

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## AMERICAN CRYOSTEM Corp

**Form: 10-Q**

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Corporate Issuer CIK: 1468679

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2019

or

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-54672

**American CryoStem Corporation**

(Exact 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, Suite 5, Eatontown, NJ 07724

(Address of Principal Executive Offices) (Zip Code)

(732) 747-1007

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered

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.

x Yes o No

Indicate by check mark whether the registrant has submitted electronically 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 such files).

x Yes o 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 o  
Non-accelerated filer x

Accelerated filer o  
Smaller reporting company x  
Emerging growth company o

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. o

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of February 17, 2020, the issuer's \$0.001 par value Common Stock totaled 50,262,918 shares outstanding.

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PART I – FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

American CryoStem Corporation  
 Consolidated Balance Sheets  
 As of December 31, 2019 and September 30, 2019

	<u>31-Dec-19</u> (Unaudited)	<u>30-Sep-19</u> (Audited)
<b>ASSETS</b>		
Current Assets:		
Cash	\$ 82,205	\$ 23,800
Accounts Receivable - net of allowance for bad debt	450,000	330,154
Inventory	25,840	25,855
Total Current Assets	<u>558,045</u>	<u>379,809</u>
Other Assets:		
Investment in Baoxin - at cost	300,000	300,000
Security Deposit	13,540	13,540
Patents and Patents Development - net of accumulated amortization	362,502	362,490
Fixed Assets - net of accumulated depreciation	132,420	238,078
Finance Lease - Right-of-Use-Asset	98,072	—
Operating Lease Right-of-Use-Asset	40,089	—
Total Assets	<u>\$ 1,504,668</u>	<u>\$ 1,293,917</u>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts Payable & Accrued Expenses	\$ 229,955	\$ 321,738
Legal & Accounting Payable	100,965	97,235
Consultants Payable	184,286	189,227
Bridge Notes Payable	226,500	226,500
Convertible Notes Payable	453,000	398,500
Derivative Liability	259,078	—
Finance Lease Liability	36,948	35,673
Operating Lease Liability	29,665	—
Deferred Revenues	16,667	23,333
Total Current Liabilities	<u>1,537,064</u>	<u>1,292,206</u>
Long Term Liabilities:		
Convertible Notes Payable - Net of Debt Discount	110,479	102,288
Finance Lease Liability - Net of Current Portion	16,993	26,722
Operating Lease Liability - Net of Current Portion	10,424	—
Accrued Executive Salaries	960,186	900,186
Payable to Related Parties	204,387	210,520
Total Liabilities	<u>2,839,533</u>	<u>2,531,922</u>
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, 2019 and September 30, 2019	0	0
Common Stock - \$.001 par value, 300,000,000 shares authorized, 50,262,918 shares issued and outstanding at December 31, 2019 and 49,387,918 issued and outstanding at September 30, 2019	50,264	49,389
Additional Paid in Capital	14,105,625	13,931,500
Accumulated Deficit	(15,490,754)	(15,218,894)
Total Shareholders' Deficit	<u>(1,334,865)</u>	<u>(1,238,005)</u>
Total Liabilities & Shareholders' Deficit	<u>\$ 1,504,668</u>	<u>\$ 1,293,917</u>

See the notes to the financial statements.

**American CryoStem Corporation**  
**Consolidated Statements of Operations**  
**For the Quarters Ended December 31, 2019 and 2018**  
**Unaudited**

	<u>31-Dec-19</u>	<u>31-Dec-18</u>
<b>Revenues</b>		
Product Sales	\$ 1,460	\$ —
Tissue Processing & Storage		4,777
Licensing Fees & Royalties	131,666	110,614
<b>Total Revenues</b>	<u>133,126</u>	<u>115,391</u>
Less Cost of Revenues	<u>(5,187)</u>	<u>(4,963)</u>
<b>Gross Margin</b>	127,939	110,428
<b>Operating Expenses</b>		
Laboratory Expense	36,574	146,323
Sales & Marketing	13,801	3,978
Professional Fees	34,148	1,873
Stock Compensation Expense	—	30,121
General & Administrative	133,359	189,493
<b>Total Operating Expenses</b>	<u>217,882</u>	<u>371,788</u>
<b>Net Loss from Operations</b>	(89,943)	(261,360)
<b>Other Income (Expenses):</b>		
Gain on Value of Derivative	1,873	
Foreign Taxes	(6,561)	(4,117)
Loss on Loan Issuance	(92,951)	
Amortization of Debt Discount	(42,000)	
Interest Expense	(21,587)	(16,453)
Interest Expense (beneficial conversion feature-debenture)	<u>(20,691)</u>	<u>(12,500)</u>
<b>Net Loss before Provision for Income Taxes</b>	(271,860)	(294,430)
<b>Provision for Income Taxes</b>	<u>—</u>	<u>—</u>
<b>Net Loss</b>	<u>\$ (271,860)</u>	<u>\$ (294,430)</u>
<b>Basic &amp; Fully Diluted Net Income (Loss) per Common Share:</b>	\$ (0.005)	\$ (0.006)
<b>Weighted Average of Common Shares Outstanding - Basic &amp; fully diluted</b>	49,503,304	48,224,018

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

**American CryoStem Corporation**  
**Consolidated Statements of Cash Flows**  
**For the Quarters Ended December 31, 2019 and 2018**  
**Unaudited**

