

AMERICAN CRYOSTEM Corp  
Form 10-Q  
May 14, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

For the six month period ended March 31, 2018

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

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth 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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Yes  No

As of May 7, 2018, there were 47,266,192 shares of common stock outstanding.

**TABLE OF CONTENTS**

	Page No.
<b>PART I. - FINANCIAL INFORMATION</b>	
<u>Item 1.</u> <u>Financial Statements.</u>	3
<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Plan of Operations.</u>	18
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	35
<u>Item 4.</u> <u>Controls and Procedures.</u>	35
 <b>PART II - OTHER INFORMATION</b>	
<u>Item 1.</u> <u>Legal Proceedings.</u>	36
<u>Item 1A.</u> <u>Risk Factors.</u>	36
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds.</u>	36
<u>Item 3.</u> <u>Defaults Upon Senior Securities.</u>	36
<u>Item 4.</u> <u>Mine Safety Disclosures</u>	36
<u>Item 5.</u> <u>Other Information.</u>	36
<u>Item 6.</u> <u>Exhibits.</u>	36

**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements****American CryoStem Corporation****Consolidated Balance Sheets****As of March 31, 2018 and September 30, 2017**

	31-Mar-18 (unaudited)	30-Sep-17 (audited)
<b>ASSETS</b>		
Current assets:		
Cash	\$ 323,682	\$ 410,342
Accounts receivable- net of allowance for bad debt	163,917	171,860
Prepaid expenses	18,000	33,333
Inventory	31,069	27,704
Total current assets	536,668	643,239
Other assets:		
Investment in Autogenesis- at cost	1,000	1,000
Investment in Baoxin- at cost	300,000	0
Security deposit	13,540	13,540
Patent and patents development- net of accumulated amortization	315,278	299,057
Fixed assets- net of accumulated depreciation	155,658	52,357
Total assets	\$ 1,322,144	\$ 1,009,193
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable & accrued expenses	\$ 390,275	\$ 362,576
Deferred revenues	151,095	25,664
Bridge notes payable	226,500	226,500
Convertible notes payable	489,000	864,000
Commitments & contingencies (equipment lease)	31,001	0
Total current liabilities	\$ 1,287,871	\$ 1,478,740
Other liabilities:		
Salaries payable to officers	478,360	443,360
Commitments & contingencies (equipment lease)	62,386	0
Payable to related party (ACS Global Inc.)	107,020	108,651
Total liabilities	\$ 1,935,637	\$ 2,030,751

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Shareholders' equity:

Common stock- \$.001 par value, authorized 300,000,000 shares authorized, issued and outstanding, 46,269,016 shares at March 31, 2018 and 43,409,580 at September 30, 2017	\$46,270	\$43,410
Additional paid in capital	12,746,798	11,581,197
Accumulated comprehensive income	1,700	0
Accumulated deficit	(13,408,261)	(12,646,165)
Total shareholders' deficit	(613,493 )	(1,021,558 )
 Total Liabilities & Shareholders' Deficit	 \$1,322,144	 \$1,009,193

See the notes to the financial statements.

American CryoStem Corporation

**(unaudited)****Consolidated Statements of Operations**

For the Six Months and Quarters Ended March 31, 2018 and March 31, 2017

	6 Months 31-Mar-18	6 Months 31-Mar-17	3 Months 31-Mar-18	3 Months 31-Mar-17
Tissue storage & processing	\$ 604,215	\$ 670,142	\$ 191,616	\$ 389,671
Licensing	175,634	80,000	48,967	40,000
Total revenues	\$ 779,849	\$ 750,142	\$ 240,583	\$ 429,671
Less cost of revenues	(162,485 )	(273,221 )	(79,111 )	(149,916 )
Gross margin	\$ 617,364	\$ 476,921	\$ 161,472	\$ 279,755
General and administrative expenses:				
Professional fees	\$ 59,013	\$ 108,104	\$ 31,787	\$ 27,667
Salary expense	171,882	196,000	82,473	59,888
Option grant to consultant	549,588	0	0	0
Laboratory expenses	276,567	112,354	149,392	86,437
Administration	173,578	95,434	62,669	77,179
Total general & administrative expenses	1,230,628	511,892	326,321	251,171
Net loss from operations	(\$613,264 )	(\$34,971 )	(\$164,849 )	\$ 28,584
Other income (expenses):				
Loss on settlements	(96,621 )	0	(20,184 )	0
Interest expense	(52,211 )	(72,617 )	(22,670 )	(40,891 )
Net loss before provision for income taxes	(\$762,096 )	(\$107,588 )	(\$207,703 )	(\$12,307 )
Provision for income taxes	0	0	0	0
Net loss	(\$762,096 )	(\$107,588 )	(\$207,703 )	(\$12,307 )
Basic & fully diluted net loss per common share:				
Net loss	(\$0.02 )	(\$0.00 )	(\$0.00 )	(\$0.00 )
Weighted average of common shares outstanding:				
Basic & fully diluted	44,630,031	37,598,437	45,519,016	37,857,967

See the notes to the financial statements.

American CryoStem Corporation

**Consolidated Statements of Comprehensive Loss**

**(unaudited)**

**For the Six Months Ended March 31, 2018 and March 31, 2017**

	31-Mar-18	31-Mar-17
Net loss	(\$ 762,096 )	(\$ 107,588 )
Other comprehensive income:		
Foreign currency translation adjustment	1,700	0
Comprehensive loss	(\$ 760,396 )	(\$ 107,588 )

See the notes to the financial statements.

