SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AMERICAN CRYOSTEM Corp

Form: 10-K

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

FORM 10-K

☑ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended September 30, 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	**26-4574088**
(State or Other Jurisdiction of Incorporation or Organization)	(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)

Securities registered pursuant to Section 12(b) of the Act: **None**

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

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

Common Stock, par value $0.001

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically 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). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☑	Smaller Reporting Company	☑
		Emerging Growth Company	☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Act). Yes ☐ No ☑

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. Based on a closing price of $0.44 on March 29, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $21,730,683.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of January 11, 2020, the registrant had 50,262,918 shares of its common stock, par value $0.001, outstanding.

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FORWARD LOOKING STATEMENTS

Included in this Form 10-K are “forward-looking” statements, as well as historical information. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot assure you that the expectations reflected in these forward-looking statements will prove to be correct. Our actual results could differ materially from those anticipated in forward-looking statements as a result of certain factors, including matters described in the section titled “Risk Factors.” Forward-looking statements include those that use forward-looking terminology, such as the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “project,” “plan,” “will,” “shall,” “should,” and similar expressions, including when used in the negative. Although we believe that the expectations reflected in these forward-looking statements are reasonable and achievable, these statements involve risks and uncertainties and we cannot assure you that actual results will be consistent with these forward-looking statements. We undertake no obligation to update or revise these forward-looking statements, whether to reflect events or circumstances after the date initially filed or published, to reflect the occurrence of unanticipated events or otherwise.

PART I

Item 1. Business.

Company Overview

History

We were 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 our common stock, par value $0.001 per share, 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 including, but not limited to, the appointment of our present officers and directors as well as the resignation by the former chief executive officer and sole director. Our fiscal year ends September 30 of each calendar year.

Upon the closing of the Asset Purchase: (i) ACS Global became our majority shareholder, (ii) John Arnone was appointed as our chief executive officer and president and Anthony Dudzinski was appointed as our chief operating officer, treasurer and secretary, and (iii) John Arnone and Anthony Dudzinski were appointed to our board of directors, with Mr. Arnone being appointed as Chairman of the Board. Mr. Dudzinski is also a director and the president and treasurer of ACS Global and Mr. Arnone is a director and secretary of ACS Global.

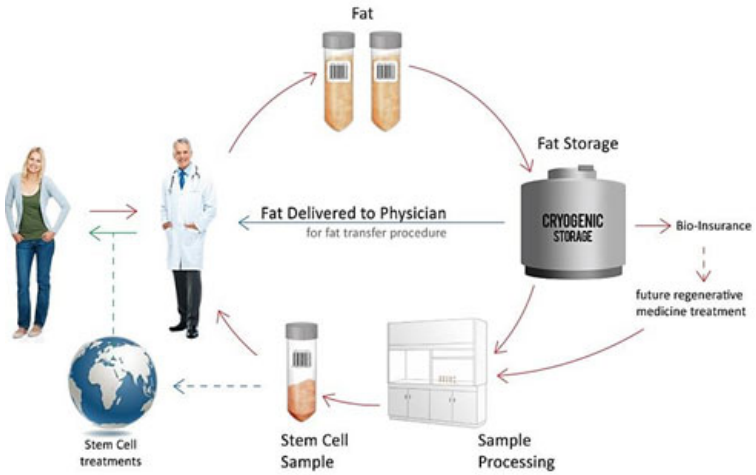
Our Business

About American CryoStem Corporation

American CryoStem Corporation; (CRYO) founded in 2008, has evolved to become a biotechnology pioneer, standardizing adipose tissue derived technologies (Adult Stem Cells) for the fields of Regenerative and Personalized Medicine. The Company operates a state-of-art, FDA-registered, laboratory in Monmouth Junction, New Jersey and licensed laboratories in Hong Kong, China, Japan, and Thailand which operate on our proprietary platform, dedicated to the collection, processing, bio-banking of adipose tissue (fat) and culturing and differentiation of adipose derived stem cells (ADSCs) for current or future use in regenerative medicine. CRYO maintains a strategic portfolio of intellectual property (IP) that surrounds our technology which supports a growing pipeline of stem cell applications and biologic products. We are leveraging our platform and a developed product portfolio to create a domestic and global footprint of licensed laboratory affiliates, physicians networks, patients and research organizations who purchase tissue collection, processing and storage consumables from our Company. Our laboratory stem cell products foundation are characterized adult human Mesenchymal Stem Cell (MSC’s) derived from adipose tissue that work in conjunction with our patented (non-animal) medium lines.