	<u>31-Dec-19</u>	<u>31-Dec-18</u>
<b>Operating Activities:</b>		
Net loss	\$ (271,860)	\$ (294,430)
Adjustments to reconcile net loss items not requiring the use of cash:		
Derivative change in fair value	(1,873)	
Amortization of Debt Discount	(42,000)	
Bad Debt Expense	2,000	5,388
Stock Compensation	—	30,121
Interest Expense- Beneficial Conversion Feature	20,691	12,500
Depreciation & Amortization Expense	9,010	7,671
Changes in operating assets and liabilities		
Accounts receivable	(121,846)	(90,248)
Other Receivable - Related Parties	—	(1,172)
Prepaid expense	—	36,699
Inventory	15	463
Accounts Payable and Accrued Expenses	(92,994)	168,590
Salaries Payable	60,000	
Deferred Revenue	(6,666)	(10,000)
Loss on Loan Issuance	92,951	
Net cash used by operations	<u>(268,572)</u>	<u>(134,418)</u>
Investing activities:		
Purchase of lab equipment & furniture	—	(25,679)
Patents development	(1,436)	(5,572)
Net cash used by investing activities	<u>(1,436)</u>	<u>(31,251)</u>
Financing activities:		
Issuance of common shares	175,000	35,000
Issuance of convertible note	168,000	—
Paid down Finance Lease	(8,454)	(7,347)
Payable to related party	(6,133)	96,921
Net cash provided by financing activities	<u>328,413</u>	<u>124,574</u>
Net change in cash	58,405	(41,095)
Cash balance at beginning of the period	<u>23,800</u>	<u>68,320</u>
Cash balance at end of the period	<u>\$ 82,205</u>	<u>\$ 27,225</u>
Supplemental disclosures of cash flow information:		
Interest paid during the period	\$ 2,105	\$ 3,212
Income taxes paid during the period	—	—

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

**American CryoStem Corporation**  
**Consolidated Statements of Changes in Shareholders' Deficit**  
**For the Quarters Ended December 31, 2019 and 2018**  
**Unaudited**

	<u>Common Shares</u>	<u>Par Value</u>	<u>Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Deficit</u>
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	<u>48,347,249</u>	<u>\$ 48,348</u>	<u>\$ 13,475,423</u>	<u>\$ (14,431,107)</u>	<u>\$ (907,336)</u>
Balance at September 30, 2019	49,387,918	\$ 49,389	\$ 13,931,500	\$ (15,218,894)	\$ (1,238,005)
Issuance of common shares	875,000	875	174,125		175,000
Net loss				(229,860)	(229,860)
Balance at December 31, 2019	<u>50,262,918</u>	<u>\$ 50,264</u>	<u>\$ 14,105,625</u>	<u>\$ (15,448,754)</u>	<u>\$ (1,292,865)</u>

See the notes to the financial statements.

**American CryoStem Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2019**  
**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, 2019 are condensed and all necessary adjustments have been made. These Financial Statements should be read in conjunction with the Company's Form 10K for the year ended September 30, 2019.

*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.

*Accounting for Investments* - The Company accounts for investments based upon the type and nature of the investment and the availability of current information to determine its value. Investments in marketable securities in which there is a trading market will be valued at market value on the nearest trading date relative to the Company's financial reporting requirements. Investments which there is no trading market from which to obtain recent pricing and trading data for valuation purposes will be valued based upon management's review of available financial information, disclosures related to the investment and recent valuations related to the investment's fundraising efforts.



**American CryoStem Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2019**  
**Unaudited**

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

*Research and Development* - Research and development expenses include both external and internal expenses. External expenses primarily include costs of intellectual property development, clinical trial development, fees paid for third party testing services, clinical supply and manufacturing expenses, regulatory filing fees, consulting and professional fees as well as other general costs related to the execution of research and development activities. Internal expenses primarily include compensation of employees engaged in research and development activities. Research and development expenses are expensed as incurred. Manufacturing costs are generally expensed as incurred.

*Revenue Recognition* - Effective October 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers ("ASC 606"), using the modified retrospective transition method. We recognized the cumulative effect of applying the new revenue standard to all contracts with customers that were not completed as of October 1, 2018. The comparative information has not been restated and continues to be reported under the accounting standards in effect for the periods presented, since there is no material effect on the presentation of the financial positions or statements of operations. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, certain collaboration arrangements and financial instruments. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The adoption of ASC 606 did not have an impact on the amount of reported revenues. See Note 3 "Revenue Recognition" for additional information.

*Advertising* – Advertising Cost are reported as they are incurred. Advertising Costs were \$0 for the quarter ended December 31, 2019 and \$200 for the quarter ended December 31, 2018, which is included 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 \$12,865 at December 31, 2019 and \$10,865 at September 30, 2019.

*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 \$25,840 at December 31, 2019 and \$25,855 at September 30, 2019.

*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

*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.

**American CryoStem Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2019**  
**Unaudited**

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

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, 2019 and September 30, 2019, 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 2018 are subject to IRS and State of New Jersey audit.

*Recently Issued Accounting Pronouncements*

In June 2016, the FASB issued ASU No. 2016-13 *Financial Instruments-Credit Losses*. The new guidance provides better representation about expected credit losses on financial instruments. This Update requires the use of a methodology that reflects expected losses and requires consideration of a broader range of reasonable and supportive information to inform credit loss estimates. This ASU is effective for reporting periods beginning after December 15, 2022, with early adoption permitted. The company is studying the impact of adopting the ASU in fiscal year 2024, and what effect it could have. The Company believes the accounting change would not have a material effect on the financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 which requires lessees to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months; and requires expanded disclosures about leasing arrangements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods in fiscal years beginning after December 15, 2018, with early adoption permitted. ASU 2016-02 and additional ASUs are now codified as Accounting Standards Codification Standard ("ASC") 842 - *Leases* ("ASC 842"). The Company adopted ASC 842 on October 1, 2019 and used the modified retrospective transition approach and did not restate its comparative periods. As of the date of implementation on October 1, 2019, the impact of the adoption of ASC 842 resulted in the recognition of a Finance Lease Right-of-Use-Asset and an Operating Lease Right-of-use-Asset and corresponding Lease Liability Obligations on the Company's consolidated balance sheets. The Company elected to not recognize lease assets and lease liabilities for leases with an initial term of 12 months or less.

As the Right of use asset and the corresponding Lease Liability obligation were the same upon adoption of ASC 842, there was no cumulative effect impact on the Company's accumulated deficit. Since the Equipment Asset related to the Capital Lease and the Finance Lease Asset established had different values, the Company recorded a cumulative effect modification on October 31, 2019 by a reducing equity (increasing the accumulated deficit) by \$41,804.

In November 2018, the FASB issued ASU 2018-18, *Clarifying the Interaction between Topic 808 and Topic 606*. This new ASU applies to companies that have collaborative arrangements, or agreements that involve two parties that actively participate in a joint operating activity. We believe our contract with Baoxin falls under the collaborative arrangements guidance in (ASC 808). ASU 2018-18 is effective for public companies for years beginning after December 15, 2019. The Company plans to implement ASU 2018-18 in Fiscal 2021 and is currently assessing the impact on its contracts.

