

AMERICAN CRYOSTEM Corp  
Form 10-Q  
February 19, 2019

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

For the three month period ended December 31, 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

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  Smaller reporting company   
Emerging growth 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 February 15, 2019 there were 48,854,043 shares of common stock outstanding.

**TABLE OF CONTENTS**

	Page No.
<b><u>PART I. - FINANCIAL INFORMATION</u></b>	3
<u>Item 1. Financial Statements.</u>	3
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Plan of Operations.</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk.</u>	33
<u>Item 4. Controls and Procedures.</u>	33
<b><u>PART II - OTHER INFORMATION</u></b>	34
<u>Item 1. Legal Proceedings.</u>	34
<u>Item 1A. Risk Factors.</u>	34
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.</u>	34
<u>Item 3. Defaults Upon Senior Securities.</u>	34
<u>Item 4. Mine Safety Disclosures</u>	34
<u>Item 5. Other Information.</u>	34
<u>Item 6. Exhibits.</u>	35

**PART I – FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****American CryoStem Corporation****Consolidated Balance Sheets****As of December 31, 2018 and September 30, 2018**

	31-Dec-18 Unaudited	30-Sep-18 Audited
<b>ASSETS</b>		
Current Assets:		
Cash	\$27,225	\$68,320
Accounts Receivable - net of allowance for bad debt	302,178	217,318
Other Receivable - Related Parties	1,962	790
Prepaid Expenses	12,232	48,931
Inventory	33,235	33,698
Total Current Assets	376,832	369,057
Other Assets:		
Other Receivable	159	159
Investment in Autogenesis - at cost	1,000	1,000
Investment in Baoxin - at cost	300,000	300,000
Security Deposit	13,540	13,540
Patents and Patents Development - net of accumulated amortization	342,585	337,962
Fixed Assets - net of accumulated depreciation	263,664	244,707
Total Assets	\$1,297,780	\$1,266,425
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable & Accrued Expenses	\$330,411	\$307,214
Legal & Accounting Payable	66,035	65,561
Consultants Payable	194,167	131,667
Bridge Notes Payable	226,500	226,500
Convertible Notes Payable	323,500	323,500
Equipment Lease Payable	32,099	31,001
Deferred Revenues	16,667	26,667
Total Current Liabilities	1,189,379	1,112,110
Long Term Liabilities:		
Convertible Note Payable - Net of Debt Discount	37,500	25,000
Equipment Lease Payable	53,941	62,386

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Accrued Executive Salaries	720,186	660,186
Payable to Related Party (ACS Global Inc.)	204,110	107,189
Total Liabilities	2,205,116	1,966,871
Commitments and Contingencies	0	0
Shareholders' Deficit:		
Preferred Stock - \$.0001 par value, 50,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2018 and September 30, 2018	0	0
Common Stock - \$.001 par value, 300,000,000 shares authorized, 48,347,249 shares issued and outstanding at December 31, 2018 and 48,196,210 issued and outstanding at September 30, 2018	48,348	48,197
Additional Paid in Capital	13,475,423	13,388,034
Accumulated Deficit	(14,431,107)	(14,136,677)
Total Shareholders' Deficit	(907,336 )	(700,446 )
Total Liabilities & Shareholders' Deficit	\$1,297,780	\$1,266,425

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

American CryoStem Corporation

**Consolidated Statements of Operations**

For the Quarters Ended December 31, 2018 and 2017

**Unaudited**

	3 Months 31-Dec-18	3 Months 31-Dec-17
Revenues		
Tissue Processing & Storage	\$ 4,777	\$ 412,599
Licensing Fees & Royalties	110,614	126,667
Total Revenues	115,391	539,266
Less Cost of Revenues	(4,963 )	(83,374 )
Gross Margin	110,428	455,892
Operating Expenses		
Laboratory Expense	146,323	150,595
Sales & Marketing	3,978	22,887
Professional Fees	1,873	27,226
Stock Compensation Expense	30,121	549,588
General & Administrative	189,493	154,011
Total Operating Expenses	371,788	904,307
Net Loss from Operations	(261,360 )	(448,415 )
Other Income (Expenses):		
Loss on Settlement of Legal Bill	—	(76,437 )
Foreign Taxes	(4,117 )	—
Interest Expense	(16,453 )	(29,541 )
Interest Expense (beneficial conversion feature-debenture)	(12,500 )	—
Net Loss before Provision for Income Taxes	(294,430 )	(554,393 )
Provision for Income Taxes	—	—
Net Loss	\$ (294,430 )	\$ (554,393 )
Basic & Fully Diluted Net Income (Loss) per Common Share:	(\$0.01 )	(\$0.01 )
Weighted Average of Common Shares Outstanding - Basic & fully diluted	48,224,018	43,757,135

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



American CryoStem Corporation

**Consolidated Statements of Cash Flows**

For the Quarters Ended December 31, 2018 and 2017

**Unaudited**

	3 Months 31-Dec-18	3 Months 31-Dec-17
<b>Operating Activities:</b>		
Net loss	\$(294,430)	\$(554,393)
Adjustments to reconcile net loss items not requiring the use of cash:		
Bad Debt Expense	5,388	—
Loss on Settlement of Legal Bill	—	76,437
Stock Compensation Expense	30,121	549,588
Interest Expense- Beneficial Conversion Feature	12,500	—
Depreciation & Amortization Expense	7,671	8,504
Decrease (increase) in operating assets		
Accounts receivable	(90,248 )	(248,019 )
Other Receivable - Related Parties	(1,172 )	
Prepaid expense	36,699	23,333
Inventory	463	(3,365 )
Increase (decrease) in operating liabilities		
Accounts Payable and Accrued Expenses	168,590	18,370
Deferred Revenue	(10,000 )	174,336
Net cash provided (used) by operations	(134,418 )	44,791
<b>Investing activities:</b>		
Investment in Baoxin	—	(300,000)
Purchase of lab equipment & furniture	(25,679 )	(27,470 )
Patents development	(5,572 )	(10,975 )
Net cash used by investing activities	(31,251 )	(338,445)
<b>Financing activities:</b>		
Issuance of common shares	35,000	—
Paid down capital lease	(7,347 )	—
Options exercised	—	25,000
Payable to related party	96,921	(1,124 )
Net cash provided by financing activities	124,574	23,876
Net change in cash	(41,095 )	(269,778)
Cash balance at beginning of the period	68,320	410,342
Cash balance at end of the period	\$27,225	\$140,564



Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Supplemental disclosures of cash flow information:

Interest paid during the period	\$3,212	\$—
Income taxes paid during the period	\$—	\$—

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

**See Note 14 for non-cash transactions.**

5

American CryoStem Corporation

**Consolidated Statement of Changes in Shareholders' Deficit****For the Quarters Ended December 31, 2018 and 2017****Unaudited**

	Common Shares	Par Value	Paid in Capital	Accumulated Deficit	Total Deficit
Balance at September 30, 2017	43,409,580	\$43,410	\$11,581,197	\$(12,646,165)	\$(1,021,558)
Convertible notes exercised	1,241,667	1,242	223,758		225,000
Options exercised	600,000	600	24,400		25,000
Shares issued to pay interest due	23,705	24	19,268		19,292
Shares issued to pay legal bill	219,290	219	186,177		186,396
Issuance of options			549,023		549,023
Net loss				(554,393)	(554,393)
Balance at December 31, 2017	45,494,242	\$45,495	\$12,583,823	\$(13,200,558)	\$(571,240)
Balance at September 30, 2018	48,196,210	\$48,197	\$13,388,034	\$(14,136,677)	\$(700,446)
Issuance of common shares	116,667	117	34,883		35,000
Shares issued to pay interest due	34,372	34	22,385		22,419
Stock Compensation Expense			30,121		30,121
Net loss				(294,430)	(294,430)
Balance at December 31, 2018	48,347,249	\$48,348	\$13,475,423	\$(14,431,107)	\$(907,336)

See the notes to the financial statements.

## **American CryoStem Corporation**

### **Notes to the Consolidated Financial Statements**

**December 31, 2018**

#### **Unaudited**

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

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

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

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

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

The accompanying consolidated financial statements include the accounts of American CryoStem Corporation and its wholly owned subsidiaries. The Company’s subsidiaries are APAC CryoStem Limited, a Hong Kong company and APAC CryoStem (Shenzhen) Ltd. which were established to support its licensing agreement and operations, and collect the licensing fees in Hong Kong and China. Currently Mr. Arnone and Mr. Dudzinski serve as management and directors of both companies. All significant intercompany accounts and transactions have been eliminated in the consolidation. Management believes all amounts have been adjusted properly.

Accounting policies refer to specific accounting principles and the methods of applying those principles to present fairly the company’s financial position and results of operations in accordance with generally accepted accounting principles. The policies discussed below include those that management has determined to be the most appropriate in preparing the company’s financial statements.

The Consolidated Financial Statement Disclosures for the quarter ended December 31, 2018 are condensed and all necessary adjustments have been made. These Financial Statements should be read in conjunction with the Company's Form 10-K for the year ended September 30, 2018.

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

*Cash* - For the purpose of calculating changes in cash flows, cash includes all cash balances and highly liquid short-term investments with an original maturity of three months or less. Occasionally, the Company maintains cash balances at financial institutions that exceed federally insured limits.

*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. Product Sales revenues are recognized when the product has shipped. 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 and Consulting Fees are recognized when earned and collection is reasonably 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.

**American CryoStem Corporation**

**Notes to the Consolidated Financial Statements**

**December 31, 2018**

**Unaudited**

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

The Company has adopted ASC 606, which requires the company to disclose sufficient information to enable users of the financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. There has been no material effect on income, net income and per share amounts. There are no restated amounts or adjustments. The Company has adopted a retrospective approach to adopting these standards. These standards have been implemented by management and there are no outstanding issues to be addressed.

*Reclassification* – Some of the Balance Sheet items for September 30, 2018 and the Statement of Operations for the three months ended December 31, 2017 have been reclassified. None of these reclassifications affect the presentation of the Company’s financial position or results of operations.

*Advertising* – Advertising Cost are reported as they are incurred. Advertising Costs were \$200 for the quarter ended December 31, 2018 and \$2,961 for the quarter ended December 31, 2017, which is in Sales and Marketing Expenses within the Consolidated Statements of Operations.

*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 Allowance for Doubtful Accounts was \$5,387 at December 31, 2018 and \$0 at September 30, 2018.

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

Inventory was composed of Raw Materials and Finished Goods, which was valued at \$33,235 at December 31, 2018 and \$33,698 at September 30, 2018.

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

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

Office Equipment	5 years
Lab Equipment & Furniture	7 years
Lab Software	5 years

15 years

Leasehold Improvements

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

The Company follows the accounting requirements associated with uncertainty in income taxes using the provisions of Financial Accounting Standards Board (FASB) ASC 740, Income Taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not the positions will be sustained upon examination by the tax authorities. It also provides guidance for derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of December 31, 2018 and September 30, 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.

**American CryoStem Corporation**

**Notes to the Consolidated Financial Statements**

**December 31, 2018**

**Unaudited**

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

*Recently Issued Accounting Pronouncements*

In February 2016, the FASB issued ASU No. 2016-02 which supersedes 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 fiscal year 2020 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 Company has adopted this pronouncement and the accounting change does not have a material effect on our financial statements.

The Company has adopted ASC 606, which requires the company to disclose sufficient information to enable users of the financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. There has been no material effect on income, net income and per share amounts. There are no restated amounts or adjustments. The Company has adopted a retrospective approach to adopting these standards. These standards have been implemented by management and there are no outstanding issues to be addressed.

In February 2018 the FASB Issued ASU No. 2018-02 *Income Statement – Reporting Comprehensive Income (Topic 220) Concerning the Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*. The amendments in this Update allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. Consequently, the amendments eliminate the stranded tax effects resulting from the Tax Cuts and Jobs Act and will improve the usefulness of information reported to financial statement users. However, because the amendments only relate to the reclassification of the income tax effects of the Tax Cuts and Jobs Act, the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations is not affected. The amendments in this Update also require certain disclosures about stranded tax effects. The amendments in this Update are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company has reviewed the ASU and does not expect the accounting change to have a material effect on our financial statements.

