identical genetic profiles. We believe the clinical processing methods, data collection and testing of our ATCELL™ and the ability to make multiple cell types from the same donor line allows research teams to focus on application development and avoid bench to commercialization delays. The Company is preparing to distribute its ATCELL™ cell products to users of its ACSelerate™ cell culture media during 2017. The Company is investigating new sources of human mesenchymal cell lines for production and distribution to the cellular therapy research market.

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

The Company recently entered into a licensing and manufacturing agreement with PeproTech a life sciences company formed in 1988. PeproTech is the trusted source for the development and manufacturing of high quality cytokine products for the life-science and cell therapy markets. Over the past 26 years the company has grown into a global enterprise with state-of-the-art manufacturing facilities in the US, and offices around the world. With over 2,000 products PeproTech has developed and refined innovative protocols to ensure quality, reliability and consistency. During 2016 the Company and PeproTech completed the optimization and scale up manufacturing studies and expect the licensed medium marketed under both PeproTech's PeproGrow™ and the Company's ACSelerate-Max™ brands in 2017. In January 2017 the first medium line ACSelerate Max™ was manufactured and released for sale globally through PeproTech's global sales force under their PeproGrow™ brand and for sale by the Company under our ACSelerate-Max™ brand. Additionally, the company will fill orders for its ATCELL™ research grade adipose derived stem cells to purchasers of either the PeproGrow™ or ACSelerate Max™ branded cell culture mediums.

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. Additionally, in 2014 the Company filed a continuation of this granted patent with additional claims and improvements, U.S. Serial No. 13/194,900. On November 8, 2016 the Company was granted additional claims from the continuation U.S. Serial No. 13/194,900 issued as a new Patent Serial No. 9,487,755. Prior to the issuance the Company filed a continuation in part (CIP) containing additional claims related to our ongoing media development.

Published cell culture research indicates the most widely used cell culture medium today for growing and differentiating stem cell cultures for in vitro diagnostics and research contains fetal bovine serum (FBS) and other animal derived products. The use of FBS and other animal products in clinical cellular therapy application development and manufacture raises concerns and generates debates within the scientific and regulatory community relating to potential human/animal cross-contamination. These same concerns may lead to additional expensive and expansive testing and documentation requirements with the FDA during the application and approval process for new cellular therapies manufactured with or containing animal or animal derived products. FDA concerns are evidenced in their Guidance's and Guidelines regarding cellular therapy involving human cells, tissues and products (HCT/Ps) published and maintained by the FDA. Management believes that eliminating or greatly reducing FBS in cellular manufacturing, applications and products can eliminate or ease these scientific and regulatory concerns and may prove to be a winning strategy for cellular therapy application developers seeking FDA approval.

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

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

- *ACSelerate-MAX*™ xeno serum free cell culture media,
- *ACSelerate-SFM*™ animal serum free cell culture media,;
- *ACSelerate-LSM*™ low FBS (0.05%) cell culture media,
- *ACSelerate-CY*™ for differentiation of *ATCELL*™ into chondrocytes (*ATCELL-CY*)™,
- *ACSelerate-OB*™ for differentiation of *ATCELL*™ into osteoblasts (*ATCELL-OB*)™
- *ACSelerate-AD*™ for differentiation of *ATCELL*™ into adipocytes (*ATCELL-AD*)™
  - *ACSelerate-MY*™ for differentiation of *ATCELL*™ into myocytes (*ATCELL-MY*)™
- *ACSelerate-CP*™ non-DMSO (Dimethyl Sulfoxide) cellular cryopreservation media
- *ACSelerate-TR*™ sterile transportation medium designed to maintain the viability of the tissue during the shipment of adipose tissue to our processing facility.

The Company continues to optimize additional versions of *ACSelerate*™ media through further research and testing to develop versions for differentiation of *ATCELL*™ ADSCs into neural, lung and other specific cell types that may be necessary for use in future clinical applications. On December 31, 2014 the Company filed a patent application for an advanced medium formulation titled Human Albumin Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells. (US Serial No. 62/098799) representing the most recent results of this ongoing optimization program. On December 31, 2015, the Company converted the provisional application to an international PCT filing (PCT/US/68350) under the title Human Serum for Cell Culture for Clinical Growth of Human Adipose Stromal Cells.