**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 this report. Management's plans with regard to this matter are to continue to fund its operations through fundraising activities in fiscal 2020 for future operations and business expansion.

**NOTE 3. Revenue Recognition**

On October 1, 2018, we adopted ASC 606 applying the modified retrospective transition method to all contracts that were not completed as of October 1, 2018. Results for reporting periods beginning after October 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for prior periods, since there was no material effect on the financial statements.

**American CryoStem Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2019**  
**Unaudited**

**NOTE 3. Revenue Recognition (continued)**

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

- a. Identify the contract(s) with a customer;
- b. Identify the performance obligations in the contract;
- c. Determine the transaction price;
- d. Allocate the transaction price to the performance obligations in the contract; and
- e. Recognize revenue when (or as) the performance obligations are satisfied.

We only apply the five step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, if the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Our major sources of revenue during the reporting periods were 1. Tissue Collection, Processing and Storage revenue from various customers; 2. Annual Storage Fees for our ATGRAFT and ATCELL products, from customers who have had stored in our laboratory facility, along with former Bio-Life and Cytori storage customers purchased by American CryoStem; 3. Licensing and other fees from Baoxin, Cell Source, CryoViva, Pepto-Tech and Personal Cell Sciences; and 4. Products sales revenues from Baoxin and CryoViva. The adoption of ASC 606 did not have an impact on the pattern or timing of recognition of our Tissue Processing, Storage Fees or Product Sales Revenue, since:

1. Tissue Collection, Processing & Storage Revenue is recognized on the date the process is completed and stored in our facility.
2. Storage Fees are charged annually.
3. Licensing and other Fees - This is based on the passage of time and as the customer has access to the license. The Company reviewed and analyzed the contract with Baoxin. Management's judgments are:
  - a. Baoxin qualifies as a customer since American CryoStem does not take significant risks or receive significant gains from the agreement.
  - b. The right to use the license does not have significant standalone functionality because consulting is required by American CryoStem in order for the customer to be able to use the license.
4. The majority of our Product Sales Revenue continues to be recognized when the customer takes control of the product.

**Revenue and Allowances**

The following table provides information about Fees and Product Sales Revenue for the quarters ended December 30, 2019 and 2018.

	<b>Quarters Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Licensing &amp; Other Fees</b>		
Baoxin	\$ 125,000	\$ 100,000
Cell Source	6,667	10,000
Personal Cell Sciences	—	614
<b>Total</b>	<b>\$ 131,667</b>	<b>\$ 110,614</b>
<b>Product Sales</b>		
Baoxin	\$ 1,460	—
<b>Total</b>	<b>\$ 1,460</b>	<b>—</b>

**American CryoStem Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2019**  
**Unaudited**

**NOTE 3. Revenue Recognition (continued)**

**Performance Obligations**

At contract inception, we assess the goods and services promised in our contracts and identify the performance obligations for each promise to transfer to the customer goods or to provide the customer with a service that is distinct. To identify the performance obligations, we consider all of the goods and services promised in the contract regardless of whether they are specifically stated or are implied by customary business practices. We determined that the following distinct goods or services represent separate performance obligations:

- ATGRAFT and ATCELL Customer Tissue Processing Fees
- ATGRAFT and ATCELL Customer Storage Fees
- Licensing and other Fees
- Supply of our Tissue Collection, Processing and Storage Products to Baoxin and CryoViva

We principally sell our products to end users, who have agreements with us to utilize our processing and storage technology. We provide processing and storage services to individual customers. We charge various fees for consulting services or licensing of our technologies; which includes processing and storage agreements, arrangements with biotechnology processing facilities for the provision of our services within a limited geographic area.

For the customers that purchase our Tissue Collection, Processing and Storage Products we transfer control at the point in time when the goods are shipped from our facility, shipping costs are paid by the customer and these costs are not accrued when the related revenue is recognized.

*Variable Consideration*

Under ASC 606, we are required to make estimates of the net sales price, including estimates of variable consideration (such as rebates and discounts) and recognize the estimated amount as revenue when we transfer control of the product or provide the service to our customers. Variable Consideration must be determined using either an "expected value" or a "most likely amount" method. At the current time the Company does not offer rebates or discounts on our provision of ATGRAFT and ATCELL customer processing and storage fees; Licensing and other Fees; and offer Tissue Collection, Processing and Storage products; therefore we have not made any provisions for variable consideration related to discounts or rebates.

*Product Returns*

We only offer product returns in the event a delivered product is found to be defective for which we offer replacement only. The Company has not had any product returned based upon a defective product claim however return experience may change over time.

**NOTE 4. 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 8,761,500 and 12,306,500 shares of Common Stock issuable upon exercise of all outstanding stock options and warrants for the quarters ended December 31, 2019 and 2018, respectively; and 134,784 and 1,680,237 shares issuable on the conversion of outstanding Convertible Notes for quarters ended December 31, 2019 and 2018, respectively.

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

	<b>3 months</b>	<b>3 months</b>
	<b>Dec 31, 2019</b>	<b>Dec 31, 2018</b>
Net Loss	\$ (141,109)	\$ (294,430)
Weighted average shares outstanding, basic and diluted	49,503,304	48,224,018
Basic & fully diluted net loss per common share	\$ (0.005)	\$ (0.006)

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**NOTE 5. Fixed Assets**

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

	December 31, 2019	September 30, 2019
Laboratory Equipment	\$ 257,904	\$ 386,579
Laboratory Leasehold Improvements	110,286	110,286
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	(266,061)	(289,078)
Net Property and Equipment	<u>\$ 132,420</u>	<u>\$ 238,078</u>

Depreciation expense for quarters ended December 31, 2019 and 2018 were \$1,459 and \$6,722.

**NOTE 6. 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. Amortization Expense for the quarters ended December 31, 2019 and 2018 were \$1,424 and \$949, respectively.

Patents still in the application process have not been amortized. The unamortized costs of patents in the application process are \$290,318 as of December 31, 2019 and \$288,882 as of September 30, 2019. Amortizable Patent Costs were \$96,000 at December 31, 2019 and \$96,000 at September 30, 2019.

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.

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.