**NOTE 2. Going Concern**

The accompanying consolidated financial statements have been presented in accordance with generally accepted accounting principles in the U.S., which assume the continuity of the Company as a going concern. However, the Company has incurred significant losses since its inception which raises substantial doubt about the Company's ability to continue as a going concern. Management has made this assessment for the period one year from date of the issuance of these financial statements. Management's plans with regard to this matter are to continue to fund its operations through fundraising activities in fiscal 2019 to fund future operations and business expansion.

**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.

The Company had 11,631,500 and 13,841,500 shares of Common Stock issuable upon exercise of all outstanding stock options and warrants for the quarters ended December 31, 2018 and 2017, respectively; and, 1,680,237 and 3,261,548 shares issuable on the conversion of outstanding Convertible Notes for quarters ended December 31, 2018 and 2017, respectively.

Net Loss per share for the following quarters is computed below:

	3 months Dec 31, 2018	3 months Dec 31, 2017
Net Loss	\$(294,430 )	\$(554,393 )
Weighted average shares outstanding, basic and diluted	48,224,018	43,757,135
Basic & fully diluted net loss per common share	\$(0.01 )	\$(0.01 )



**American CryoStem Corporation****Notes to the Consolidated Financial Statements****December 31, 2018****Unaudited****NOTE 4. Fixed Assets**

The fixed assets accounts of the Company are comprised as follows:

	December 31, 2018	September 30, 2018
Laboratory Equipment	\$ 416,879	\$ 416,879
Laboratory Leasehold Improvements	110,286	84,608
Laboratory Furniture	1,841	1,841
Office Equipment	23,988	23,988
Office Leasehold Improvements	2,650	2,650
Office Furniture	1,812	1,812
Accumulated Depreciation	(293,793 )	(287,071 )
Net Property and Equipment	\$ 263,663	\$ 244,707

Depreciation expense for quarters ended December 31, 2018 and December 31, 2017 was \$6,722 and \$5,963 respectively.

**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 capitalizes Legal and Administrative Fees incurred in the process of filing for its patents. The Company has only been amortizing the patents issued. Accumulated Amortization as of December 31, 2018 and September 30, 2018 was \$18,014 and \$17,065, respectively. Amortization Expense for the quarters ended December 31, 2018 and 2017 was \$949 and \$2,521, respectively.

Patents still in the application process have not been amortized. The unamortized costs of patents in the application process are \$296,598 for the quarter ended December 31, 2018 and \$291,027 for Fiscal 2017.

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.

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

On July 3, 2018, the Company was awarded U. S. Patent No. US 10,014,079 B2 titled “Business Method for Collection, Cryogenic Storage and Distribution of a Biologic Sample Material originally filed as US Serial No 13/702,304 filed June 6, 2011 with a priority date of June 6, 2010. The patent covers the Company’s comprehensive business method for collecting, processing, cryogenic storage and distribution of a biologic sample material. The Company has filed a continuation of the patent to cover addition claims and will file additional Continuation in Part claims for improvements that it has developed since the original patent filing,

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.

**American CryoStem Corporation****Notes to the Consolidated Financial Statements****December 31, 2018****Unaudited****Note 5. Patent & Patents Filings (continued)**

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 as of December 31, 2018:

Debt	Carrying Value	Maturity	Rate
Bridge Notes	\$ 226,500	Demand	8.00 %
Convertible Notes @ 40 cents	\$ 100,000	Fiscal 2020	8.00 %
Convertible Notes @ 35 cents	\$ 83,500	Demand	8.00 %
Convertible Notes @ 30 cents	\$ 45,000	Demand	8.00 %
Convertible Notes @ 20 cents	\$ 155,000	Demand	8.00 %
Convertible Notes @ 15 cents	\$ 40,000	Demand	8.00 %
Capital Lease	\$ 86,040	Fiscal 2021	14.00 %

The convertible notes are exercisable at any time and have exercise prices ranging from \$0.15 to \$0.40 with the amount of shares exercisable based on the face value of the convertible note. The holders of the bridge notes also have an option to purchase 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.

On April 6, 2018, the Company issued a debenture and received proceeds of \$100,000. The debenture matures in March 2020 and has an exercise price of \$.40 with interest at 8%. The entire Carrying Value of \$100,000 is due in March 2020.

As a result of the issue, the Company recognized interest expense of \$100,000 as a beneficial conversion feature of the debenture which has been amortized over the life of the note. The Interest Expense due to the Beneficial Conversion Feature for the Quarter Ended December 31, 2018 was \$12,500. The note is discounted due to the Beneficial Conversion Feature in the amount of \$62,500 as of December 31, 2018 and \$75,000 as of September 30, 2018.

**Note 7. Common Stock Issuances**

During fiscal 2018, the Company issued 3,072,976 shares for Convertible Notes exercised at a value of \$540,500. The share prices for these conversions were determined from the convertible note agreements.

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

During fiscal 2018, the Company issued 1,145,000 shares for Options exercised at a value of \$165,500. The share prices for these option exercises were determined from the option grants.

During fiscal 2018, the Company issued 80,000 shares to consultants for services rendered valued at \$64,050. The share prices were determined by the market price on the date the shares were issued.

During fiscal 2018, the Company issued 118,461 shares to pay interest due to holders of the bridge notes and convertible notes. The value of the interest paid was \$62,232. The share prices were determined by the aggregate market price for the week in which the shares were issued.

During fiscal 2018, the Company issued 219,290 shares to pay an outstanding legal bill. The shares issued were valued at \$186,396. The share prices were determined by the market price on the date the shares were issued.

During fiscal 2018, the Company issued 35,013 shares to build a “clean room” at the laboratory. The shares issued were valued at \$33,262. The share prices were determined by the market price on the date the shares were issued.

During fiscal 2018, the Company issued 115,890 for nine months of rent from May 2018 through January 2019. The shares issued were valued at \$110,096. The share prices were determined by the market price on the date the shares were issued.