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

**Contract Manufacturing, Autokine-CM® Anti-Aging, Autologous Skin Care Product Line** – Under agreement with Personal Cell Sciences Corp. (PCS), we manufacture the key ingredient Autokine-CM® (autologous adipose derived stem cell conditioned medium) for PCS' U-Autologous™ anti-aging topical formulation. Each product is genetically unique to the patient and custom blended, deriving its key ingredients from the individual client's own stem

cells. The Company provides its CELLECT<sup>®</sup> Tissue Collection service to collect the required tissue to manufacture the U-Autologous<sup>™</sup> product and processes it under the same Standard Operating Procedures that it developed for the ATGRAFT<sup>™</sup> and ATCELL<sup>™</sup> cell processing services utilizing ACSelerate<sup>™</sup> cell culture media. The Company receives collection, processing and long term storage fees and earns a royalty on all U-Autologous product sales. The utilization of the Company's core services in its contract manufacturing relationships provides opportunities for the Company to promote ATGRAFT<sup>™</sup> and ATCELL<sup>™</sup> products.

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

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

The Company believes it can take advantage of the significant growth of the global cellular therapy market through its international licensing and marketing efforts. A recently published study by Transparency Market Research predicts that the Stem Cell market will grow at a CAGR of 24.2% upon its value of US \$26.23 billion in 2013 and will reach an approximate value of US \$119.52 billion by 2019. The report, titled "Stem Cells Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2012 - 2018"; which can be found at: (<http://globenewswire.com/news-release/2014/12/22/693419/10113247/en/Global-Stem-Cells-Market-to-grow-at-a-CAGR-of->

In June of 2015, The Company entered into an initial agreement with CellSource, LTD. ("CellSource") located in Shibuya, Tokyo Japan for the licensing of our AGRAFT<sup>TM</sup> tissue processing and storage technology and the purchase of our CELLECT<sup>®</sup> collection products which include our ACSelerate-TR<sup>TM</sup> transport medium. The Company also assisted TCCS in upgrading its facility in Japan and provided training in the ATGRAFT<sup>TM</sup> processing and recordkeeping procedures. CellSource began marketing the new services initially within its existing network of 5 clinics throughout Japan and begin purchasing its CELLECT<sup>TM</sup> and ACSelerate-CP<sup>TM</sup> cryoprotectant from the Company in the third quarter of 2015. Upon execution of the Agreement the Company received an upfront payment and will receive additional minimum annual payments, and consumable product sales revenue in future years. The Agreement also provided CellSource with a two year (2) opportunity to exercise a right of first refusal for the licensing and distribution of other products marketed by the Company in Japan.

## **Product Development**

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



bio-materials development.

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

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## **Collaboration / Partnering Opportunities / Acquisitions**

PeproTech, Inc.

On April 4, 2016 the Company entered into an Agreement with PeproTech, Inc of Rocky Hill, NJ. Under the Agreement PeproTech will manufacture, market and distribute the Company's ACSelerate – Max cell growth medium. During 2016 the Company and PeproTech completed the optimization and scale up manufacturing studies and expect the licensed medium marketed under both PeproTech's PeproGrow and the Company's ACSelerate- Max brands in early 2017. PeproTech will leverage its current global sales relationships which reach a majority of all research laboratories worldwide to maximize distribution of the optimized media while the Company will concentrate its sales efforts on its collaborative and licensing partners. Additionally, the Company and PeproTech are discussing the licensing of additional American CryoStem patented media and products for production and distribution by PeproTech, any additional media licensed to PeproTech will undergo similar optimization and scale up production testing prior to being released for sale. We expect that the media will be initially released in the first quarter of 2017.

In January 2017 the first medium line ACSelerate Max™ was manufactured and released for sale globally through PeproTech's global sales force under their PeproGrow™ brand and for sale by the Company under our ACSelerate-Max™ brand. Additionally the company will fulfill orders for its ATCELL™ research grade adipose derived stem cells to purchasers of either the PeproGrow™ or ACSelerate Max™ branded cell culture mediums.