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**NOTE 6. Patent & Patents Filings (continued)**

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

Human Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells, International PCT filing PCT/US/68350 filed December 31, 2015 with a priority date of December 31, 2014. During 2017 the Company extended the filing into China, the EU, India, Japan, the Kingdom of Saudi Arabia, Canada and Mexico.

**NOTE 7. Debt**

The following table describes the Company's debt outstanding as of December 31, 2019:

<b>Debt</b>	<b>Carrying Value</b>	<b>Maturity</b>	<b>Rate</b>
Bridge Notes	\$ 226,500	Demand	8.00%
Convertible Notes @ 48 cents	\$ 168,000	Fiscal 2020	10.00%
Convertible Notes @ 40 cents	\$ 100,000	Fiscal 2020	8.00%
Convertible Notes @ 35 cents	\$ 83,500	Demand	8.00%
Convertible Notes @ 33 cents	\$ 150,000	Demand	5.00%
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%
Finance Lease Liability	\$ 53,941	Fiscal 2021	14.00%

The convertible notes are exercisable at any time and have exercise prices ranging from \$0.15 to \$0.48 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 Quarters Ended December 31, 2019 and 2018 were \$12,500 and \$12,500, respectively. The note is discounted due to the Beneficial Conversion Feature in the amount of \$12,500 as of December 31, 2019 and \$25,000 as of September 30, 2019.

In April 2019, the Company issued debentures and received proceeds of \$150,000. The debentures mature in 2021 and have an exercise price of \$.33 with interest at 5%. The entire Carrying Value of \$150,000 is due in Fiscal 2021.

As a result of the issue, the Company recognized interest expense of \$61,364 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, 2019 was \$8,191. The note is discounted due to the Beneficial Conversion Feature in the amount of \$39,521 as of December 31, 2019 and \$47,712 as of September 30, 2019.

On October 3, 2019, the Company issued a debenture and received proceeds of \$168,000, with interest at 10%. The Note is convertible at the rate of \$0.48 per share for the initial 180 days; and thereafter at a 30% discount to the average of the three lowest trading prices during the 10 trading days prior to the date of conversion. The entire Carrying Value of \$168,000 is due in Fiscal 2020. We recorded a debt discount of \$168,000 and a Derivative liability of \$260,951 at inception. Debt Discount of \$42,000 was amortized for the quarter. The Gain in the value of the Derivative Liability was \$1,873 for the quarter.

The Company used the American Option Binomial Tree Pricing model to estimate the fair value of the derivative liability as of the date of issuance and as of December 31, 2019, using the following key inputs: market price of the Company's common stock \$0.32 per share, volatility of 176.56% and discount rate of 2.25%. The fair value of the derivative was determined to be \$259,078 as of December 31, 2019.

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**Note 8. Common Stock Issuances**

During the quarter ended December 31, 2018, the Company issued 116,667 shares and received proceeds of \$35,000. The share price was \$0.30 per share. The share price was determined by agreement with the purchasers, based upon the current market price less a discount for purchasing restricted securities.

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.

During the quarter ended December 31, 2019, the Company issued 875,000 shares and received proceeds of \$175,000. The share price was \$0.20 per share. The share price was determined by agreement with the purchasers, based upon the current market price less a discount for purchasing restricted securities.

**NOTE 9. Option Issuances**

The Company applies ASC 718, "Accounting for Stock-Based Compensation" to account for its option issues. Accordingly, all options granted are recorded at fair value using a generally accepted option pricing model at the date of the grant. The Company uses the Black-Sholes option pricing model to measure the fair values of its option grants. For purposes of determining the option values at issuance, the fair value of each option granted is measured at the date of the grant by the option pricing model using the parameters of the volatility of the Company's share prices and the risk free interest rate. The 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 for the quarter ended December 31, 2018. The company did not issue any options for the quarter ended December 31, 2019.

	<u>Amount</u>	<u>Exercise Price Range</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Term (Yrs)</u>
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	<u>12,306,500</u>	\$0.05 - \$0.40	\$ 0.26	2.10
Outstanding at September 30, 2019	8,761,500	\$0.05 - \$0.40	\$ 0.26	1.85
Granted	—			
Exercised	—			
Expired	—			
Forfeited	—			
Outstanding at December 31, 2019	<u>8,761,500</u>	\$0.05 - \$0.40	\$ 0.26	1.80

All outstanding stock options at December 31, 2019 are vested and exercisable.

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**NOTE 10. Fair Values of Financial Instruments**

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

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

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

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

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

The Company valued Accounts Receivable, Bridge Notes and Convertible Notes at cost. Financial instruments' carrying value approximates fair value. Stock Options and Derivative Liability are valued using level 3 of the fair value hierarchy.

**Note 11. Leases**

The Company determines whether a contract is or contains a lease at inception of the contract and whether that lease meets the classification criteria of finance or operating lease. When available, the Company uses the rate implicit in the lease to discount lease payments to present value; however, one of the Company's leases does not provide a readily determinable implicit rate. Therefore, the Company must discount lease payments based on an estimate of its incremental borrowing rate which is based on the interest rate of similar debt outstanding. Effective October 1, 2019, the Company adopted the provision of ASC 842 Leases.

**Finance Lease**

The Company leases Equipment at its laboratory from NFS Leasing, Inc. The final lease payment is scheduled for May 1, 2021. When the final payment is made, the Company will own the equipment. The table below presents the lease related asset and liability recorded on the Company's consolidated balance sheets as of December 31, 2019:

	<u>Classification on Balance Sheet</u>	<u>December 31, 2019</u>
<b>Assets</b>		
Finance Lease Asset	Finance lease right of use asset	\$ 98,072
<b>Total Finance lease assets</b>		<b>\$ 98,072</b>
<b>Liabilities</b>		
<b>Current Liabilities</b>		
Finance lease liability	Current finance lease liability	\$ 36,948
<b>Noncurrent liabilities</b>		
Finance lease liability	Long-Term finance lease liability	16,993
<b>Total operating lease liability</b>		<b>\$ 53,941</b>

Lease obligations at December 31, 2019:

2020	\$ 31,677
2021	28,157
<b>Total Payments</b>	<b>59,834</b>
Amount representing interest	(5,893)
<b>Operating lease obligation, net</b>	<b>53,941</b>
Operating lease obligation, current portion	(36,948)
<b>Operating lease obligation, long-term portion</b>	<b>\$ 16,993</b>



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**Note 11. Leases (continued)**

The lease expense for the three months ended December 31, 2019 was \$8,232, which consisted of amortization expense of \$6,127 and interest expense of \$2,105. At December 31, 2019, the remaining lease term was 1.42 years (17 months) and the discount rate was 14.17%.