The Company believes the reproducibility of scientific studies has become a substantial issue in life science research from drug discovery and development through trials as researchers throughout the world continue to use different protocols for processes associated with sample preparation, cryopreservation and cold chain management. We believe the scientific community is becoming more aware of factors that affect sample integrity and experimental variability. By standardizing handling, storage, and transportation protocols we can substantially improve the quality and reproducibility of adipose tissue and cell collection, processing, storage and retrieval which will help to accelerate the transition from lab research to therapy 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, patented 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 stem cell therapies. Currently, we believe there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments 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 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 CELLECT® tissue collection boxes, and patented media products.

***CELLECT*® Collection, Transportation, and Storage System** – An unbreakable "chain of custody" solution for physicians to collect and deliver tissue samples utilizing proprietary and patent pending methods and materials. The CELLECT® service is monitored in real-time and assures the highest cell viability upon laboratory receipt. The CELLECT® system incorporates our ACSelerate–TR™ transport medium into all collection bags which supports the health of the tissue during transport. The CELLECT® kit is an integral part of our ATGRAFT™ and ATCELL™ technology to be used by all licensees of our technologies. The CELLECT® 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® service the International Blood Banking identification, 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 laboratory facility. The Company will promote this standard in all laboratories that license or utilize our technology.

***ATGRAFT*™ Adipose Tissue Storage Service –** An adipose tissue (fat) collection, processing and storage solution allowing physicians to provide their patients with multiple tissue products and cell storage options. The ATGRAFT™ service, through one liposuction procedure allows individuals to prepare for multiple future cosmetic or regenerative procedures by using their own stored adipose tissue as a natural biocompatible filler, or the components for multiple cellular therapy application without the trauma of further liposuctions. ATGRAFT™ procedures may include breast reconstruction, layered augmentation, buttocks enhancement or volume corrections of the hands, feet, face and neck areas that experience significant adipose tissue (fat) volume reduction as we age. ATGRAFT™ is processed and stored utilizing our standards so that any stored fat tissue sample may be retrieved in the future and re-processed to create stem cells, "ATCELL™", for use in Regenerative Medicine applications. The ATGRAFT™ 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's charges standardized fees for *ATGRAFT™* tissue processing and minimum annual storage fees depending on the volume of tissue processed. These processing and storage fees may be paid by the collecting/treating physician or the consumer. The Company earns additional fees upon sample retrieval, for the thawing, packaging and shipment of the stored samples to the physician, clinic or "point-of-care" for immediate use upon receipt. Additionally, physicians may request that any stored ATGRAFT™ tissue sample of 25ml or greater be reprocessed utilizing the Company's ATCELL™ and Autokine-CM™ processing to create therapy or cosmetic products, on-demand.

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

***ATCELL*™ Adipose Derived Stem Cells (ADSCs) –** Processed and characterized adipose derived regenerative cells (ADRCs) created using the Company's proprietary Standard Operating Procedures (SOPs) and ACSelerate™ patented cell culture media. ATCELL™ is the Company's trademarked name for its ADRCs and differentiated cell products and processing methodology. The Company maintains for research purposes multiple master and differentiated cell lines and labels them according to their characterization, ie. ATCELL™ (adipose derived stem cells), ATCELL-SVF™ (stromal vascular fraction), ATCELL – CH™ (differentiated chondrocytes), etc. Cell lines may be custom created for patients desiring to store their cells for their own future use in Regenerative Medicine procedures. The Company charges its customers a fee to reprocess previously stored ATGRAFT™ (pure fat) samples and for newly collected client tissue samples to be processed into cellular samples. Customer samples are processed utilizing 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 8,20146.

The Company's ATCELL™ cell lines are processed and cultured in our patented ACSelerate ™ cell culture media. All CRYO processed samples; tissue, cells, and research materials made available for therapies, tissue transfer or sale to research institutions are tested for sterility, disease, lifespan, and population doubling rate (PDL). Additionally, we believe ATCELL™ cells are suited for any type of cellular therapy or regenerative medicine research. Cell morphology is confirmed by (i) flow cytometry and (ii) differentiation analysis using ACSelerate™ differentiation media. Each ATCELL™ line can be further cultured and differentiated allowing the Company to provide genetically matched 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 sought after by private researchers and universities for use in pre-clinical trial studies and in-vitro research due to our processing methodology, donor sample data, the ability to create multiple cell types that have identical genetic profiles, and achieving repeatable results. We believe the 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 the ability to focus on application development and avoid bench to commercialization delays. The Company is prepared to distribute 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. 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.