## **BioLife Customer and Physician Acquisition**

In February 2015 the Company entered into a binding asset purchase agreement with BioLife Cell Bank Dallas, LLC and BioLife Cell Bank Management, LLC (collectively "BioLife"), to purchase all of BioLife's adipose tissue, stem cell storage clients samples, and physician network. The transaction was concluded in March of 2015. Transfer of the adipose tissue samples was completed on April 24, 2015 and the Company undertook a complete physical inventory of the transferred samples. The Company initiated annual storage fee billing to the acquired storage clients in June of 2015. Management believes that, with the acquisition of BioLife, the Company became one of the largest commercial adipose tissue storage facility in the United States.

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

In 2012, American CryoStem entered into a Memorandum of Understanding (MOU) outlining our initial collaborative efforts with Protein Genomics, Inc. (PGEN) to test and develop new products by combining certain components of our respective intellectual property and patented products. We have provided PGEN and its research partner, Development Engineering Sciences (DES), with Adipose Derived Stem Cells (ATCELL)™ and our patented cell culture mediums (ACSelerate)™ for testing with PGEN's products designed for the wound healing market. Research and development has been ongoing since late 2012 and notable progress has been achieved.

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

During 2013 and 2014, the collaborative efforts resulted in successful initial "proof of concept" combining PGEN's unique biomaterial and the Company's ATCELL™ and ACSelerate™ products. Management believes the publication of the preliminary results showed successful healing of full depth wounds on the backs of immune deficient mice.

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

### **INTEGRA LifeSciences:**

On June 4, 2015, the Company and Autogenesis, Corp. entered into Non-Disclosure and Material Transfer Agreements with Integra LifeSciences, under which the parties are exploring certain combinations of American CryoStem's, ATCELL<sup>TM</sup> stem cells, Integra products and other biomaterials for the development of new products and services. Integra LifeSciences, a NYSE traded (INT) New Jersey based company, is a world leader in medical technology and wound healing. Integra offers innovative solutions, including leading regenerative technologies, in specialty surgical solutions, orthopedics and tissue technologies. (<http://www.integralife.com/>)

Under the terms of the Agreement the Company supplies biomaterials to Integra and utilize its AGRFAFT<sup>TM</sup>, CELLECT<sup>®</sup>, ATCELL<sup>TM</sup> and ACSelerate<sup>TM</sup> products for the development of new devices and biologic products. To date the Company has delivered biomaterials to Integra for use in the development of the new biomaterials and initiated the processing and testing of porcine (pig) adipose tissue for use in the initial animal studies. The Company is currently working with Integra to advance the product development combining our ATCELL<sup>TM</sup> and ACSelerate<sup>TM</sup> products with the new materials to form new biologic products to be used as wound coverings and bandages for the treatment of bed sores, leg ulcers, and non healing wounds that are common to the diabetic and other systemic disease.

### **Rutgers University**

In May of 2012, American CryoStem entered into Material Transfer Agreements with three research scientists at Rutgers University allowing them to utilize the Company's autologous Adipose-Derived Stem Cells (ATCELL<sup>TM</sup>) and patented, serum free, GMP grade cell culture and differentiation mediums (ACSelerate<sup>TM</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.

During the last quarter of 2015 the Company undertook a review of the collaborative efforts between the Company and Dr. Lee pending the expiration of the agreements in November of 2015. Management believes that potential commercialization of the licensed technologies would require a number of years of additional study and experimentation and requires substantial investment by the Company. In November of 2015 the Collaboration and Research Agreement and the Licensing Agreement were terminated.

### **Cells on Ice:**

In August of 2015 the company entered into an Agreement with Cells On Ice, Inc. (COI) located in Los Angeles, California to process and cryopreserve adipose tissue and adipose derived cellular samples for future use in Regenerative Medicine. COI is a network of physicians interested in the development and use of adipose tissue and adipose derived cellular samples in regenerative therapies and cellular medicine. The Company has agreed to distribute its CELLECT<sup>®</sup> collection boxes and provide its ATGRAFT<sup>TM</sup> and ATCELL<sup>TM</sup> processing services for the collection, processing and storage of tissue samples at its NJ facility. Under the agreement, COI will pay the Company for the processing and storage of each sample generated by COI network physicians. COI plans to seek regulatory approval for use of the stored samples in clinical studies utilizing adipose tissue processed into Stromal Vascular Fraction (SVF) and ultimately expanded adipose derived mesenchymal adult stem cells. The Company is incorporating its existing Standard Operating Procedures (SOPs), processing protocols and patented products into COI's studies and may provide processing and other data to COI in support of their ongoing efforts to develop and obtain regulatory approval of its cellular therapies. COI has initiated several IRB approved studies including a recently completed transportation study approved in August of 2016 to measure the survivability of cell samples shipped in a newly developed return transport medium, animal studies for traumatic brain injury approved in September of 2016, and the safety of intravenously delivered autologous ATCELL<sup>TM</sup> products approved in October of 2016. This initial work will become the basis for a series of regulatory filings with the FDA in 2017.