**Operating Lease**

The Company leases its office facility, in Eatontown, New Jersey, from Eaton Holdings LLC. The lease expires on April 30, 2021 and the Company can exercise a renewal option for an additional three years. The table below presents the lease related asset and liability recorded on the Company's consolidated balance sheets as of December 31, 2019:

	<b>Classification on Balance Sheet</b>	<b>December 31, 2019</b>
<b>Assets</b>		
Operating Lease Asset	Operating lease right of use asset	\$ 40,089
<b>Total Operating lease assets</b>		<b>\$ 40,089</b>
<b>Liabilities</b>		
<b>Current Liabilities</b>		
Operating lease liability	Current operating lease liability	\$ 29,665
<b>Noncurrent liabilities</b>		
Operating lease liability	Long-Term operating lease liability	10,424
<b>Total operating lease liability</b>		<b>\$ 40,089</b>

Lease obligations at December 31, 2019:

2020	\$ 23,850
2021	18,550
<b>Total Payments</b>	<b>42,400</b>
Amount representing interest	(2,311)
<b>Operating lease obligation, net</b>	<b>40,089</b>
Operating lease obligation, current portion	(29,665)
<b>Operating lease obligation, long-term portion</b>	<b>\$ 10,424</b>

The lease expense for the three months ended December 31, 2019 was \$7,950, which consisted of amortization expense of \$7,368 and interest expense of \$582. The cash paid under the operating lease during the three months ended December 31, 2019 was \$7,950. At December 31, 2019, the remaining lease term was 1.33 years (16 months) and the discount rate was 8%.

The Company leases its laboratory facility, in Monmouth Junction, New Jersey, from Princeton Corporate Plaza LLC. The lease expires on March 31, 2020 and the Company can exercise a renewal option for an additional 6 months. Since the lease obligation is less than twelve months, the Company does not report a lease related asset or liability for this lease. Rent paid for the laboratory facility for the three months ended December 31, 2019 was \$7,167.

**NOTE 12. Concentration of Credit**

The Company received 100% of its revenues in for the quarter ended December 31, 2019 from two clients, Baoxin and Cell Source and approximately 95% of its revenues in the quarter ended December 31, 2018 from the same two clients. The Company also had accounts receivable from Baoxin of \$450,000 at December 31, 2019 and \$300,000 at December 31, 2018. Due to the current economic and health conditions in China, including increased tariffs and the Corona virus, the Company is closely monitoring the impact of these circumstances.

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**NOTE 13. Investments**

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, 2019 and September 30, 2019. The Company annually reviews its investments for impairment. After reviewing recent investment transactions of Baoxin, the Company has determined that no impairment of its investment is necessary for the quarter ended December 31, 2019. Due to the current economic and health conditions in China, including increased tariffs and the Corona virus, the Company is closely monitoring the impact of these circumstances.

Baoxin will develop, own and operate multiple laboratory/treatment/training facilities in China using 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 a 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 14. 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 \$204,387 as of December 31, 2019 and \$210,520 and as of September 30, 2019. 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. Management does not foresee paying the accrued amounts until the Company has adequate funds to do so.

**NOTE 15. Subsequent Events**

The Company has made a review of material subsequent events from December 31, 2019 through the date of issuance of this report. There are no subsequent events to report as of the issuance of these financial statements.

## 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. To this end, we have licensed affiliates operating on our cellular collection-processing and storage platform in Tokyo, Japan, Thailand, Hong Kong, and China. Significant to our efforts to advance our technology and business methods, the Company filed its first Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) for our ATCELL cellular therapy product. The IND filing is titled “*ATCell™ Expanded Autologous Adipose Derived Mesenchymal Stem Cells deployed via Intravenous Infusion for the Treatment of Post Concussion Syndrome (PCS) in Retired Athletes and Military Personnel*” File number 19089 was accepted for review by the FDA on October 22, 2019. In advance of the filing the Company built and validated a new cGMP clean room processing and manufacturing area at our facility in Monmouth Junction NJ, implemented and validated new Standard Operating Procedures and installed a new Quality Management System.

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.

## 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™* 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®* Collection, Transportation, and Storage System and *ACSelerate™* 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 tissue collection boxes (CELLECT®), and patented media products (ACSelerate™).

**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. The CELLECT<sup>®</sup> service is included in our granted patent “Business Method for Collection, Processing, Cryogenic Storage and Distribution of a Biologic Sample Material” US Patent Number 10,014,079, issued July 3, 2018.

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 promotes this standard in all laboratories that license or utilize our technology.

**ATGRAFT<sup>™</sup> Adipose Tissue Storage Service** – A clinical fat storage solution allowing physicians to provide their patients with multiple tissue and cell storage options. The ATGRAFT<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup>” for use in Regenerative medicine applications. The ATGRAFT<sup>™</sup> service is included in our granted patent “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 Company charges standardized fees for ATGRAFT<sup>™</sup> 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<sup>™</sup> tissue sample of 25ml or greater be reprocessed utilizing the Company’s ATCELL<sup>™</sup> and Autokine-CM<sup>™</sup> processing. The Company charges fees for the reprocessing of a 25ml stored ATGRAFT<sup>™</sup> sample and may charge additional fee’s if expansion of the newly created ATCELL<sup>™</sup> sample is also requested.

The Company believes the ATGRAFT<sup>™</sup> service may create significant revenue opportunities and patient retention for the participating physician. The ATGRAFT<sup>™</sup> 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<sup>™</sup> 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, 2016.

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 also is prepared to research samples of its ATCELL™ cell products to users of its ACSelerate™ cell culture media for application development.

The Company filed its first Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) for the ATCELL cellular therapy product titled "*ATCell™ Expanded Autologous Adipose Derived Mesenchymal Stem Cells deployed via Intravenous Infusion for the Treatment of Post Concussion Syndrome (PCS) in Retired Athletes and Military Personnel*", File number 19089, which was accepted for review by the FDA on October 22, 2019. The Company has received initial comments from the FDA regarding this application and is in the process of preparing responses. The Company will update the IND application upon completion of the responses for review by the FDA.