American CryoStem Corporation

**Consolidated Statements of Cash Flows****(unaudited)****For the Six Months Ended March 31, 2018 and March 31, 2017**

	6 Months 31-Mar-18	6 Months 31-Mar-17
Operating Activities:		
Net loss	(\$762,096 )	(\$107,588 )
Adjustments to reconcile net loss items not requiring the use of cash:		
Bad debt expense	0	12,620
Interest expense- beneficial conversion feature (debentures issued)	0	72,617
Consulting fees & salaries (paid from stock)	563,338	66,000
Depreciation & amortization expense	30,408	20,567
Loss on settlement of legal bill	96,621	0
Changes in other operating assets and liabilities :		
Accounts receivable	7,943	(81,456 )
Prepaid expense	15,333	(2,801 )
Inventory	(3,365 )	(2,446 )
Deferred revenue	125,431	(4,098 )
Salaries payable to officers	35,000	35,000
Accounts payable and accrued expenses	136,202	(37,593 )
Net cash provided (used) by operations	\$ 244,815	(\$29,178 )
Investing activities:		
Patents development	(\$19,670 )	(\$26,234 )
Investment in Baoxin	(300,000)	0
Purchase of lab equipment	(27,470 )	(8,318 )
Net cash used by investing activities	(347,140)	(34,552 )
Financing activities:		
Issuance of common shares	\$ 0	\$ 135,625
Options exercised	25,000	0
Paid down capital lease	(9,403 )	0
Payable to related party (ACS Global Inc.)	(1,631 )	(7,604 )
Net cash provided by financing activities	13,966	128,021
Net change in cash	(\$88,359 )	\$ 64,291
Effect of exchange rate changes on cash	1,700	—
Cash balance at beginning of the period	410,342	37,251
Cash balance at end of the period	\$ 323,683	\$ 101,542

Supplemental disclosures of cash flow information:



Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Interest paid during the period	\$ 3,465	\$ 4,504
Income taxes paid during the period	\$ 0	\$ 0

See the notes to the financial statements.

See Note 15 for non-cash transactions.

6

**American CryoStem Corporation**

**(unaudited)**

**Notes to the Consolidated Financial Statements**

**For the Six Months Ended March 31, 2018 and March 31, 2017**

**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 ACS.

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 Consolidated Financial Statements for the period ended March 31, 2018 should be read in conjunction with the Company’s Form 10K for the period ended September 30, 2017.

*Use of Estimates* - The preparation of the consolidated 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.

*Consolidation*- the accompanying consolidated financial statements include the accounts of the Company and its subsidiaries. All significant inter-company balances have been eliminated.

*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.

7

*Revenue Recognition* – The Company recognizes tissue storage 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.

Management evaluated its various revenues to determine whether there are different operating segments based upon their respective source of revenue. Management determined, at this time, that all types of revenue currently represent one segment.

*Bad Debt Expense*- The Company provides, through charges to income or loss, a charge for bad debt expense, which is based upon management’s evaluation of numerous factors. These factors include economic conditions prevailing, a predictive analysis of the outcome of the current portfolio by client, and prior credit loss experience of each client. The Company uses the information from this analysis to develop an estimate of bad debt reserve based upon the amount of accounts receivable by client at the balance sheet date. The Company’s reserve for bad debt is \$23,436 at March 31, 2018 and September 30, 2017.

*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.

Inventory is composed as follows at March 31, 2018 and September 30, 2017.

	31-Mar-18	30-Sep-17
--	-----------	-----------

Materials	\$ 31,069	\$ 27,704
-----------	-----------	-----------

*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 7 years

Furniture 15 years

Leased equipment assets are depreciated over the estimated life of the asset or its lease term, whichever is less.

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

The Company follows the accounting requirements associated with uncertainty in income taxes using the provisions of Financial Accounting Standards Board (FASB) ASC 740, *Income Taxes*. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not the positions will be sustained upon examination by the tax authorities. It also provides guidance for derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of March 31, 2018, the Company has no uncertain tax positions that qualify for either recognition or disclosure in the financial statements. All tax returns from fiscal years 2014 to 2017 are subject to IRS and State of New Jersey audit.

*Recently Issued Accounting Pronouncements*- In February 2016, the FASB issued ASU No. 2016-02 which supercedes ASC 840, *Accounting for Leases*. The new guidance requires the recognition of lease assets and lease liabilities for operating leases with lease terms of more than twelve months. Presentation of leases within the consolidated statements of operations and consolidated statement of cash flows will be generally consistent with current lease accounting guidance. The amended ASU is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. We plan to adopt the amended ASU in the first quarter of fiscal year 2019 and do not expect the accounting change to have a material effect on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which was an updated standard on revenue recognition. The ASU provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies that report using the International Financial Reporting Standards or U.S.GAAP. The main purpose of the ASU is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also enhances disclosures about revenue, providing guidance for transactions not previously addressed comprehensively and improves the guidance for multiple-element arrangements. The FASB deferred approval of the ASU to effective date for periods after December 15, 2017. The Company is currently evaluating the impact on its consolidated financial statements.

## **Note 2. Going Concern**

As of the date of this annual 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 proposed business.

We have suffered recurring losses from operations since our inception. In addition, we have yet to generate an internal cash flow from our business operations or successfully raised the financing required to expand 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. Our continued existence is dependent upon our ability to resolve our liquidity problems and achieve 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.

### 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:

	6 Months 31-Mar-18	6 Months 31-Mar-17	3 Months 31-Mar-18	3 Months 31-Mar-17
Net loss	(\$762,096 )	(\$107,588 )	(\$207,703 )	(\$12,307 )
Weighted average shares outstanding	44,630,031	37,598,437	45,519,016	37,857,967
Basic & fully diluted net loss per common share:	(\$0.02 )	(\$0.00 )	(\$0.00 )	(\$0.00 )

### Note 4. Fixed Assets

The fixed assets owned by the Company are comprised as follows.

	31-Mar-18	30-Sep-17
Office equipment	\$26,637	\$26,637
Furniture	2,455	2,455
Lab equipment	418,953	288,693
Accumulated depreciation	(292,387 )	(265,428 )
Fixed assets- net	\$155,658	\$52,357

## Note 5. Patent & 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 Company at this time has only been amortizing those patents which have been issued to the Company. Patents still in the application process have not to date been amortized. The unamortized costs of the patents in the application process are \$266,455. 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 November 8, 2016 under patent Number 9,487,755. 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, US Patent Application No. 15/344,805.