### *Additional Collaborations*

The Company is in the early stages of developing collaborations with additional industry and university partners. These developing relationships in their earliest stages are covered by Confidential Disclosure Agreements and those that are more advanced also include Material Transfer Agreements under which the Company supplies either ATCELL™ or ACSelerate™ medium products for evaluation, testing, and the development of new cellular therapy applications.

To date the Company has a Material Transfer Agreement with the University of Miami, University of Washington, UHV Technologies, and STEMCell Technologies and has provided both ATCELL™ and ACSelerate™ products to these entities under Agreement. No assurance can be given that these relationships will progress to full collaborative agreements or ultimately result in new technology for future commercialization. As of December 31, 2016 these relationships have yet to result in a commercial product.

Additionally in August of 2015 the Company entered into a Confidential Disclosure Agreement and a Material Transfer Agreement with Dr. Sazlay, a research scientist currently investigating unique cancer treatments at the University of Wurzburg in Germany and the University of California in San Diego. Following execution of the Agreement, the Company delivered a number of ATCELL-SVF™, ATCELL™ and ACSelerate™ samples to Dr. Sazlay for testing and determination of usefulness of our products for development of his novel treatments. Dr. Sazlay has reported positive results of this initial work and the Company and Dr. Sazlay are currently negotiating additional collaborative agreements for further development of the treatments.

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

In an effort to make it easier for other physicians and researchers to study the safety of SVF and ADSCs, in 2014 we obtained an institutional review board (IRB) to review our protocols for the processing of SVF and culturing of mesenchymal stem cells from autologous adipose tissue. The protocols provide appropriate processing, storage and testing methods necessary to move the clinical investigative process towards uniform treatments. The collection of processing and outcome data under IRB review from is required by prevailing FDA regulations and guidance for approval of regenerative cellular therapies, including potency (cell count), contamination testing and cell viability. The objective of the IRB review was to assess these protocols to ensure the highest patient safety possible and to minimize the risks for those participating in innovative research and investigational studies.

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

In 2014, the Company became the Sponsor of an IRB study with The DaVinci Center, Dr. Louis Cona, Principal Investigator, in George Town, Grand Cayman Island entitled ***Impact and Safety of Cultured Expanded Autologous, Adipose-Derived Stem Cells deployed via Intravenous Injection for the Treatment of Multiple Sclerosis Protocol: CRYO-MS-ADSC-006***. On July 23, 2014 the study was approved for 100 patients. The study filing can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), (ClinicalTrials.gov Identifier NCT02326935). The Company renewed the IRB studies with

The Institute of Regenerative Cellular Medicine in 2015 and 2016 for another one year period. The Company is continuing to recruit patients for inclusion in this study.

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

Moreover, we further 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 cosmeticceuticals. The clinical methods and products we have developed are designed to permit a variety of treatments for any patient with their own genetically matched raw materials utilizing our ATCELL™ and ATGRAFT™ products prepared with our patented line of ACSelerate™ cell culture mediums. We believe that autologous cellular therapies have shown promising results for safety and efficacy in a variety of applications in published early stage clinical trial results and application studies.