**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.

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

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

The Company continues to optimize additional versions of *ACSelerate*<sup>™</sup> media through further research and testing to develop medium versions for differentiation of ATCELL<sup>™</sup> ADSCs into neural, lung and other specific cell types that may be necessary for use in future clinical applications. On December 31, 2014 the Company filed a patent application for an advanced medium formulation titled Human Albumin Serum for Cell Culture Medium for Clinical Growth of Human Adipose Stromal Cells. (US Serial No. 62/098799). On December 31, 2015, the Company converted the provisional application to an international PCT filing (PCT/US/68350) under the title Human Serum for Cell Culture for Clinical Growth of Human Adipose Stromal Cells. To date the patent has also been filed in the following additional countries: China and Hong Kong, India, Mexico, Brazil, the European Union, US, Japan, Thailand, Brazil, Russia, Australia, New Zealand, Canada, and Saudi Arabia.

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

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

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

<https://www.transparencymarketresearch.com/pressrelease/stem-cells-market.htm>

## **China**

On July 12, 2018 the Company announced the national launch of CRYO's ATGRAFT<sup>™</sup> 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<sup>™</sup> 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 approximately 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. Mr. Arnone resigned as a board Member of Baoxin in 2019. Mr. Dudzinski continues to serve the Company's interests as a board member of Baoxin.

## **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<sup>™</sup> 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<sup>™</sup> storage media, CELLECT<sup>™</sup> 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 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.

The Company has been assisting CRYOVIVA with the development of their branding and marketing campaign for Thailand and providing technical assistance and support for their import of consumables purchased from the Company. CRYOVIVA has scheduled the launch of its marketing campaign for the first quarter of 2020 and the Company believes that it will see an increase in the sale of consumables and licensing fees from CRYOVIVA in fiscal 2020.

## **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 AGRAFT™ tissue processing and storage technology and the purchase of our CELLECT® collection products which include our ACSelerate-TR™ transport medium. The Company also assisted CellSource in upgrading its facility in Japan and provided training in 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.

The Company filed its first Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) for the ATCELL cellular therapy product. The IND filing is titled "ATCell™ Expanded Autologous Adipose Derived Mesenchymal Stem Cells deployed via Intravenous Infusion for the Treatment of Post Concussion Syndrome (PCS) in Retired Athletes and Military Personnel", File number 19089, which was accepted for review by the FDA on October 22, 2019. The Company upon Phase 1 approval by FDA intends to invite additional developers of cellular therapies to initiate additional arms of the clinical study focused on the use of ATCELL for use in systemic inflammatory response relief for patient suffering from systemic diseases. A number of these additional study targets have been identified and ongoing discussions support the Company's belief that additional investigations can be developed and rapidly added upon completion of the new study protocol and outcome assessment methodologies.

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

PeproTech, Inc.

On April 4, 2016 the Company entered into an Agreement with PeproTech, Inc of Rocky Hill, NJ. Under the Agreement PeproTech manufactures, markets and distributes the Company's ACSelerate – Max cell growth medium. The Company and PeproTech completed the optimization and scale up manufacturing studies and the licensed medium is marketed under both PeproTech's, PeproGrow and the Company's ACSelerate MAX™ brands. PeproTech 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 PeproTech are discussing the licensing of additional American CryoStem patented media and products for production and distribution by PeproTech, any additional media licensed to PeproTech will undergo similar optimization and scale up production testing prior to being released for sale. The Company is in ongoing discussion with PeproTech related to increasing the visibility and sales of the medium and the optimization of additional medium products focused on the differentiation of adult stem cells that are synergistic to the cell culture medium.

#### **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 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 paid the Company for the processing and storage of each sample generated by COI network physicians. COI planned 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 incorporated 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. This initial work will become the basis for Investigational New Drug and Investigational Device Exemption filings with the FDA. In January 2018 the Company ceased shipping all ATCELL products in response to a warning letter issued to the Company by 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 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 ceased shipment of its ATCELL™ product within the United States and entered into discussions with the FDA concerning the filing of an IND. Since the Company's initial response to the Warning letter it has spent considerable time and effort to comply with the concerns and observations highlighted in the letter. Specifically the Company designed and filed its first Investigation New Drug Application with FDA which was accepted for review on October 22, 2019. Additionally, the Company has implemented, qualified and validated as appropriate its completely redesigned its manufacturing SOPs and Quality Management program and new clean manufacturing space in its facility in Monmouth Junction, N.J, The Company has completed its final responses to FDA regarding the Warning Letter which was delivered to FDA OTAT in January 2020.

#### **Additional Collaborations**

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

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

## Intellectual Property

From the Company's formation, our strategy has been to invest time and capital in intellectual property protection. This strategy is intended to strengthen our Company's foundation in any defensive or offensive legal challenge. In addition, we are developing our IP portfolio to ensure and enhance our business flexibility and allow us to gain favorable terms in potential future collaborative partnerships with third parties. Our intellectual property portfolio currently includes 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:

Title	Technology	Patent / Application Number
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 Continuation of US Patent No. 7,989,205
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Continuation of Granted Patent covering additional improvements	US Patent Application No. 15/344,805 Continuation of US Patent No. 7,989,205
Human serum for cell culture medium for growth of human adipose stromal cells	A cell culture medium for growth of human adipose stromal cells for human and therapeutic applications	PCT/US15/68350 30 month National Phase entry date of June 31, 2017, additional International Filings for China, India, the European Union, Saudi Arabia, Israel, Brazil, Mexico, Australia and New Zealand.
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology Covers CELLECT Kit, Transport and Cryopreservation Medium for ATGRAFT and ATCELL Products	US Serial No 13/194,900 Filed June 6, 2010 Patent Application Published December 5, 2013 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 Continuation covering Improvements	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/194,900 imminent (PCT Application filing planned)
Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation	Adipose Tissue Digestion Laboratory Processing Methods	U.S. Serial No. 13/646,647 filed October 6, 2011, Claims Granted US Patent No.10,154,664 December 18,2018. Continuation filed upon issuance.
Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation	Adipose Tissue Digestion Laboratory Processing Methods	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/646,900 imminent (PCT Application filing planned)
Compositions and Methods for collecting, Washing, Cryoprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures"	Company Adipose Tissue Storage Platform for Cosmetic Procedures Covers the core processing adipose tissue for ATGRAFT adipose tissue dermal filler product	U.S. Serial No. 14/406,203 National Phase entry date of December 5, 2014 based on PCT/US2013/044621  European Union Application No. EPI3800847.9 China Application No. 2013800391988
Compositions and Methods for "Collecting, Washing, Cryoprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures"	Company Adipose Tissue Storage Platform for Cosmetic Procedures Covers additional claims related to ATGRAFT process not included in original application	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 14/406,203 imminent (PCT Application filing planned)