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.

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. Additionally, this patent has been filed European Union Application No. EPI3800847.9 and China Application No. 2013800391988

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. During 2017 the Company extended the filing into China, the EU, India, Japan, the Kingdom of Saudi Arabia, Canada and Mexico.

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



**Note 6. Debt**

The following table describes the Company's debt outstanding at March 31, 2018.

<u>Debt</u>	Carrying Value	Fair Value	Maturity	Rate
Bridge notes	\$226,500	\$229,820	Demand	8.00 %
Convertible notes 35 cents	\$86,000	\$87,261	Demand	8.00 %
Convertible notes 30 cents	\$45,000	\$45,660	Demand	8.00 %
Convertible notes 20 cents	\$162,500	\$164,882	Demand	8.00 %
Convertible notes 15 cents	\$195,500	\$198,366	Demand	8.00 %
Capital lease	\$93,387	\$94,756	Fiscal 2021	14.00 %

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 "Fair Value" is derived using a mathematical model used for similar debt, the debt is classified as a Level 2 financial instrument as per Note 10. The holders of the bridge notes also have an option to purchase the 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, 36,500 of these options remain outstanding.

**Note 7. Administration Expense**

A detail of administrative expenses in the statements of operations for the six months ended is as follows.

	31-Mar-18	31-Mar-17
Administration	\$53,254	\$20,224
Sales & marketing	3,446	5,457
Bad debt expense	0	12,620
Consulting (shares issued)	39,208	0
Depreciation & amortization	30,408	20,567
Dues & subscriptions	3,760	230
Insurance	8,316	590
Rent	10,600	15,900
Telephones	4,844	4,428
Travel	17,783	14,373
Web site maintenance	1,959	1,045
<b>Total</b>	<b>\$173,578</b>	<b>\$95,434</b>

**Note 8. Common Stock Issuances**

During the first six months of fiscal 2018, the Company issued 600,000 shares upon the exercise of options held by shareholders. The Company received proceeds of \$25,000.

During the first six months of fiscal 2018, the Company issued 23,705 shares to pay interest due to debenture holders and bridge note holders. The value of the interest paid is \$18,727.

During the first six months of fiscal 2018, the Company issued 219,290 shares to pay an outstanding legal bill. The shares issued were valued at \$186,396. The Company recognized a loss on settlement of \$76,437 on the transaction.

During the first six months of fiscal 2018, the Company issued 25,000 shares to a consultant for services rendered valued at \$13,750.

During the first six months of 2018, debenture holders exercised \$375,000 of debentures and were issued 1,991,441 shares.

During fiscal year 2017, the Company issued 91,667 shares of common stock and received proceeds of \$13,750.

During fiscal year 2017, holders of \$468,000 convertible notes exercised and were issued 2,396,548 shares.

During fiscal year 2017, option holders exercised their options and received 2,640,000 shares of common stock. The Company received proceeds of \$110,400 upon exercise.

During fiscal year 2017, the Company issued 425,000 shares of common stock to consultants for services rendered valued at \$175,250. The fair value of the common stock issued at the date of issuance was used to value the transactions

During fiscal year 2017, the Company issued 200,000 shares of common stock for to its lawyers to settle an outstanding legal invoice. The fair value of the common stock issued at the date of issuance was used to value the transaction. The Company recognized a loss on the settlement of \$113,617 on the transaction.

During fiscal year 2017, the Company issued 534,656 shares of common stock to pay for interest due to holders of the bridge notes and convertible notes. The fair value of the common stock issued at the date of issuance was used to value the transactions.

**Note 9. Option Issuances**

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 and consultants at the end of each fiscal year. Using the Black-Sholes valuation method, the Company recorded salaries and consulting expense of \$549,588 and \$-0- in the first six months of 2018 and 2017, respectively.

The following is a summary of common stock options outstanding at March 31, 2018:

	Amount	Wgt'd Avg Exercise Price	Wgt'd Years to Maturity
Outstanding at September 30, 2016	14,371,500	\$ 0.22	3.17
Issues	1,885,000		
Exercises	(2,640,000 )		
Expired	(150,000 )		
Outstanding at September 30, 2017	13,466,500	\$ 0.25	2.75
Issues	500,000		
Exercises	(600,000 )		
Expired	0		
Outstanding at March 31, 2018	13,366,500	\$ 0.22	2.07

#### Note 10. Fair Values of Financial Instruments

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

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

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

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

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

The following classifies the Company's investments as per the above hierarchy.

Investments: 3/31/18	Level I	Level II	Level III
Investment in Autogenesis- at cost	\$ 0	\$ 0	\$1,000
Investment in Baoxin- at cost	0	0	300,000
Totals	\$ 0	\$ 0	\$301,000

Investments: 9/30/17	Level I	Level II	Level III
Investment in Autogenesis- at cost	\$ 0	\$ 0	\$1,000
Totals	\$ 0	\$ 0	\$1,000

#### Note 11. 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.

2018	\$15,460
2019	\$23,190
Net minimum lease payments	\$38,650

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 entered into a lease for lab equipment in the first quarter of 2018. The minimum lease payments due on the capital lease are as follows.

	2018 balance	\$21,118
	2019	42,235
	2020	42,235
	2021	7,039
Total minimum lease payments		\$112,627
Less amounts representing interest		(19,240 )
Present value of net minimum lease payments		\$93,387

Depreciation expense for the leased equipment for the first quarter of 2018 was \$14,101.

The Company is not party to any litigation against it and is not aware of any litigation contemplated against it as of March 31, 2018.

#### **Note 12. Concentrations of Credit**

From time to time, the Company maintains cash balances at financial institutions that exceed federally insured limits.