## **Regulatory Information**

The Company believes that its processing methodologies and the testing laboratory facilities are designed to be in compliance with all current regulations 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 Monmouth Junction, NJ laboratory facility is registered with the FDA (FEI 3008307548) as a processing and storage facility for Human Cells, Tissues and Cellular and Tissue Based Products (HCT/Ps) since 2010. In 2013, we registered the facility with the State of New York (CP169TP136) and the State of California (CNC80948) the only states in the U.S. requiring registration. These state registrations required the submission of our operating procedures for review by the respective State Health Departments, and annual updates to maintain the registrations are required. In addition, we have discussed our operations with the State of New Jersey Health Department and Department of Environmental Protection (DEP) to ascertain any special regulations to which we may be subject. Based upon these discussions, and our use of a registered medical waste disposal company, we do not at this time have any special registrations or regulations for compliance with the State of New Jersey.

Our Standard Operating Procedures (SOPs) are the key to properly operating our clinical tissue processing facility. To ensure delivery of the highest quality services, we incorporate these SOPs, which are designed to provide a basis for accreditation by the American Association of Blood Banks (AABB), the American Association of Tissue Banks (AATB) and the Foundation for the Accreditation of Cellular Therapy (FACT-JACIE). We have consistently endeavored to ensure that our processes, methodologies and procedures remain among the highest standards in the global tissue collection, processing and storage market. To this end, we have equipped ourselves with state-of-the-art quality processing and testing equipment, which we believe helps to ensure that every sample collected and processed is sterile (free from adventitious agents), viable and capable of significant cellular growth and expansion.

## **Quality Management**

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

### *Chain of Custody Control*



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

***Testing Design and Standard Operating Procedures (SOPs)***

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

**Intellectual Property**

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

<b>PATENT TITLE</b>	<b>USE OF PATENT</b>	<b>APPLICATION #</b>
A Business Method for "Collection, Cryogenic Storage and Distribution of a Biological Sample Material"	Company Core Tissue Collection Processing and Storage Methodology	U.S. Serial No. 13/702,304 filed June 6, 2011, and claiming a priority date of June 7, 2010 from provisional application 61/352,217 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
Systems and Methods for "The Digestion of Adipose Tissue Samples Obtained From a Client for Cryopreservation"	Adipose Tissue Digestion Laboratory Processing Methods	PCT/US13/44621 Filed June 6, 2013 and claiming a priority date of June 7, 2012 U. S. Serial No. 14/196,616 filed March 4, 2014 and claiming a priority date from provisional application 61/773,112 filed March 5, 2013 U.S. Serial No. 14,250,338 and claiming a priority date from provisional application 61/810,970 filed April 11, 2013
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	U.S. Serial No. 14,250,338 and claiming a priority date from provisional application 61/810,970 filed April 11, 2013
Stem Cell-Based Therapeutic Devices and Methods	Combining ADRCs with Biomaterials for healing and tissue growth	U.S. Serial No. 14,250,338 and claiming a priority date from provisional application 61/810,970 filed April 11, 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 improvements to Media Formulations International PCT filing of US Provisional Application Serial Number 62/098799 Filed December 31, 2014	U.S. Serial No. 13/194,900
Human Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells	Provisional Application Serial Number 62/098799 Filed December 31, 2014	PCT/US/68350 Filed December 31, 2015

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Systems and Methods to isolate and Expand Stem Cells from Urine    New Provisional Patent Application for a new source of human stem cells    Provisional Patent Application No. 62/335,426

Additionally, the Company has in-licensed IP with the following collaborations and joint ventures;

<b>PATENT TITLE</b>	<b>USE OF PATENT</b>	<b>APPLICATION #</b>
Cosmetic compositions including tropoelastin isomorphs	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #5,726,040
Cosmetic compositions	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #6,451,326
Recombinant hair treatment compositions	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #6,572,845
Wound healing compositions and methods using tropoelastin and lysyl oxidase	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO: #6,808,707
Business methods, processes and systems for collection, cryogenic storage and distribution of cosmetic formulations from an obtained stem cell based biological	Personal Cell Sciences and American CryoStem collaboration	USPTO application #61/588,841

### **Trademarks**

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

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

### **Marketing and Distribution**

The key objective of our marketing strategy is to position American CryoStem in the market as the “Gold Standard” for adipose tissue collection, cell processing and cryogenic storage, therapeutic applications, and research/commercial uses of adipose tissue within the current regulatory framework. The combination of a traditional sales approach supported by continuous internal and external marketing programs, are closely coordinated with the expansion of our laboratory processing capabilities. Our initial marketing efforts intend to disseminate current and future uses of adipose tissue and adult stem cells which support our business model, products and services. In 2017, we intend to continue to employ both print advertising and social media sales campaigns. In addition, we plan to continue to utilize key leaders, and early adopters in the medical community as a marketing resource to enhance awareness of our proprietary, patented products and services and to increase the number of surgeons who join our network, university and private collaboration and consumers who use our products and services.