During the quarter ended December 31, 2018, the Company issued 116,667 shares and received proceeds of \$35,000. The share price was .30 per share.

**American CryoStem Corporation****Notes to the Consolidated Financial Statements****December 31, 2018****Unaudited****Note 7. Common Stock Issuances (continued)**

During the quarter ended December 31, 2018, the Company issued 34,372 shares to pay interest due to holders of the bridge notes and convertible notes. The value of the interest paid was \$22,419. The share prices were determined by the aggregate market price for the week in which the shares were issued.

**NOTE 8. 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 intrinsic value of the shares underlying the options is zero.

The Company normally issues options to its key personnel and consultants at the end of each fiscal year or as may be included in retainer or employment agreements. The Company prepares an option agreement for each option grant that includes the date of the grant, the vesting schedule, the expiration date and other terms of the granted options. The Company's option plan calls for the immediate expiration and cancellation of the granted options in the event of the termination of employment or the contract associated with the original option grant except for certain circumstances including retirement or disability. The Company's method for exercising options is to require delivery of the executed option agreement with the payment of the option price to the Company by the option holder. Upon receipt and confirmation of payment of the exercise price by Company management, the Company prepares board minutes and issues instructions to the Company's transfer agent to issue the requisite number of shares underlying the option exercise. Using the Black-Sholes valuation method the company issued options and recorded compensation of \$30,121 and \$549,023 for the quarters ended December 31, 2018 and 2017, respectively and there is \$70,281 of unrecognized expense due to unvested options as of December 31, 2018.

	Amount	Exercise Price Range	Weighted Average Exercise Price	Weighted Average Remaining Term (Yrs)
Outstanding at September 30, 2017	14,776,500	\$ 0.05 - \$0.40	\$ 0.25	2.75
Granted	500,000	\$0.01		
Exercised	(1,145,000)	\$ 0.01 - \$0.40		
Expired	(1,825,000)	\$0.15 - \$0.40		

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Forfeited	—				
Outstanding at September 30, 2018	12,306,500	\$0.05 - \$0.40	\$ 0.26		2.31
Granted	—				
Exercised	—				
Expired	—				
Forfeited	—				
Outstanding at December 31, 2018	12,306,500	\$0.05 - \$0.40	\$ 0.26		2.10
Exercisable at December 31, 2018	11,631,500	\$ 0.05 - \$0.40	\$ 0.25		2.02

12

**American CryoStem Corporation**

**Notes to the Consolidated Financial Statements**

**December 31, 2018**

**Unaudited**

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

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

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

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

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

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

The Company valued its investments in Baoxin and Autogenesis along with the Bridge Notes and Convertible Notes at cost for the quarter ended December 31, 2018 and Fiscal 2018. Stock Options were valued using level 3 hierarchy.

**NOTE 10. Commitments & Contingencies**

The Company was committed to a non-cancelable lease for 1,628 square feet lab space in South Brunswick, New Jersey for a rent of \$5,343 per month.

On May 1, 2018, the Company expanded its laboratory facilities by leasing an additional 722 square feet for a Clean Room. For the nine months from May 1, 2018 to January 2019, the rent increased to \$7,732 per month. The Company paid for 50% of the rent for the nine month period by issuing shares of common stock to the landlord.

Minimum lease payments under this lease are as follows:

Fiscal 2019	\$ 3,865
Total minimum lease payments	\$3,865

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

These remaining lease payments are due in cash.

The Company also leases office space in Eatontown, New Jersey. The lease term is from May 1, 2018 to April 30, 2021 for \$2,650 per month. Minimum payments for this lease are as follows:

Fiscal 2019	\$ 23,850
Fiscal 2020	31,800
Fiscal 2021	18,550
Total minimum lease payments	\$82,150

Rent Expense was \$56,244 for the quarter ended December 31, 2018 and \$23,979 for the quarter ended December 31, 2017.

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

Fiscal 2019	31,676
Fiscal 2020	42,235
Fiscal 2021	28,157
Total minimum lease payments	\$ 102,069
Less amounts representing interest	(16,029 )
Present value of net minimum lease payments	\$86,040

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



**American CryoStem Corporation**

**Notes to the Consolidated Financial Statements**

**December 31, 2018**

**Unaudited**

**NOTE 11. Concentration of Credit**

The Company received approximately 86% of its revenues in for the quarter ended December 31, 2018 from one client, Baoxin. The Company also had accounts receivable from Baoxin of \$300,000 for the quarter ended December 31, 2018.

**Note 12. 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 since its inception.

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 December 31, 2018. The Company annually reviews its investments for impairment and has determined that no impairment of its investment is necessary for the quarter ended December 31, 2018.

Baoxin will develop, own and operate multiple laboratory/treatment/training facilities in China using the American CryoStem's intellectual property. American CryoStem has received an upfront fee of \$300,000 USD and a 5 year minimum annual guarantee of \$500,000 USD per year from Baoxin. Additionally, as part of the transaction American CryoStem 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 its 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 13. Related Party Transactions**

The Company was indebted to a company that is majority owned by the Company's two officers/directors in the amount of \$204,110 for the quarter ended December 31, 2018 and \$107,189 for Fiscal 2018. The advances are

unsecured, and carry no interest rate and are collectible at the discretion of the company's two officers/directors. The officers/directors do not anticipate collecting this in the next twelve months. The Company has accrued salaries for Mr. Arnone and Mr. Dudzinski and we do not foresee paying the accrued amounts until the Company has adequate funds to do so.

**Note 14. Non-Cash Transactions**

During the quarter ended December 31, 2018, the Company issued shares of common stock to pay interest expense on the convertible notes and bridge notes in the amount of \$22,419.

**NOTE 15. Subsequent Events**

The Company has made a review of material subsequent events from December 31, 2018 through the date of issuance of this report. There are no subsequent events to report as of the issuance of this report.

## 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. Additionally, the Company has been engaged in upgrading its facility from a tissue bank to a biologic drug manufacturing facility. These upgrades include the addition of new space and a new clean room, retention of consultants to assist the company with upgrades to our procedures,

methods and materials to ensure compliance with FDA regulations.

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.