During the first six months of fiscal year 2018, client Cells on Ice accounted for 60% of gross revenues. Also, at March 31, 2018, client Baoxin Ltd. accounted for 61% of the accounts receivable balance.

#### **Note 13. Investments**

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 during fiscal years 2017 and 2016.

During the first quarter of 2018, the Company invested \$300,000 in Baoxin Ltd., a Chinese company that is involved in tissue storage and processing in Baoxin, China. Baoxin is not a publically traded corporation and the investment is carried at cost at March 31, 2018.

Baoxin will develop, own and operate multiple laboratory/treatment/training facilities in China. The Company has received an upfront fee of \$300,000 USD and a 5 year minimum annual guarantee of \$500,000 USD per year. Additionally, as part of the transaction the Company has invested \$300,000 into Baoxin to obtain 5% minority equity in Baoxin (China) and an option to acquire up to a 20% equity ownership interest in the Regenerative Medicine Center in Hong Kong (HK). The short term goals are to set up two additional GMO grade adipose tissue processing and storage facilities in Beijing and Shanghai to cover the need of the whole China region, and a proper education facility in China to promote the use of ATGRAFT as a more natural dermal filler over artificial fillers.

#### **Note 14. Related Party Transactions**

At March 31, 2018, the Company was indebted to a company that is majority owned by the Company's two chief executive officers for \$107,020. The advances are due on demand, are unsecured, and carry no interest rate.

#### **Note 15. Non- Cash Transactions**

As an addendum to the statement of cash flows, the following are non-cash transactions taking place in the first six months of 2018:

The Company entered into a lease for office equipment in December 2017. The amount financed by the lease was \$102,790.

During the first six months of fiscal 2018, the Company issued 219,290 shares to pay an outstanding legal bill. The shares issued were valued at \$186,396. The Company recognized a loss on settlement of \$76,437 on the transaction.

During the first six months of 2018, a debenture holder exercised \$225,000 of debentures and was issued 1,241,667 shares.

During the first six months of 2018, the Company issued 25,000 shares to a consultant for services rendered valued at 13,750.

**Note 16. Subsequent Events**

The Company has made a review of material subsequent events from March 31, 2018 through the date this report became available to be issued and found no material subsequent events reportable during this period.

On May 1, 2018 The Company entered into an agreement with Eaton Holdings, LLC to extend its lease for the executive offices at 1 Meridian Road, Eatontown, NJ 07748 for the period of May 1, 2018 until April 20, 2021.

In May of 2018 the holder of a \$100,000 note converted his note and \$6,692 in accrued interest and was issued 711,285 shares

In April of 2018 the Company renegotiated its laboratory lease with the landlord and issued 150,903 shares to the landlord for a reduction in lease payment until April 1, 2019 and for certain leasehold improvements to the facility.

In April of 2018 the holder of a \$7,500 note converted his note and was issued 37,500 shares.

In April of 2018 the Company issued 25,000 shares to a consultant for services rendered with a value of \$21,250

In April of 2018 the company issued 22,488 shares as interest payments to the holders of certain outstanding debentures.

## 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, laboratory dedicated to 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, services and international licensing opportunities. Our FDA registered laboratory 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 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 collection and processing platform and products as a complete adipose stem cell solution. We are expanding our international laboratory and product footprint, through internal research and development and scientific collaborations. We intend to generate revenue through the sale and licensing of our patented collection, processing and storage products, laboratory tools, and physician/researcher 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 processing platform allows for the collection, preparation and cryo-preservation of adipose tissue without manipulation, bio-generation or the addition of animal-derived products or other chemical materials which require removal from the tissue sample upon retrieval or prior to use. Management believes this core process makes each tissue sample suitable for use in cosmetic grafting procedures or for further processing to adult stem cells for other types of stem cell therapies. Currently, we believe there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments identified or in use globally. As of May 7, 2018, 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 (2922), adult stem cells (5,755), adipose derived stem cells (227), mesenchymal stem cells (836), and stromal vascular fraction (89).

## 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, transportation and cryopreservation mediums, 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, ACSelerate Max cell culture media, and ACSelerate-CP adipose tissue cryoprotectant 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 or researchers 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 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 platform technologies.

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 storing multiple samples of their own adipose tissue to be returned in the future as a natural biocompatible filler, or the sample may be further processed to create cellular therapy applications 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™.”

The Company charges standardized fees for ATGRAFT™ tissue processing and a minimum annual storage fee depending on the volume of tissue stored. These processing and storage fees may be paid to the Company by the collecting/treating physician or the consumer. The Company earns additional fees, for the thawing, packaging and shipment of the stored samples back to the physician or clinic for immediate use upon receipt. Additionally, physicians or patients 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 significant revenue opportunities and patient retention for the participating physician. The ATGRAFT™ service lowers physician/patient 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'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). 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 will also distribute its ATCELL™ cell products to users of its ACSelerate™ cell culture media for research and development. 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 has entered into a licensing and manufacturing agreement with PeproTech, Inc 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. 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. The Company and PeproTech completed the optimization and scale up manufacturing studies and the licensed medium is marketed under PeproTech's, PeproGrow™ and the Company's ACSelerate-Max™, brands. Additionally, the company offers its ATCELL™ research grade adipose derived stem cells to purchasers of either the PeproGrow™ or ACSelerate Max™ branded cell culture mediums for research and development.

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 research grades and grades the Company believes suitable for cell culture of adipose-derived stem cells intended for use in humans. Additionally 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 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 materials for these research and development collaborators, partners and other third parties extends the Company's ability to become a primary source of autologous cellular materials and services necessary to support approved applications and treatments.