We plan to continue direct marketing programs focused on reaching plastic and cosmetic surgeons to join the initial group of providers that began to offer our services to their patients in 2015. This marketing initiative has been implemented using a traditional sales approach common to the pharmaceutical and biotechnology industries. This fundamental sales approach at the core of our marketing activities is being strategically and tactically expanded using a combination of in-house sales personnel and outside independent channels.

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

## Market Size and Opportunities

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

## Global Stem Cells Market

A report from Transparency Market Research (TMR) forecasts that the global stem cells market will grow at a remarkable CAGR of 24.2% from 2012 to 2018. According to TMR, a market intelligence firm, the global stem cells market, which in 2013 stood at US\$26.23 bn, is anticipated to reach US\$119.52 bn by the end of the forecast period. The report, titled '**Stem Cells Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2012 - 2018**', <http://www.transparencymarketresearch.com/pressrelease/stem-cells-market.htm>

A report published by Markets and Markets Research in July 2014 titled "Cell Culture Market by Equipment (Bioreactor, Incubator, Centrifuge), by Reagent (Media, Sera, Growth Factors, Serum Free Media), by Application (Cancer Research, Gene Therapy, Drug Development, Vaccine Production, Toxicity Testing) - Global Forecast to 2018" July 2014. (<http://www.marketsandmarkets.com/Market-Reports/cell-culture-market-media-sera-reagents-559.html>)

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

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

*segment of the stem cell market. Geographically, North America and Europe will remain well ahead of the competition.”*

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

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

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

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

*TriMark Publications.com cites in its “Regenerative Medicine Markets” report (March 2013) that the Regenerative Medicine market continues to witness significant advances in clinical efficacy, regulatory approval and product commercialization of cell based therapies which will catapult to over \$35 billion by 2019. Affirmative results produced from the application of adult stem cells have resulted in greater government and private sector investment in research and development of new cell therapies. Investment made into the regenerative medicine market include firms that harvest, process, purify, expand, cryopreserve, store or administer stem cells”<sup>1</sup> In a study from Market Research Reports, released “Global Regenerative Medicine Market (Technology, Applications, Geography) – Industry Analysis, Trends, Opportunities and Forecast, 2013-2020.” In it, the market analysis firm found the global regenerative medicine market will be worth some \$67.6 billion by 2020 – a stark and notable increase from the \$16.4 billion valuation it received in 2013. Between 2014 and 2020, the report expects the regenerative medicine market to grow at a compounded annual growth rate of 23.2 percent.*

*According to Allied Market Research, on the basis of geography, this market can be classified into North America, Europe, Asia-Pacific and LAMEA. Currently, North America dominates the global market due to heavy investment in development of regenerative products as well as more number of commercialized products. However, the growing focus on research and development in Japan and South Korea makes Asia-Pacific the fastest growing region at a CAGR of 30.9% during 2014-2020.*

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

*As stated by the Global Wellness Institute; adding up all expenditures made by international/inbound and domestic, primary and secondary wellness tourists, we estimate the wellness tourism industry to be \$494 billion in 2013, a 12.7% increase over 2012. Wellness tourism accounts for 14.6% of all tourism expenditures and is growing much faster than the 7.3% growth rate for overall tourism expenditures from 2012-2013. The \$494 billion in wellness tourism expenditures represent 586.5 million wellness trips taken in 2013, across 211 countries. Wellness tourism accounts for about 6.2% of all domestic and international tourism trips taken in 2013.*

[http://www.globalwellnesssummit.com/images/stories/gsws2014/pdf/GWI\\_Global\\_Spa\\_and\\_Wellness\\_Economy\\_Monitor\\_Fu](http://www.globalwellnesssummit.com/images/stories/gsws2014/pdf/GWI_Global_Spa_and_Wellness_Economy_Monitor_Fu)