16

## 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 incorporates its proprietary and patented or patent pending laboratory products, such as our *ACSelerate*<sup>™</sup> cell culture media, into our processing product production and contract manufacturing services. Additionally, the Company requires licensee's of our tissue and cell processing technologies to purchase the consumable products required in the collection, processing and storage of tissue/stem cells as part of the licensing agreement including our **CELLECT**<sup>®</sup> Collection, Transportation, and Storage System and *ACSelerate*<sup>™</sup> Cell Culture Media Products.

To date, we have generated minimal revenue; however, subject to, among other factors, obtaining the requisite financing, management believes that we are well positioned to utilize our developed products and services as the foundation for domestic and international distribution through licensees of our technologies, and a host of Regenerative Medicine application uses and future therapy products. In the US we operate an FDA registered facility that generates revenue from; the processing and storage of adipose tissue (ATGRAFT), the processing of adipose tissue into its cellular components for future use (ATCELL) and the production and sale of our **CELLECT**<sup>®</sup> tissue collection boxes, and patented media products.

### **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 proprietary ACSelerate-TR<sup>™</sup> transport medium into all collection bags which supports the health of the tissue during transport. The **CELLECT**<sup>®</sup> kit is an integral part of our validated ATGRAFT<sup>™</sup> and ATCELL<sup>™</sup> technology platform to be used by licensees of our platform technologies.

On July 3, 2018 the Company's was awarded U. S. Patent No. US 10,014,079 B2 titled “Business Method for Collection, Cryogenic Storage and Distribution of a Biologic Sample Material originally filed as US Serial No 13/702,304 filed June 6, 2011 with a priority date of June 6, 2010. The patent covers the Company's comprehensive business method for collecting, processing, cryogenic storage and distribution of a biologic sample material. The Company has filed a continuation of the patent to cover additional claims and will file additional Continuation in Part claims for improvements that it has developed since the original patent filing.

American CryoStem is the first tissue bank to globally incorporate through its **CELLECT**<sup>®</sup> 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)** – 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.

Additionally, the Company believes it will earn additional fees based upon the proposed storage configuration of the final ATCELL™ sample, and for future product creation by culturing additional samples in the ACSelerate™ cell culture and differentiation media. Cell culturing and differentiation can be performed upon receipt of the raw tissue sample or at any time on a previously processed and cryopreserved ATGRAFT™ or ATCELL™ sample. ATCELL™ has shown that it is ideally suited for expansion and differentiation into additional cell types utilizing the ACSelerate™ line of culture and differentiation mediums. The ATCELL™ processing, products and services are incorporated into our granted patent “Systems and Methods for the Digestion of Adipose Tissue Samples Obtained from a Client for Cryopreservation” US 10,154,664 issued December 18, 2018, and “Business Method for Collection, Processing, Cryogenic Storage and Distribution of a Biologic Sample Material” US Patent Number 10,014,079, issued July 3, 2018. The ACSelerate Medium products are incorporated into our granted patents “Cell Culture Media, Kits and Methods of Use”, US Patent No. 7,989,205 issued August 2, 2011 with additional claims granted in US Patent No. 9,487,755 granted November 8, 2014.

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 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 entered into a licensing and manufacturing agreement with PeproTech (April 4, 2016) 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. PeproTech 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 licensed medium is marketed under both PeproTech's PeproGrow and the Company's ACSelerate MAX brands.

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.

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™ cell culture media including:

- ACSelerate-MAX™ xeno serum free cell culture media,
- ACSelerate-SFM™ animal serum free cell culture media,

- *ACSelerate-LSM*<sup>TM</sup> low FBS (0.05%) cell culture media,
- *ACSelerate-CY*<sup>TM</sup> for differentiation of *ATCELL*<sup>TM</sup> into chondrocytes (*ATCELL-CY*<sup>TM</sup>),
- *ACSelerate-OB*<sup>TM</sup> for differentiation of *ATCELL*<sup>TM</sup> into osteoblasts (*ATCELL-OB*<sup>TM</sup>)
- *ACSelerate-AD*<sup>TM</sup> for differentiation of *ATCELL*<sup>TM</sup> into adipocytes (*ATCELL-AD*<sup>TM</sup>)  
    *ACSelerate-MY*<sup>TM</sup> for differentiation of *ATCELL*<sup>TM</sup> into myocytes  
    (*ATCELL-MY*<sup>TM</sup>)
- *ACSelerate-CP*<sup>TM</sup> non-DMSO (Dimethyl Sulfoxide) cellular cryopreservation media
- *ACSelerate-TR*<sup>TM</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>TM</sup> media through further research and testing to develop medium versions for differentiation of *ATCELL*<sup>TM</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™ Laboratory Product Sales, Contract Manufacturing and Professional Services** – ACS Laboratories is a division of American CryoStem Corporation, responsible for the manufacturing and sale of all the Company’s patented and patent pending cellular, cell culture, processing and testing products to professional, institutional and commercial clients. The Company operates a separate website (*acslaboratories.com*) to distinguish the sale of commercial and research products from its consumer products and services, which are marketed on its main website (*americancryostem.com*). ACS Laboratories manufactures a full line of ACSelerate™ cell culture media and ATCELL™ products; and provides these products to our collaborative partners and international licensees as further discussed below.

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

*China*

On July 12, 2018 the Company announced the national launch of CRYO's ATGRAFT™ tissue collection, processing and storage technology by Baoxin Asia Pacific Biotechnology (Shenzhen) Co. Ltd. ("Baoxin") in China. The Company's management team traveled throughout south east China with the management and marketing team of Baoxin to present the ATGRAFT™ platform to leading plastic and cosmetic surgery hospitals in Shenzhen, Nanning, Guangzhou, Guangxi and Changsha. Additionally, Mr. Arnone and Mr. Dudzinski attended the signing of investment documents between Baoxin and Chinese government and Banking officials in Shenzhen, China as well as the official launch presentation and evening gala hosted by Baoxin in Shenzhen.