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

- *ACSelerate-MAX*<sup>™</sup> xeno serum free cell culture media,
- *ACSelerate-SFM*<sup>™</sup> animal serum free cell culture media,
- *ACSelerate-LSM*<sup>™</sup> low FBS (0.05%) cell culture media,
- *ACSelerate-CY*<sup>™</sup> for differentiation of *ATCELL*<sup>™</sup> into chondrocytes (*ATCELL-CY*<sup>™</sup>),
- *ACSelerate-OB*<sup>™</sup> for differentiation of *ATCELL*<sup>™</sup> into osteoblasts (*ATCELL-OB*<sup>™</sup>)
- *ACSelerate-AD*<sup>™</sup> for differentiation of *ATCELL*<sup>™</sup> into adipocytes (*ATCELL-AD*<sup>™</sup>)
- *ACSelerate-MY*<sup>™</sup> for differentiation of *ATCELL*<sup>™</sup> into myocytes (*ATCELL-MY*<sup>™</sup>)
- *ACSelerate-CP*<sup>™</sup> non-DMSO (Dimethyl Sulfoxide) cellular cryopreservation media
- *ACSelerate-TR*<sup>™</sup> 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*<sup>™</sup> media through further research and testing to develop medium versions for differentiation of *ATCELL*<sup>™</sup> ADSCs into neural, lung and other specific cell types that may be necessary for use in future clinical applications. On December 31, 2014 the Company filed a 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). 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<sup>™</sup> 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*<sup>™</sup> cell culture media and *ATCELL*<sup>™</sup> products; and provides these products to our collaborative partners and international licensees as further discussed below.

**Contract Manufacturing, Autokine-CM<sup>®</sup> Anti-Aging, Autologous Skin Care Product Line** – Under agreement with Personal Cell Sciences Corp. (PCS), we manufacture the key ingredient Autokine-CM<sup>®</sup> (autologous adipose derived stem cell conditioned medium) for PCS' U-Autologous<sup>™</sup> anti-aging topical formulation. Each product is genetically unique to the individual 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 for its 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 many jurisdictions outside the US currently permit use of cellular therapies and regenerative medicine applications. The Company has received 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->

On March 23, 2018 the Company entered into an Agreement with Cryoviva (Thailand) Ltd., (“Cryoviva”) established in 2007, under which the Company licensed the rights to utilize the Company’s Standard Operating Procedures (SOP’s) to create and market the Company’s ATGRAFT™ tissue storage service and ATCELL™ adipose derived stem cell processing and storage services in Thailand. The Agreement calls for the payment of certain training fees and, a percentage of the gross revenue subject to annual minimum payments generated from our products. Additionally, the Agreement calls for the purchase of CRYO consumable products required for ATGRAFT and ATCELL sample processing including CRYO’s ACSelerate™ non-DMSO cryogenic tissue storage media, transportation media, Collect™ tissue collection kit, and ACSelerate – Max™ cell culture medium.

Baoxin Asia Pacific Biotechnology (Shenzhen) Co., Ltd

During 2017 the Company entered into additional agreements with HIT to allow for the transfer of their rights to an affiliated Company Baoxin Asia Pacific Biotechnology Co, Ltd (“Baoxin”) in Shenzhen China. Baoxin will develop, own and operate multiple laboratory/treatment/training facilities in China. CRYO has received, a fee of \$100,000 for the transfer of the rights to Baoxin and a 5 year minimum annual guarantee of \$500,000 USD per year. Additionally, as part of the transaction CRYO has invested \$300,000 into Baoxin to obtain 5% minority equity in Baoxin (China) and an option to acquire up to a 20% equity ownership interest in the Regenerative Medicine Center in Hong Kong (HK) being developed by HIT. The short term goals are to set up two additional GMP grade adipose tissue processing and storage facilities in Beijing and Shanghai to cover the needs of the China region, and a proper education facility in China to promote the use of ATGRAFT as a better more natural dermal filler over artificial fillers.

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™ tissue processing and storage technology and the purchase of our CELLECT® collection products which include our ACSelerate-TR™ transport medium. The Company also assisted CellSource in upgrading its facility in Japan and provided training in ATGRAFT™ processing and laboratory recordkeeping procedures. 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. The right of first refusal expired on June 2, 2017.

## **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® collection materials in providing ATGRAFT™ 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.

23

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

## **Collaboration / 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. The Company and PeproTech completed the optimization and scale up manufacturing studies and the licensed medium is marketed under both PeproTech's PeproGrow and the Company's ACSelerate-Max brands.. PeproTech will leverage its current global sales relationships which reach a majority of all research laboratories worldwide to maximize distribution of ACSelerate-Max and other optimized media lines Additionally, the Company and PeproTech have discussed 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.

### **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)<sup>™</sup> and our patented cell culture mediums (ACSelerate)<sup>™</sup> for testing with PGEN's products designed for the wound healing market.

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. The collaborative efforts resulted in successful initial "proof of concept" combining PGEN's unique biomaterial and the Company's ATCELL<sup>™</sup> and ACSelerate<sup>™</sup> products. Management believes the preliminary results showed successful healing of full depth wounds on the backs of immune

deficient mice.

24

### **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® 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 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. This initial work will become the basis for a series of regulatory filings for product approval and registration with the FDA.

On January 3, 2018 the Company received a warning letter from the US FDA concerning its contract manufacturing services provided to Cells On Ice. The FDA has informed the Company through the letter that the FDA has determined that its autologous adipose derived cell product ATCELL is a drug under current FDA regulations and guidance and requested that the Company to file an Investigational New Drug (IND) application. In response to the letter the Company has ceased shipment of its ATCELL product within the United States and is currently in discussions with the FDA concerning the filing of the Investigational New Drug Application in the near future.

### *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.

The Company has entered into Non-Disclosure and Material Transfer Agreements with a number of potential collaborators. No assurance can be given that these relationships will progress to full collaborative agreements or ultimately result in new technology for future commercialization.