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

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

According to MarketsandMarkets, *“the global cell culture market was valued at an estimated \$14,772 million in 2013. This market is expected to grow at a CAGR of 10.71% between 2013 and 2018, to reach \$24,574 million in 2018. The cell culture media, sera, and reagents market consists of six segments, namely, contamination detection kits, cryoprotective agents, lab reagents, media, serum, and other reagents. Of these, the serum product segment had the largest share of the cell culture media, sera, and reagents market in 2013, whereas the media product segment is expected to grow at the highest CAGR between 2013 and 2018.”*

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



### ***Cosmeceutical Market***

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

In a report titled *Global Cosmeceuticals Market Outlook 2016, published February 2013, RNCOS reports that the worldwide market is estimated to be valued at \$30.5 billion and is likely to grow at a consistent CAGR of 7.7% during the period 2012 through 2016.*<sup>2</sup> In a separate report, Transparency Market Research, a U.S. - based market intelligence firm states that the global facial care market is expected to report an approximate value of \$39.75 billion by 2019. The report, titled **'Facial Care Market (By Product Type - Skin Whitening/ Lightening and Anti-Ageing, Facial Creams, Face Wash, Cleansing Wipes, Serums and Masks and Others (fade creams, pore strips and toners))-Asia-Pacific Industry Analysis, Size, Share, Growth, Trends and Forecast 2013 – 2019.**  
<http://globenewswire.com/news-release/2014/10/17/674123/10103135/en/Global-Facial-Care-Market-to-be-Worth-39-75-Billion>

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

#### **Cells on Ice**

In August of 2015 the Company entered into an Agreement with Cells On Ice, Inc. (COI) located in Los Angeles, California to process adipose tissue and adipose derived cellular samples for future use in Regenerative Medicine. COI is a network of physicians interested in the development and use of adipose tissue and adipose derived cellular samples in regenerative therapies and cellular medicine. The Company has agreed to distribute its CELLECT® collection boxes and provide its ATGRAFT™ and ATCELL™ processing services for the collection, processing and storage of tissue samples at its NJ facility. Under the agreement, COI will pay the Company for the processing and storage of each sample generated by COI network physicians. COI plans to seek regulatory approval for use of the stored samples in clinical studies and trials utilizing adipose tissue processed into Stromal Vascular Fraction (SVF) and ultimately expanded adipose derived mesenchymal adult stem cells. The Company is incorporating its Standard Operating Procedures (SOPs), processing protocols and products into COI's studies and providing processing and other data to COI in support of their ongoing efforts to develop and obtain regulatory approval of its cellular therapies.

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

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

and preparation of cellular therapies as they are developed and approved for patient use by the FDA.

### **Regenerative Medicine Institute**

The Company recently announced that Dr. Vincent Giampapa, MD F.A.C.S has joined its Medical and Scientific Advisory Board. Dr. Giampapa is the founder /director of the Regenerative Medicine Institute (RMI) located in Costa Rica and the US, the Plastic Surgery Center International and The Giampapa Institute for Anti-Aging Medical Therapy located in Montclair, NJ. Dr. Giampapa's research focuses on stem cell technologies and their clinical applications to improve the cellular aging process in order to enhance health span and quality of life. As a result of his research, Dr. Giampapa has been awarded medical and intellectual property patents with the United States Patent and Trademark Office for developments involving unique cell culture delivery techniques, new drug delivery systems, stem cell reprogramming, DNA repair, and telomerase maintenance. He is a co-founder of The Academy of Anti-Aging Medicine (A4M), comprised of over 26,000 members representing over 110 nations, the first president of the Board of Anti-Aging Medicine and the founder of healthycell®, an advanced cell health nutritional supplement and StemBank™, a blood derived stem cell extraction and storage company. Dr. Giampapa will have an active role assisting the Company with the development of its "From laboratory to clinic/physician's office" services and applications platform.