The China launch activities are in support of the Company's previously announced licensing and supply agreement with Baoxin, under which Baoxin will pay the Company a minimum annual guarantee against a fixed fee per process and purchase certain necessary consumables from CRYO required for the collection, processing and storage of the collected adipose tissue. Under the terms of the Agreements signed in Fiscal 2018, the Company invested in and currently holds five percent (5%) of Baoxin shares. Additionally, Mr. Arnone and Mr. Dudzinski were elected to serve as Directors of Baoxin during their visit to Shenzhen, China.

### ***Hong Kong***

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 for Hong Kong. The Agreement called for upfront fees, royalties and the purchase by HIT of certain consumables manufactured by the Company. The Company and HIT 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 kits as well as other American CryoStem products necessary for clinical adipose tissue processing and storage at the Shenzhen 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.

In 2017 as part of the Company’s transaction with Baoxin, HIT and the Company agreed to transfer certain product and distribution rights granted to HIT under its 2014 agreement to Baoxin. The Company was paid of fee of US\$100,000 in the transaction and was provided with an initial ownership position in a planned Regenerative Treatment Center to be established by HIT in Hong Kong.

### ***Thailand***

On April 5, 2018 the Company announced further expansion of its global laboratory and cellular technology footprint by entering into an agreement dated March 23, 2018 to license its ATGRAFT™ and ATCELL adipose tissue (fat) processing and storage technologies with Cryoviva (Thailand) Ltd., 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 has 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 generally, call 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.

### ***Japan***

In June 2015, The Company entered into a licensing agreement with CellSource, LTD. (“CellSource”) located in Shibuya, Tokyo Japan for the licensing of our ATGRAFT™ 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 the ATGRAFT™ processing and recordkeeping procedures. CellSource began marketing the new services initially within its existing network of clinics throughout Japan and began purchasing its CELLECT™ and ACSelerate-CP™ cryoprotectant from the Company in the third quarter of 2015. Upon execution of the Agreement the Company received an upfront payment and will receive additional minimum annual payments, and consumable product sales revenue - in future years. The non-exclusive agreement expires in June of 2020 and may be renewed for an additional term upon expiration.

### **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.

We focus our efforts on expanding our product and services pipelines based upon our intellectual property portfolio, collaborative development relationships, product sales and distribution, and international licensing and partnering opportunities. Our current activities include supporting collaborations by providing our products and services (ACSelerate™ and ATCELL™) 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.

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

#### **PeperoTech, Inc.**

On April 4, 2016 the Company entered into an Agreement with PeperoTech, Inc of Rocky Hill, NJ. Under the Agreement PeperoTech manufactures, markets and distributes the Company's ACSelerate – Max cell growth medium. The Company and PeperoTech completed the optimization and scale up manufacturing studies and the licensed medium is marketed under both PeperoTech's, PeperoGrow and the Company's ACSelerate MAX brands. PeperoTech plans to leverage its current global sales relationships which reach a majority of all research laboratories worldwide to maximize distribution of the optimized media while the Company will concentrate its sales efforts on its collaborative and international licensing partners. Additionally, the Company and PeperoTech are discussing the licensing of additional American CryoStem patented media and products for production and distribution by PeperoTech, any additional media licensed to PeperoTech will undergo similar optimization and scale up production testing prior to being released for sale.

#### **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 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 IND in the near future.



Since receiving the Warning Letter from the FDA in January the Company undertook a complete reorganization and remediation of its facility and operations and an expansion of its existing facilities. Working with its landlord at its Monmouth Junction Facility, NJ facility the Company has leased additional space and is in the final stages of installing and certifying a new Clean Room designed specifically for cellular expansion, medium filling and tissue processing. In addition, the Company has retained new consultants to assist its personnel in the review and revalidation of its operating procedures, equipment and processing methods as well as designing new procedures for upgraded and newly acquired laboratory operating and testing equipment. This work has been performed in expectation of a pending Investigational New Drug Application (IND) with the FDA for the use of autologous adipose derived cells by its clients for the relief of inflammation associated with certain conditions resulting from trauma. During the course of these efforts, the Company has been engaged with representatives of the FDA regarding our responses to the Warning Letter and scheduled and completed a Pre-IND meeting with FDA to clarify some of the requirements of the IND application process and documentation. The Company filed a preliminary IND brief with the FDA in April of 2018 and requested a Pre-IND meeting with the FDA which was held by on June 1, 2018. The Company received additional comments from the FDA late June of 2018 and has incorporated these comments into the pending Application. Additionally the Company has initiated a focused questionnaire program to obtain additional treatment and outcome data from all participants under the COI program. The Company believes that it can complete this work and prepare and submit the Application to FDA in 2019. The Company continues to implement the necessary facility and operational upgrades necessary to convert its tissue banking facility into a cGMP drug manufacturing facility. This has included the hiring of new consultants, upgrades to the existing facility infrastructure, additional leased space and the installation of a new clean room processing area within the new space. To date the installation, certification and qualification validation of the new clean room and the accompanying equipment has been completed and training and material validation and qualification have been initiated. The Company believes that it can complete the remaining qualification, certification, validation, testing, and documentation requirements in the second calendar quarter of 2019.

#### *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<sup>TM</sup> or ACSelerate<sup>TM</sup> 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 four issued U.S. patents (No. 7,989,205, and Serial No. 9,487,755, *Cell Culture Media Kits and Methods of Use*, "Systems and Methods for the Digestion of Adipose Tissue Samples Obtained from a Client for Cryopreservation" US 10,154,664 issued December 18, 2018, and "Business Method for Collection, Processing, Cryogenic Storage and Distribution of a Biologic Sample Material" US Patent Number 10,014,079, issued July 3, 2018); and has additional pending patent applications which are detailed in the following chart:

<b>Title</b>	<b>Technology</b>	<b>Patent / 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 PCT/US15/68350
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	30 month National Phase entry date of June 31, 2017, additional International Filings for China, India, the European Union, Saudi Arabia, Israel, Brazil, Mexico, Australia and New Zealand. US Serial No 13/194,900
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	Filed June 6, 2010 Patent Application Published December 5, 2013 Claims Granted US Patent No. 10,014,079. Continuation filed upon issuance.
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/194,900 imminent (PCT Application filing planned)