## 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 two issued U.S. patents (No. 7,989,205, and Serial No. 9,487,755, *Cell Culture Media Kits and Methods of Use*); and has additional pending patent applications which are detailed in the following chart:

<b>Title</b>	<b>Technology</b>	<b>Application Number</b>
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Covers 12 types of Medium	US Patent No. 7,989,205 Issued August 2, 2011
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Additional claim Granted for all 12 medium types	US Patent No. 9,487,755 Issued November 8, 2016
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Continuation of Granted Patent covering additional improvements	Continuation of US Patent No. 7,989,205 US Patent Application No. 15/344,805
Human serum for cell culture medium for growth of human adipose stromal cells	A cell culture medium for growth of human adipose stromal cells for human and therapeutic applications	PCT/US15/68350 30 month National Phase entry date of June 31, 2017
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology Covers CELLECT Kit, Transport and Cryopreservation Medium for ATGRAFT and ATCELL Products	US Serial No 13/194,900 Filed June 6, 2010 Patent Application Published December 5, 2013
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology Continuation covering Improvements	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/194,900 imminent (PCT Application filing planned)
Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation	Adipose Tissue Digestion Laboratory Processing Methods	U.S. Serial No. 13/646,647 filed October 6, 2011
Systems and Methods for the Digestion of Adipose Tissue Samples	Adipose Tissue Digestion Laboratory Processing Methods	Developed Improvement established; Divisional, Continuation-In-Part

Obtained From a Client For  
Cryopreservation

claiming priority to US Serial No.  
13/646,900 imminent (PCT Application  
filing planned)  
U.S. Serial No. 14/406,203 National  
Phase entry date of December 5, 2014  
based on PCT/US2013/044621

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  
Covers the core processing adipose  
tissue for ATGRAFT adipose tissue  
dermal filler product

European Union Application No.  
EPI3800847.9

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  
Covers additional claims related to  
ATGRAFT process not included in  
original application

China Application No. 2013800391988  
Developed Improvement established;  
Divisional, Continuation-In-Part  
claiming priority to US Serial No.  
14/406,203 imminent (PCT Application  
filing planned)

Systems and methods to isolate and  
expand stem cells from urine

Isolation of stem cells from urine of  
patients for use in research and  
therapeutics

US Serial Nos. 62/335,426 and  
62/439,106



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

Cosmetic compositions including tropoelastin isomorphs

Protein Genomics and American  
CryoStem (Autogenesis) USPTO #5,726,040  
collaboration

(wound healing)

Cosmetic compositions

Protein Genomics and American  
CryoStem (Autogenesis) USPTO #6,451,326  
collaboration

(wound healing)

Recombinant hair treatment compositions

Protein Genomics and American  
CryoStem (Autogenesis) USPTO #6,572,845  
collaboration

(wound healing)

Wound healing compositions and methods using tropoelastin  
and lysyl oxidase

Protein Genomics and American  
CryoStem (Autogenesis) USPTO:  
collaboration #6,808,707

(wound healing)

Business methods, processes and systems for collection,  
cryogenic storage and distribution of cosmetic formulations  
from an obtained stem cell based a biological

Personal Cell Sciences and  
American CryoStem USPTO application  
collaboration #61/588,841

(PCS)

### **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. We intend to continue to employ 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 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, we are 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 is expected to register a healthy CAGR of 13.8% during the period from 2017 to 2025 to become worth US\$270.5 bn by 2025. Depending upon geography, the key segments of the global stem cells market are North America, Latin America, Europe, Asia Pacific, and the Middle East and Africa. At present, North America dominates the market because of the substantial investments in the field, impressive economic growth, rising instances of target chronic diseases, and technological progress. As per the TMR report, the market in North America will likely retain its dominant share in the near future to become worth US\$167.33 bn by 2025.

A report published by Markets and Markets Research in 2017 titled "Cell Expansion Market by Product (Reagent, Media, Flow Cytometer, Centrifuge, Bioreactor), Cell Type (Human, Animal), Application (Regenerative Medicine & Stem Cell Research, Cancer), End user (Research Institute, Cell Bank) - Global Forecasts to 2021". The report states: The global cell expansion market is expected to reach USD 18.76 Billion by 2021 from USD 8.34 Billion in 2016 at a CAGR of 17.6%. Geographically, the cell expansion market is dominated by North America, followed by Europe, Asia, and the Rest of the World (RoW). Growth in the North American segment is primarily driven by increasing incidence of chronic diseases in the North American countries. According to the American Medical Association and the American Medical Group Association, more than 50% of Americans suffered from one or more chronic diseases in 2012; the number of Americans suffering from chronic diseases was around 133 million in 2005 and this figure is expected to reach around 157 million by 2020. With this significant growth in the number of patients suffering from chronic diseases, the market for cell expansion is expected to grow in this region in the coming years.

## ***Regenerative Medicine Market***

The Global Translational Regenerative Medicine market is expected to grow significantly over the forecast period. The Global Translational Regenerative Medicine market was valued at \$5.8bn in 2016. Visiongain forecasts this market to increase to \$14.5bn in 2021. The market is estimated to grow at a CAGR of 19.9% in the first half of the forecast period and 17.7% from 2016 to 2027.

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

As stated by the Global Wellness Institute; The global wellness economy, which encompasses 10 diverse sectors chart was worth an estimated \$3.7 trillion in 2015.

[https://static1.squarespace.com/static/54306a8ee4b07ea66ea32cc0/t/58862a472994ca37b8416c61/1485187660666/GWI\\_Wellness\\_Economy\\_2017\\_FINALweb.pdf](https://static1.squarespace.com/static/54306a8ee4b07ea66ea32cc0/t/58862a472994ca37b8416c61/1485187660666/GWI_Wellness_Economy_2017_FINALweb.pdf)

***Cell Culture Market***

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

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.*”

## **Development of Regional 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.

*Development of International Markets*

**International Licensing Program** – Globally, many jurisdictions outside the US permit the use of adipose tissue based 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®, ATGRAFT™ and ATCELL™ 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 regenerative cell samples for their clients with the comfort and confidence that they are providing services that have been developed to conform to US FDA standards. Core to the relationship is the developed proprietary and patent pending processing and laboratory operational methodologies contained in our Standard Operating Procedures, Training, and Continuous Quality Management, Testing Program, and Laboratory Operations manuals.