<sup>2</sup> <http://www.researchandmarkets.com/research/mbmvbh/global>

### *Development of International Markets*

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

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

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

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

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

### **CellSource, LTD. – Tokyo, Japan**

On June 2, 2015 the Company and Cell Source Ltd entered into an Agreement for licensing the *ATGRAFT*<sup>™</sup> technology to Cell Source Ltd. for Japan. The Agreement calls for Cell Source Ltd to purchase consumables from us including the *CELLECT*<sup>®</sup> collection boxes and *ACSelerate*<sup>™</sup> Cryopreservation Medium. The agreement also provides

Cell Source with a twenty four month limited Right of First Refusal for licensing additional technologies from the Company for the Japanese market. According to Allied Market Research, World Regenerative Medicines Market Currently, North America dominates the global Regenerative Medicine market due to heavy investment in development of regenerative products as well as more number of commercialized products. However, the growing focus on research and development in Japan and South Korea makes Asia-Pacific the fastest growing region at a CAGR of 30.9% during 2014-2020.

### **Health Information Technology Company, LTD – Hong Kong and Shenzhen, China**

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

### **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 Monmouth Junction, New Jersey at 7 Deer Park Rd, Monmouth Junction, NJ. 08852. Our laboratory website address is [www.acslaboratories.com](http://www.acslaboratories.com).

### **Available Information**

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

### **Going Concern**

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

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

generate capital financing. The failure to generate sufficient revenues or raise additional capital may have a material and adverse effect upon us and our shareholders.

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

### **Liquidity and Capital Resources**

We had a cash balance of \$34,247 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 \$16,436 during the three months ended December 31, 2016 in professional fees (legal, accounting and consultants) and \$41,589 in Laboratory expenses

### **Commitments**

The Company leases approximately 1,628 square feet of laboratory facilities at 7 Deer Park Drive in Monmouth Junction, New Jersey. The term of the lease is from February 1, 2016 to January 31, 2019. The monthly rent and operating expenses are \$5,225.

The Company's main office facility is located at 1 Meridian Road, Eatontown, New Jersey 07724. The lease expired during fiscal 2015 and is currently on a month to month basis with monthly rent of \$2,650. The total rent for office facilities for the three months ended December 31, 2016 was \$7,950.

The Company has unsecured liabilities without interest of \$117,184 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.

### **Related Party Transactions**

At December 31, 2016, the Company has an advance receivable from Autogenesis, discussed in Note 12, for \$10,880. The advance receivable has no interest rate, is unsecured, and due on demand.

At December 31, 2016, the company was indebted to a Corporation that is the majority owner of the Company \$117,184. The advances are due on demand, are unsecured, and carry no interest rate.

At December 31, 2016, the company was indebted to Company that is majority owned by the Company's chief executive officer for \$14,316. The advances are due on demand, are unsecured, and carry no interest rate.

At December 31, 2016, the company was indebted to a Corporation that is majority owned by one Company's chief executive officers for \$2,237. The advances are due on demand, are unsecured, and carry no interest rate.

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 June 30, 2016, 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 June 30, 2016.

**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 fiscal year 2016, the Company issued 687,500 shares of common stock and received proceeds of \$137,501.

During fiscal year 2016, a holder of a \$7,000 convertible note exercised and received 20,000 shares

During fiscal year 2016, option holders exercised their options and received 709,500 shares of common stock. The Company received proceeds of \$55,476 upon exercise.

During fiscal year 2016, the Company issued 425,000 shares of common stock to consultants for services rendered valued at \$95,750.

During fiscal year 2016, the Company issued 50,000 shares of common stock for a security deposit on its new lab location in Princeton, New Jersey. The value of the deposit is \$10,450.

During fiscal year 2016, the Company issued 557,591 shares of common stock to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid is \$168,763.

During the three months ended December 31, 2016, the Company issued 91,667 shares of common stock and received proceeds of \$15,000.

During the three months ended December 31, 2016, the Company issued 300,000 shares of common stock to consultants for services rendered valued at \$66,000.

During the three months ended December 31, 2016, the Company issued 152,023 shares of common stock to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid is \$43,269.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None

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**ITEM 6. EXHIBITS**

(a) Exhibits furnished as Exhibits hereto:

<b>Exhibit No.</b>	<b>Description</b>
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

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**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**

February 21, 2017 By: /s/ John Arnone  
John Arnone, Chief Executive Officer  
(Principal Executive Officer)

February 21, 2017 By: /s/ Anthony Dudzinski  
Anthony Dudzinski, Treasurer  
(Principal Financial Officer)

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