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

Patent Title	Use of Patent	Application Number
Cosmetic compositions including tropoelastin isomorphs (wound healing)	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #5,726,040
Cosmetic compositions (wound healing)	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #6,451,326
Recombinant hair treatment compositions (wound healing)	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO #6,572,845
Wound healing compositions and methods using tropoelastin and lysyl oxidase (wound healing)	Protein Genomics and American CryoStem (Autogenesis) collaboration	USPTO: #6,808,707
Business methods, processes and systems for collection, cryogenic storage and distribution of cosmetic formulations from an obtained stem cell based a biological (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. 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 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 paid the Company for the processing and storage of each sample generated by COI network physicians. COI planned 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 incorporated 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. In January 2018 the Company ceased shipping its ATCELL™ product to Cells on Ice.

## Physician Network

The Company continues to develop relationships to leverage our products and services through existing cosmetic surgery and regenerative medicine practices. The Company continues its efforts to develop and expand its network of individual physicians and surgeons seeking to adopt the Company's products and services focusing on surgeons performing liposuction, tissue transfer and regenerative procedures involving the use of adipose tissue. The Company intends to expand its efforts to 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<sup>®</sup>, ATGRAFT<sup>™</sup> and ATCELL<sup>™</sup> services in their local market. Strategically, the Company's international licensees will maintain the branding of the Company's services along the lines of the "Intel Inside" branding program.

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

Licensing programs may be initiated through a letter of intent (LOI) agreement between the Company and the prospective licensee. This LOI agreement is designed for due diligence and facility qualifications purposes. The Company may receive an initial fee under the agreement which may or may not be credited toward future royalty payments. Following evaluation of the prospective licensee the Company will enter into a final Agreement which outlines all upfront fees, minimum royalties and consumable purchase obligations of the Licensee.

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

## Cryoviva (Thailand) Ltd

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

American CryoStem licensed to Cryoviva (Thailand) Ltd., established in 2007, the rights to utilize the Company's Standard Operating Procedures (SOP's) to create and market the Company's ATGRAFT<sup>™</sup> tissue storage service and ATCELL<sup>™</sup> 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<sup>™</sup> and ATCELL<sup>™</sup> sample processing including CRYO's ACSelerate<sup>™</sup> non-DMSO cryogenic tissue storage media, transportation media, Collect<sup>™</sup> tissue collection kit, and ACSelerate – Max<sup>™</sup> cell culture medium.

The Company has been assisting CRYOVIVA with the development of their branding and marketing campaign for Thailand and providing technical assistance and support for their import of consumables purchased from the Company. CRYOVIVA has scheduled the launch of its marketing campaign for the first quarter of 2020 and the Company believes that it will see an increase in the sale of consumables and licensing fees from CRYOVIVA in fiscal 2020.

#### **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. During 2019 Mr. Arnone resigned from the board of Baoxin.

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

In the second quarter of 2015 the Company entered into negotiations with CellSource, LLC in Tokyo, Japan for the licensing of its ATGRAFT™ products and services and on June 2, 2015 the Company and Cell Source entered into an initial term sheet licensing the ATGRAFT™ technology to CellSource for Japan. 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 2020 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, 2019 increased to \$133,127 versus \$115,391 in the same period of Fiscal 2018, an increase of 15.4%. Licensing Revenue increased to \$131,667 compared to \$110,614 in Fiscal 2018, an increase of 19%.

Operating expenses decreased to \$217,882 for the quarter ended December 31, 2019, from \$371,788 for the same period in Fiscal 2018 a decrease of 41.3%. The main cause for the decrease was management's continued efforts to reduce Company overhead.

Interest expense for the quarter ending December 31, 2019 increased to \$42,278 as compared to \$28,953 for the same period last year reflecting the issuance of new debentures. The interest expense for the quarter ended December 31, 2019 and December 31, 2018 includes an additional \$20,691 and \$12,500 respectively for the effects of the beneficial conversion feature associated with debenture holders.

Net loss for the first quarter of Fiscal 2019 was \$271,860 compared to a net loss of \$294,340 for the first quarter of Fiscal 2018, a decrease of 7.6% for the same period of 2018. The loss for the first quarter of Fiscal 2019 includes \$92,951 of derivative liability associated with the issuance of a new convertible note. See Note 7 Debt: to the financial statements.

## Liquidity and Capital Resources

As of December 31, 2019, the Company had a cash balance of \$82,205, an increase of \$58,405 since September 30, 2019, our fiscal year end. Operations used \$268,572 of our cash. We used \$1,436 in cash for investments, all for patent development and maintenance. The main sources of cash provided by financing activities included new equity and note issuances of \$343,000.

Our accounts receivable increased to \$450,000 at December 31, 2019 from \$330,154 at September 30, 2019 mainly due to an increase in receivables from Baoxin for licensing fees. Due to the current economic and health conditions in China, including increased tariffs and the Corona virus, the Company is closely monitoring the impact of these circumstances.

Convertible debt increased to \$579,000 an increase of \$180,500 since September 30, 2019, \$20,691 was due to the effects of amortizing the beneficial conversion feature of these notes, and \$ 168,000 was the issuance of additional convertible notes. See Note 7: Debt to the financial statements.

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 or cease them entirely. We cannot assure you that we will generate the necessary funding to operate or develop our business. Please see "Cash Requirements" below for our existing plans with respect to raising the capital we believe will be required. In the event that we are able to obtain the necessary financing to move forward with our business plan, we expect that our expenses will increase significantly as we attempt to grow our business. Accordingly, the below 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, 2019.