Edgar Filing: AMERICAN CRYOSTEM Corp - Form 10-Q

Continuation covering  
Improvements

<p>Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation</p> <p>Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation</p>	<p>Adipose Tissue Digestion Laboratory Processing Methods</p> <p>Adipose Tissue Digestion Laboratory Processing Methods</p>	<p>U.S. Serial No. 13/646,647 filed October 6, 2011, Claims Granted US Patent No.10,154,664 December 18,2018. Continuation filed upon issuance. Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/646,900 imminent (PCT Application filing planned)</p>
<p>Compositions and Methods for collecting, Washing, Cryoprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures”</p>	<p>Company Adipose Tissue Storage Platform for Cosmetic Procedures Covers the core processing adipose tissue for ATGRAFT adipose tissue dermal filler product</p>	<p>U.S. Serial No. 14/406,203 National Phase entry date of December 5, 2014 based on PCT/US2013/044621</p> <p>European Union Application No. EPI3800847.9</p>
<p>Compositions and Methods for “Collecting, Washing, Cryoprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures”</p>	<p>Company Adipose Tissue Storage Platform for Cosmetic Procedures Covers additional claims related to ATGRAFT process not included in original application</p>	<p>China Application No. 2013800391988</p> <p>Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 14/406,203 imminent (PCT Application filing planned)</p>
<p>Systems and methods to isolate and expand stem cells from urine</p>	<p>Isolation of stem cells from urine of patients for use in research and therapeutics</p>	<p>US Serial Nos. 62/335,426 and 62/439,106</p>

Additionally, the Company has in-licensed the following IP:

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

**Trademarks**

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

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

## **Marketing and Distribution**

The key objective of our marketing strategy is to position American CryoStem in the market as the “Gold Standard” for adipose tissue collection, cell processing and cryogenic storage, therapeutic applications, and research/commercial uses of adipose tissue within the current regulatory framework. The combination of a traditional sales approach supported by continuous internal and external marketing programs, are closely coordinated with the expansion of our laboratory processing capabilities. Our initial marketing efforts intend to disseminate current and future uses of adipose tissue and adult stem cells which support our business model, products and services. 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.

### *Cell Culture Market*

**Cell Culture Market Global Forecast to 2023**, according to “marketsandmarkets” the cell culture market is expected to reach USD \$26.28 Billion by 2023 from USD \$15.32 Billion in 2018, at a CAGR of 11.4%. Growth in this market is driven by the growing number of regulatory approvals for cell culture-based vaccines, increasing demand for monoclonal antibodies (mAbs), funding for cell-based research, growing preference for single-use technologies, and the launch of advanced cell culture products.

## **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.

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 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 IND in the near future. (for additional information see Cells On Ice in the Collaboration / Partnering Opportunities / Acquisitions above)

### ***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.

### ***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 entered into an agreement to license its ATGRAFT™ and ATCELL adipose tissue (fat) processing and storage technologies with 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.

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

On July 12, 2018 The Company announced the national launch of CRYO's ATGRAFT™ tissue collection, processing and storage technology by Baoxin Asia Pacific Biotechnology (Shenzhen) Co. Ltd. ("Baoxin") in China. The management team traveled throughout south east China with the management and marketing team of Baoxin to present the ATGRAFT™ platform to leading plastic and cosmetic surgery hospitals in Shenzhen, Nanning, Guangzhou, Guangxi and Changsha. The China launch activities are in support of the Company's previously announced licensing and supply agreement with Baoxin, under which Baoxin will pay the Company a minimum annual guarantee against a fixed fee per process and purchase certain necessary consumables from CRYO required for the collection, processing and storage of the collected adipose tissue. Under the terms of the Agreements signed in Fiscal 2018, the Company invested in and currently holds five percent (5%) of Baoxin shares. Additionally, Mr. Arnone and Mr. Dudzinski were elected to serve as Directors of Baoxin during their visit to Shenzhen, China.

#### **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 agreement licensing the ATGRAFT™ technology to CellSource for Japan. The non- exclusive agreement expires in June of 2020 and may be renewed for an additional term upon expiration.

#### **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.

In 2017 as part of the Company’s transaction with Baoxin, HIT and the Company agreed to transfer certain product and distribution rights granted to HIT under its 2014 agreement to Baoxin. The Company was paid of fee in the transaction and was provided with an initial ownership position in a planned Regenerative Treatment Center to be established by HIT in Hong Kong.

## 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 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.

The accompanying consolidated financial statements have been presented in accordance with generally accepted accounting principles in the U.S., which assume the continuity of the Company as a going concern. However, the Company has incurred significant losses since its inception which raises substantial doubt about the Company's ability to continue as a going concern. Management has made this assessment for the period one year from date of the issuance of these financial statements. Management's plans with regard to this matter is to continue to fund its operations through fundraising activities in fiscal 2019 to fund future operations and business expansion.

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- Three Months**

The Company's revenue for the quarter ended December 31, 2018 decreased to \$115,391 versus \$455,892 in the same period of Fiscal 2018, a decrease of 74.6%, mainly as a result our stoppage in cellular processing revenues until we come into compliance with FDA regulations, which we expect to resume in the second quarter of fiscal 2019. Licensing Revenue decreased to \$110,614 compared to \$126,667 in Fiscal 2018, a decrease of 12.6%.

Administrative expenses decreased to \$371,788 for the quarter ended December 31, 2018, a decrease of 58.8% from the same period for Fiscal 2018. The main cause in the decrease was lower expenses associated with stock compensation expense.

Interest expense for the quarter ending December 31, 2018 decreased to \$28,953 as compared to \$29,541 for the same period last year. The interest expense for December 31, 2018 includes \$12,500 for the effects of the beneficial conversion feature associated with debenture holders converting their debentures.

Net loss for the first quarter of Fiscal 2019 was \$294,430, compared to a loss of \$554,393 for the same period of 2018.

Net loss per share for the quarter ended December 31, 2018 was \$0.01, compared to \$0.01 for the same quarter last year.