Licensing programs may be initiated through a letter of intent (LOI) agreement between the Company and the prospective licensee. This LOI agreement is designed for due diligence and facility qualifications purposes. The Company may receive an initial fee under the agreement which may or may not be 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.

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

### **Cryoviva (Thailand) Ltd**

On March 23, 2018 the Company into an agreement to license its ATGRAFT™ and ATCELL adipose tissue (fat) processing and storage technologies to Cryoviva (Thailand) Ltd., ("Cryoviva") a Bangkok, Thailand based Cord Blood processing and storage facility. Cryoviva, Thailand, currently offers collection, processing and storage of Cord Blood derived biologics to patients throughout Thailand and South East Asia.

American CryoStem licensed to Cryoviva (Thailand) Ltd., established in 2007, the rights to utilize the Company's Standard Operating Procedures (SOP's) to create and market the Company's ATGRAFT™ tissue storage service and ATCELL™ adipose derived stem cell processing and storage services in Thailand. The financial terms include the payment of certain training fees and, a percentage of the gross revenue subject to annual minimum payments generated from our products. Additionally, the Agreement calls for the purchase of CRYO consumable products required for ATGRAFT and ATCELL sample processing including CRYO's ACSelerate™ non-DMSO cryogenic tissue storage media, transportation media, Collect™ tissue collection kit, and ACSelerate – Max™ cell culture medium.

Cryoviva (Thailand) Ltd. was established in 2007 with the cooperation of leading companies in the world such as Indorama Ventures (Public) Company Limited, Thailand, Cryoviva Biotech Pvt., Ltd., (formerly known as Cryobanks International India) and RJ Corp India. Cryoviva is part of a large group engaged in healthcare comprising of stem cell banks, stem cell expansion facilities, diagnostic labs and centres and a maternal hospital. The Company has been certified by AABB and the ISO 9001: 2008 Quality Management System. Cryoviva (Thailand) Co., Ltd. is the only stem cell bank that has been approved by the Board of Investment of Thailand (BOI) and accredited by AABB in Thailand and awarded Frost & Sullivan's Thailand Stem Cell Company of the year for three consecutive years between 2015-2017.

**Baoxin Asia Pacific Biotechnology (Shenzhen) Co., Ltd**

During 2017 the Company entered into additional agreements with HIT to allow for the transfer of their rights to an affiliated Company Baoxin Asia Pacific Biotechnology Co, Ltd (“Baoxin”) in Shenzhen China. Baoxin will develop, own and operate multiple laboratory/treatment/training facilities in China. CRYO has received an upfront fee of \$300,000 USD and a 5 year minimum annual guarantee of \$500,000 USD per year. Additionally, as part of the transaction CRYO has invested \$300,000 into Baoxin to obtain 5% minority equity in Baoxin (China) and an option to acquire up to a 20% equity ownership interest in the Regenerative Medicine Center in Hong Kong (HK). The short term goals are to set up two additional GMP grade adipose tissue processing and storage facilities in Beijing and Shanghai to cover the need of the whole China region, and a proper education facility in China to promote the use of ATGRAFT as a better more natural dermal filler over artificial fillers.



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

In the second quarter of 2015 the Company entered into negotiations with CellSource, LLC in Tokyo, Japan for the licensing of its ATGRAFT™ products and services and on June 2, 2015 the Company and Cell Source entered into an initial term sheet Licensing the ATGRAFT™ technology to CellSource for Japan. 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. However, the growing focus on research and development in Japan and South Korea makes AsiaPacific 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 fax number is 732-747-7782. 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 annual 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 proposed business.

We have suffered recurring losses from operations since our inception. In addition, we have yet to generate an internal cash flow from our business operations or successfully raised the financing required to expand 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. Our continued existence is dependent upon our ability to resolve our liquidity problems and achieve 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.

### **Results of Operations- Six Months**

Management continued its focus on increasing revenue and reducing costs in the first quarter of Fiscal 2018. As a result of these efforts by Management, the Company's revenue for the six month period ended March 31, 2018 increased to \$779,849 in Fiscal 2018 versus \$750,142 in the same period of Fiscal 2017, an increase of 4%. Contributing to the total revenue increase for Fiscal 2018, Licensing Revenue increased to \$175,634 compared to \$80,000 in Fiscal 2017, an increase of 120%. Tissue Storage and Processing decreased to \$604,215 in Fiscal 2018 from \$670,142 in Fiscal 2017, a decrease of 10%.

Administrative expenses increased to \$681,040 (exclusive of the option grant to a vendor valued at \$549,588) for the six month period ended March 31, 2018 an increase of 33% from the same period for Fiscal 2017. The main cause in the increase was laboratory expenses increasing 147% from the six month period in Fiscal 2017. The increase in laboratory expenses was the result of an expansion of laboratory staff and overhead associated with increased processing levels in the first quarter in Fiscal 2018.

Interest expense for the six month period ending March 31, 2018 decreased to \$52,211 as compared to \$72,617 for the same period last year. This is a 28% decrease. The decrease was attributed to more debenture holders converting their debentures to shares in Fiscal 2018.

Net loss for the first six months of Fiscal 2018 was \$762,096, compared to \$107,588 from last year, a 605% increase of loss. Most of the loss in Fiscal 2018 can be attributed to the option granted to a vendor in the first quarter of fiscal year 2018. Using the Black Sholes option pricing model, the grant was valued at \$549,588, which was charged to administrative expense in Fiscal 2018.