### **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 and recorded a payable of \$166,667 in accounts payable. 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**

Effective October 1, 2019, the Company adopted the provision of ASC 842 Leases. The Company determines whether a contract is or contains a lease at inception of the contract and whether that lease meets the classification criteria of finance or operating lease. When available, the Company uses the rate implicit in the lease to discount lease payments to present value; however, one of the Company's leases does not provide a readily determinable implicit rate. Therefore, the Company must discount lease payments based on an estimate of its incremental borrowing rate which is based on the interest rate of similar debt outstanding.

#### **Finance Lease**

The Company leases Equipment at its laboratory from NFS Leasing, Inc. The final lease payment is scheduled for May 1, 2021. When the final payment is made, the Company will own the equipment. See Note 11: Leases of the financial statements.

#### **Operating Lease**

The Company leases its office facility, in Eatontown, New Jersey, from Eaton Holdings LLC. The lease expires on April 30, 2021 and the Company can exercise a renewal option for an additional three years. See Note 11: Leases in the financial Statements.

The Company leases a laboratory facility, in Monmouth Junction, New Jersey, from Princeton Corporate Plaza LLC. The lease expires on March 31, 2020 and the Company can exercise a renewal option for an additional 6 months. The rent is \$2,389 per month. Total rent paid for the laboratory facility for the three months ended December 31, 2019 was \$7,167.

Since the lease obligation is less than twelve months, the Company does not report a lease related asset or liability for this lease.

The Company was not party to any litigation against it and is not aware of any litigation contemplated against it as of December 31, 2019. See also Legal Proceedings below.

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, 2019, the Company was indebted to a company that is majority owned by the Company's two chief executive officers for \$204,387. The advances are due on demand, are unsecured, and carry no interest rate. and the advances are 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. See Note 1 and Note 3 to the Financial Statements for more information.

#### **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 2016-02, *Leases (Topic 842)*. ASU 2016-02 which requires lessees to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months; and requires expanded disclosures about leasing arrangements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods in fiscal years beginning after December 15, 2018, with early adoption permitted. ASU 2016-02 and additional ASUs are now codified as Accounting Standards Codification Standard ("ASC") 842 - *Leases* ("ASC 842"). The Company adopted ASC 842 on October 1, 2019 and used the modified retrospective transition approach and did not restate its comparative periods. As of the date of implementation on October 1, 2019, the impact of the adoption of ASC 842 resulted in the recognition of a Finance Lease Right-of-Use-Asset and an Operating Lease Right-of-use-Asset and corresponding Lease Liability Obligations on the Company's consolidated balance sheets. The Company elected to not recognize lease assets and lease liabilities for leases with an initial term of 12 months or less.

As the Right of use asset and the corresponding Lease Liability obligation were the same upon adoption of ASC 842, there was no cumulative effect impact on the Company's accumulated deficit. Since the Equipment Asset related to the Capital Lease and the Finance Lease Asset established had different values, the Company recorded a cumulative effect modification on October 31, 2019 by a reducing equity (increasing the accumulated deficit) by \$41,804.

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 2 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.

In November 2018, the FASB issued ASU 2018-18, *Clarifying the Interaction between Topic 808 and Topic 606*. This new ASU applies to companies that have collaborative arrangements, or agreements that involve two parties that actively participate in a joint operating activity. We believe our contract with Baoxin falls under the collaborative arrangements guidance in (ASC 808). ASU 2018-18 is effective for public companies for years beginning after December 15, 2019. The Company plans to implement ASU 2018-18 in Fiscal 2021 and begin reporting revenue for the Baoxin Contract according to ASU 2018-18 in that Fiscal Year.

## 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

The Company's disclosure controls and procedures are designed to ensure (i) that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms; and (ii) that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2019 and concluded that the disclosure controls and procedures were effective as a whole.

### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

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

We are currently not involved in any litigation that we believe could have a material adverse effect on our financial condition or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of our company or any of our subsidiaries, threatened against or affecting our Company, our common stock, any of our subsidiaries or of our companies or our subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

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

Not applicable.

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

During the quarter ended December 31, 2018, the Company issued 116,667 shares and received proceeds of \$35,000. The share price was \$0.30 per share. The share price was determined by agreement with the purchasers, based upon the current market price less a discount for purchasing restricted securities.

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.

During the quarter ended December 31, 2019, the Company issued 875,000 shares and received proceeds of \$175,000. The share price was \$0.20 per share. The share price was determined by agreement with the purchasers, based upon the current market price less a discount for purchasing restricted securities.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

(a) Exhibits furnished as Exhibits hereto:

<b>Exhibit No.</b>	<b>Description</b>
31.1	<a href="#"><u>Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
31.2	<a href="#"><u>Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
32.1	<a href="#"><u>Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>

**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, 2020

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

February 19, 2020

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

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, John Arnone, certify that:

1. I have reviewed this Form 10-Q of American CryoStem Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods present in this report;
4. Along with the Principal Accounting Officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 19, 2020

By: /s/ John Arnone

John Arnone  
Principal Executive Officer  
American CryoStem Corporation



**CERTIFICATION OF PRINCIPAL ACCOUNTING OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Anthony Dudzinski, certify that:

1. I have reviewed this Form 10-Q of American CryoStem Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods present in this report;
4. Along with the Principal Executive Officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 19, 2020

By: /s/ Anthony Dudzinski  
Anthony Dudzinski  
Principal Accounting Officer  
American CryoStem Corporation

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF  
THE SARBANES-OXLEY ACT OF 2002**

In connection with this Quarterly Report of American CryoStem Corporation (the "Company"), on Form 10-Q for the three months ended December 31, 2019, as filed with the U.S. Securities and Exchange Commission on the date hereof, I, John Arnone, Chief Executive Officer of the registrant and Anthony Dudzinski, Chief Financial Officer of the registrant, certify to the best of my knowledge, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) Such Quarterly Report on Form 10-Q for the three months ended December 31, 2019 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in such Quarterly Report on Form 10-Q for the three months ended December 31, 2019 fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 19, 2020

By: /s/ John Arnone

John Arnone  
Chief Executive Officer  
American CryoStem Corporation

February 19, 2020

By: /s/ Anthony Dudzinski

Anthony Dudzinski  
Chief Financial Officer  
American CryoStem Corporation