***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 of the Company's ACSelerate™ cell culture media lines are available in animal serum free, which may be suitable for human and therapeutic uses or available in a low serum version for application development and research purposes. The patented ACSelerate™ cell culture media line(s) 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 grade and FBS (research) grade. This patent covers both non-GMP research grades and GMP grades suitable for cell culture of adipose-derived stem cells. 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 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 supports its marketing efforts by making ATCELL ™ samples available for research purposes and for internal product development through our research programs. We believe these cell lines may be sought after by private researchers and universities for use in pre-clinical trial studies and in-vitro research. We also believe that the Company's ability to provide these materials for these research and development collaborators, partners and other third parties extends the Company's ability to become a primary source of grade materials and services necessary to support approved applications and treatments.

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

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

The Company continues to optimize additional versions of *ACSelerate™* media through further research that may be necessary for use in future applications. Many of these applications may not be currently approved by the US Food and Drug Administration. On December 31, 2014 the Company filed a patent application for an advanced medium formulation titled Human Albumin Serum for Cell Culture Medium for Growth of Human Adipose Stromal Cells. (US Serial No. 62/098799) representing the most recent results of this ongoing optimization program. On December 31, 2015, the Company converted the provisional patent application to an international PCT filing (PCT/US/68350) under the title Human Serum for Cell Culture for 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®* Anti-Aging, Autologous Skin Care Product Line – Under agreement with Personal Cell Sciences Corp. (PCS), we manufacture the key ingredient Autokine-CM® (autologous adipose derived stem cell conditioned medium) for PCS' U-Autologous ™ anti-aging topical formulation. Every product is genetically unique to the patient and custom blended, deriving its key ingredients from the individual client's own adipose derived stem cells. The Company provides its CELLECT® Tissue Collection service to collect the required tissue to manufacture the U-Autologous ™ product and processes it under the same Standard Operating Procedures (SOP's) that it developed for the ATGRAFT™ and ATCELL ™ cell processing services utilizing ACSelerate™ cell culture media. The Company receives collection, processing and long term storage fees and earns a royalty on all U-Autologous product sales. The utilization of the Company's core services in its contract manufacturing relationships provides opportunities for the Company to promote ATGRAFT ™ and ATCELL™ products.

CRYO'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 cellular therapies and regenerative medicine applications. The Company has received numerous international inquiries concerning the sale or licensing of our SOPs, products and services in the Regenerative Medicine and Medical Tourism Markets. The Company believes that the inquiries to date are a result of the global boom in Medical Tourism, Regenerative and Personalized 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, China, Thailand and, 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)

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.

China

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

The China launch activities are in support of the Company's previously announced licensing and supply agreement with Baoxin, under which Baoxin will pay the Company a minimum annual guarantee against a fixed fee per process and purchase certain necessary consumables from CRYO required for the collection, processing and storage of the collected adipose tissue. Under the terms of the Agreements signed in Fiscal 2018, the Company invested in and currently holds five percent (5%) of Baoxin shares. Additionally, Mr. Arnone and Mr. Dudzinski were elected to serve as Directors of Baoxin during their visit to Shenzhen, China 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™ tissue storage service for 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 reached further agreement to extend their relationship on a non exclusive basis to include HIT's cord blood laboratory located in Shenzhen, Guangdong Province, one of China's most successful Special Economic Zones. The HIT agreement includes, initial upfront fees and royalty payments for predetermined gross revenue volumes. HIT will also purchase CRYO ACSelerate™ storage media, CELLECT™ collection and transportation kits as well as other American CryoStem products necessary for clinical adipose tissue processing and storage at the Shenzhen facility. The final master licensing agreement is for a period of 5 years with renewal options and was executed between the parties on September 24, 2014.

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

Thailand

On April 5, 2018 the Company announced further expansion of its global laboratory and cellular technology footprint by entering into an agreement 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, Cellect™ 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.

Product Development

Our strategic approach to product development is to design, develop and launch new products and services that utilize our core processing technology, existing products and services, i.e. the use of the CELLECT® collection materials by contracted companies to collect fresh tissue for their product. Management believes that allowing other biotech companies to utilize portions of our platform will provide the Company with additional 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 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.

BioLife Customer and Physician Acquisition

In February 2015 the Company entered into a binding asset purchase agreement with BioLife Cell Bank Dallas, LLC and BioLife Cell Bank Management, LLC (collectively "BioLife"), to purchase all of BioLife's current adipose tissue, stem cell storage clients samples, and physician network. The transaction was concluded in March of 2015. Transfer of the adipose tissue samples was completed on April 24, 2015. The Company initiated annual storage fee billing to the acquired storage clients in June of 2015. Management believes that, with the acquisition of BioLife, the Company became one of the largest commercial adipose storage facilities in the United States. Additionally the Company acquired the physician customer list of approximately 60 cosmetic and plastic surgeons, and began marketing its services to all physician users of the BioLife services.