Net loss per share for the first six months ended March 31, 2018 was a loss of \$0.02, compared to \$0.00 last year.

### **Results of Operations- Three Months**

The Company's revenue for the quarter ended March 31, 2018 decreased to \$240,583 in Fiscal 2018 versus \$429,671 in the same period of Fiscal 2017, a decrease of 44%, mainly as a result of the FDA letter received in early January 2018 requiring a cessation of some of our tissue processing revenues. Licensing Revenue increased to \$48,967 compared to \$40,000 in Fiscal 2017, an increase of 23%, as the Company added the Boaxin licensing revenues in Fiscal 2018.

Administrative expenses increased to \$326,321 for the quarter period ended March 31, 2018 an increase of 30% from the same period for Fiscal 2017. The main cause in the increase was laboratory expenses increasing 71% from the quarter period in Fiscal 2017. The increase in laboratory expenses was the result of an expansion of laboratory staff and additional equipment purchased the second quarter in Fiscal 2018 in response to the FDA letter.

Interest expense for the six month period ending March 31, 2018 decreased to \$22,670 as compared to \$40,891 for the same period last year. This is a 44% decrease. The decrease was attributed to more debenture holders converting their debentures to shares in Fiscal 2018.

Net loss for the second quarter of Fiscal 2018 was \$207,703, compared to \$12,307 from last year.

Net loss per share for the quarter ended March 31, 2018 was a loss of \$0.00, compared to \$0.00 the same quarter last year.

### **Liquidity and Capital Resources**

As of March 31, 2018, the Company had a cash balance of \$323,683 a decrease of \$88,359 since September 30, 2017, our fiscal year end. Our sources of cash were \$244,815 from operations, as compared to a loss of \$29,178 for the same period in Fiscal 2017. We used \$347,140 for investing activities, mainly our investment in Baoxin (see above).

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” below 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.

There was no significant impact on the Company’s operations as a result of inflation for the six months ended March 31, 2018.

### **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 12 to 24 months. In order to finance further market development with the associated expansion of operational capabilities for the time period discussed above, we will need to raise additional working capital. 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.

In order to move our Company through its next critical growth phase of development and commercialization and to ensure we are in position to support our research collaborations and market penetration strategies, Management continues to seek new investment into the Company from existing and new investors with particular emphasis on identifying the best deal structure to attract and retain meaningful capital sponsorship from both the retail and institutional investing communities, while limiting dilution to our current shareholders. Management also focuses its efforts on increasing sales and licensing revenue and reducing expenses.

### **Commitments**

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:

2018	\$15,460
------	----------

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

2019	\$23,190
Net minimum lease payments	\$38,650

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.

In addition, we are committed to a lease for equipment as of March 31, 2018 the remaining payments due on the lease are as follow.

	2018 balance	\$21,118
	2019	42,235
	2020	42,235
	2021	7,039
Total minimum lease payments		\$112,627
Less amounts representing interest		(19,240 )
Present value of net minimum lease payments		\$93,387

The Company is not party to any litigation against it and is not aware of any litigation contemplated against it as of March 31, 2018.

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.

### **Related Party Transactions**

At March 31, 2018, the Company was indebted to a company that is majority owned by the Company's two chief executive officers for \$107,020. The advances are due on demand, are unsecured, and carry no interest rate.

### **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. The investments in Autogenesis for \$1,000 and with Baoxin for \$300,000 are carried at cost and are classified as a Level III investment in the fair value hierarchy because the securities underlying these investments are not traded.

### **Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02 which supercedes ASC 840, Accounting for Leases. The new guidance requires the recognition of lease assets and lease liabilities for operating leases with lease terms of more than twelve months. Presentation of leases within the consolidated statements of operations and consolidated statement of cash flows will be generally consistent with current lease accounting guidance. The amended ASU is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. We plan to adopt the amended ASU in the second quarter of fiscal year 2019 and do not expect the accounting change to have a material effect on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers , which was an updated standard on revenue recognition. The ASU provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies that report using the International Financial Reporting Standards or U.S.GAAP. The main purpose of the ASU is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also enhances disclosures about revenue, providing guidance for transactions not previously addressed comprehensively and improves the guidance for multiple-element arrangements. The FASB deferred approval of the ASU to effective date for periods after December 15, 2017. The Company is currently evaluating the impact on its consolidated financial statements.

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

Not Applicable

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

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

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

As of March 31, 2018, our Chief Executive Officer and Treasurer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act). Based on such evaluation, our Chief Executive Officer and Treasurer concluded that our disclosure controls and procedures were effective as of March 31, 2018.

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

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

## **PART II - OTHER INFORMATION**

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

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

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

Not applicable.

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

During the first six months of fiscal 2018, the Company issued 600,000 shares upon the exercise of options held by shareholders. The Company received proceeds of \$25,000.

During the first six months of fiscal 2018, the Company issued 23,705 shares to pay interest due to debenture holders and bridge note holders. The value of the interest paid is \$18,727.

During the first six months of fiscal 2018, the Company issued 219,290 shares to pay an outstanding legal bill. The shares issued were valued at \$186,396. The Company recognized a loss on settlement of \$76,437 on the transaction.

During the first six months of fiscal 2018, the Company issued 25,000 shares to a consultant for services rendered valued at \$13,750.

During the first six months of 2018, debenture holders exercised \$375,000 of debentures and were issued 1,991,441 shares.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

### **ITEM 5. OTHER INFORMATION**

None

### **ITEM 6. EXHIBITS**

(a) Exhibits furnished as Exhibits hereto:

**Exhibit No. Description**

31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

36

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**AMERICAN CRYOSTEM  
CORPORATION**

May 14, 2018 By: /s/ John Arnone  
John Arnone, Chief Executive Officer  
(Principal Executive Officer)

May 14, 2018 By: /s/ Anthony Dudzinski  
Anthony Dudzinski, Treasurer  
(Principal Financial Officer)

37