### **Liquidity and Capital Resources**

As of December 31, 2018, the Company had a cash balance of \$27,225 a decrease of \$41,095 since September 30, 2018, our fiscal year end. Operations used \$134,418 of our cash. We used \$31,251 in cash for investments including \$25,679 for the purchase of lab equipment and \$5,572 in patent development and maintenance. The main sources of cash provided by financing activities including new equity issuances and an additional loan from ACS Global, Inc. and from licensing fees during the three months ended December 31, 2018.

Our accounts receivable increased to \$302,178 at December 31, 2018 from \$217,318 at September 30, 2018 mainly due from Baoxin for licensing fees. Convertible debt decreased to \$347,143 as more of our debenture holders converted to shares.

The Company will continue to focus on its financing and investment activities but should we be unable to raise sufficient funds, we will be required to curtail our operating plans if not cease them entirely. We cannot assure you that we will generate the necessary funding to operate or develop our business. Please see “Cash Requirements” above for our existing plans with respect to raising the capital we believe will be required. In the event that we are able to obtain the necessary financing to move forward with our business plan, we expect that our expenses will increase significantly as we attempt to grow our business. Accordingly, the above estimates for the financing required may not be accurate and must be considered in light these circumstances.

There was no significant impact on the Company’s operations as a result of inflation for the three months ended December 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 that 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, 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. On January 14, 2019 the Company terminated its agreement with Gramatan, LLC. Fees due per the terms of the agreement are included in administrative expenses in the Company's financial statements. Management also focuses its efforts on increasing sales and licensing revenue and reducing expenses.

### **Commitments**

The Company was committed to a non-cancelable lease for 1,628 square feet lab space in South Brunswick, New Jersey for a rent of \$5,343 per month.

On May 1, 2018, the Company expanded its laboratory facilities by leasing an additional 722 square feet for a Clean Room. For the nine months from May 1, 2018 to January 2019, the rent increased to \$7,732 per month. The Company paid for 50% of the rent for the nine month period by issuing shares of common stock to the landlord.

Minimum lease payments under this lease are as follows:

Fiscal 2019	\$3,865
Total Minimum Lease Payments	\$ 3,865

These remaining lease payments are due in cash.

The Company also leases office space in Eatontown, New Jersey. The lease term is from May 1, 2018 to April 30, 2021 for \$2,650 per month. Minimum payments for this lease are as follows:

Fiscal 2019	\$23,850
Fiscal 2020	31,800
Fiscal 2021	18,550
Total minimum lease payments	\$ 82,150

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

Fiscal 2019	31,676
Fiscal 2020	42,235
Fiscal 2021	28,157
Total minimum lease payments	\$ 102,069
Less amounts representing interest	(16,029 )
Present value of net minimum lease payments	\$86,040

Depreciation Expense for the leased equipment for the first three months or Fiscal 2019 was \$4,596.

The Company is not party to any litigation against it and is not aware of any litigation contemplated against it as of December 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 December 31, 2018, the Company was indebted to a company that is majority owned by the Company's two chief executive officers for \$204,110. The advances are due on demand, are unsecured, and carry no interest rate and is not expected to be collected within the next year.

### **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.

## Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 which supersedes 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 fiscal year 2020 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 Company has adopted ASC 606, which requires the company to disclose sufficient information to enable users of the financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. There has been no material effect on income, net income and per share amounts. There are no restated amounts or adjustments. The Company has adopted a retrospective approach to adopting these standards. These standards have been implemented by management and there are no outstanding issues to be addressed.

In February 2018 the FASB Issued ASU No. 2018-02 *Income Statement – Reporting Comprehensive Income (Topic 220)* Concerning the Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. The amendments in this Update allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. Consequently, the amendments eliminate the stranded tax effects resulting from the Tax Cuts and Jobs Act and will improve the usefulness of information reported to financial statement users. However, because the amendments only relate to the reclassification of the income tax effects of the Tax Cuts and Jobs Act, the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations is not affected. The amendments in this Update also require certain disclosures about stranded tax effects. The amendments in this Update are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company has reviewed the ASU and do not expect the accounting change to have a material effect on our 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 December 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 December 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 fiscal 2018, the Company issued 3,072,976 shares for Convertible Notes exercised at a value of \$540,500. The share prices for these conversions were determined from the convertible note agreements.

During fiscal 2018, the Company issued 1,145,000 shares for Options exercised at a value of \$165,500. The share prices for these option exercises were determined from the option grants.

During fiscal 2018, the Company issued 80,000 shares to consultants for services rendered valued at \$64,050. The share prices were determined by the market price on the date the shares were issued.

During fiscal 2018, the Company issued 118,461 shares to pay interest due to holders of the bridge notes and convertible notes. The value of the interest paid was \$62,232. The share prices were determined by the aggregate market price for the week in which the shares were issued.

During fiscal 2018, the Company issued 219,290 shares to pay an outstanding legal bill. The shares issued were valued at \$186,396. The share prices were determined by the market price on the date the shares were issued.

During fiscal 2018, the Company issued 35,013 shares to build a “clean room” at the laboratory. The shares issued were valued at \$33,262. The share prices were determined by the market price on the date the shares were issued.

During fiscal 2018, the Company issued 115,890 for nine months of rent from May 2018 through January 2019. The shares issued were valued at \$110,096. The share prices were determined by the market price on the date the shares were issued.

During the quarter ended December 31, 2018, the Company issued 116,667 shares and received proceeds of \$35,000. The share price was .30 per share.

During the quarter ended December 31, 2018, the Company issued 34,372 shares to pay interest due to holders of the bridge notes and convertible notes. The value of the interest paid was \$22,419. The share prices were determined by the aggregate market price for the week in which the shares were issued.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None

34

**ITEM 6. EXHIBITS**

(a) Exhibits furnished as Exhibits hereto:

**Exhibit No. Description**

31.1	<u>Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	<u>Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	<u>Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>

35



**SIGNATURES**

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

**AMERICAN CRYOSTEM  
CORPORATION**

February 19, 2019 By: /s/ John Arnone  
John Arnone, Chief Executive Officer  
(Principal Executive Officer)

February 19, 2019 By: /s/ Anthony Dudzinski  
Anthony Dudzinski, Treasurer  
(Principal Financial Officer)