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 to study future use in Regenerative Medicine. COI is a physician network interested in the development and use of adipose tissue and adipose derived cellular samples in regenerative therapies and cellular medicine. The Company has agreed to distribute its Cellect collection boxes and provide its ATGRAFT™ and ATCELL ™ processing services under the COI brand for collection, processing and storage of tissue samples at its NJ facility. Under the agreement, COI will pay the Company for the processing and storage of each sample generated by COI network physicians. COI plans to seek regulatory approval for use of the stored samples in studies and trials utilizing adipose tissue processed into Stromal Vascular Fraction (SVF) and ultimately expanded adipose derived mesenchymal adult stem cells. The Company is incorporating its existing protocols 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. The company believes that COI has initiated several IRB approved studies. 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. (See Regulatory Information below)

Additional Collaborations

The Company recognizes the benefits of collaborations with industry and university partners and continues to seek these relationships. These relationships are generally covered by Confidential Non-Disclosure Agreements and include Material Transfer Agreements (MTA) under which the Company will supply ATCELL™ and/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 efforts or relationships will ultimately result in new technology for future commercialization.

Regulatory Information

On January 3, 2018 the Company received a warning letter from the U.S. FDA concerning its contract manufacturing services at its Monmouth Junction, NJ facility. The FDA informed the Company that the Agency has determined that its autologous adipose derived cell product, ATCELL™ is a drug under current FDA regulations and guidance. In response to the letter the Company ceased shipment of its ATCELL product within the United States and is currently in discussions with the FDA concerning the filing of an Investigational New Drug (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 it 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 is completing its final responses to FDA regarding the Warning Letter which we expect to file in early 2020.

In its ongoing efforts to address the concerns contained in the Warning Letter, the Company in expanded its existing facilities and undertook a complete remediation of its laboratory operations in expectation of a pending (IND) filing with the FDA for the use of autologous adipose derived cells for the relief of inflammation associated with certain conditions resulting from trauma. The Company has completed its Pre-IND meeting with FDA to clarify some of the requirements of the IND application process and necessary documentation. The Company leased additional space and is in the final stages of certifying and validating a new Clean Room designed specifically for cellular expansion, medium filling and tissue processing. In addition, the Company retained consultants to assist its personnel in the review and re-validation of its operating procedures, equipment and processing methods as well as designing new procedures for upgraded and newly acquired laboratory operating and testing equipment.

The Company's New Jersey laboratory facility is registered with the FDA (FEI 3008307548) as a processing and storage facility for Human Cells, Tissues and Cellular and Tissue Based Products (HCT/Ps) since 2010. In 2013, we registered the facility with the State of New York (CP169TP136) and the State of California (CNC80948) the only states in the U.S. requiring registration. We have discussed our operations with the State of New Jersey Health Department and Department of Environmental Protection (DEP) to ascertain any special regulations to which we may be subject. Based upon these discussions, and our use of a registered medical waste disposal company, we do not at this time have any special registrations or regulations for compliance with the State of New Jersey.

Our SOPs are the key to properly operating our tissue processing facility. In 2018 the Company hired a cGMP consultant to assist it with the update of all SOP's, data collection forms, Quality Control Program and laboratory operations to conform with cGMP in response to the observations made by FDA. To ensure delivery of the highest quality services, we incorporate these SOPs, which are designed to provide a basis for accreditation by the American Association of Blood Banks (AABB), the American Association of Tissue Banks (AATB) and the Foundation for the Accreditation of Cellular Therapy (FACT-JACIE).

We have consistently endeavored to ensure that our processes, methodologies and procedures remain among the highest standards in the global tissue collection, processing and storage market. To this end, we have equipped ourselves with state-of-the-art quality processing and testing equipment, which we believe helps to ensure that every sample collected and processed is sterile (free from adventitious agents), viable and capable of significant cellular growth and expansion.

Quality Management

The Company's quality management program attempts to ensure that during processing and testing of each adipose tissue, or cellular sample, the appropriate quality management tests and processing methodologies are performed and the data is collected, recorded and reviewed by the laboratory management team. In 2018 the Company hired a Quality Control consultant to assist the Company in updating its Quality Control Program, laboratory processes, SOPs, data collection, and laboratory, product and materials validation programs. The new system was completed, qualified and validated in 2019 and has been implemented in the new clean processing facility the Company qualified in 2019.

Chain of Custody Control

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

Testing Design and Standard Operating Procedures (SOPs)

Testing methods are standardized and operate under a complete set of SOPs and Quality Management (QM) processes. All SOPs are designed to be in compliance with the US Food and Drug Administration's regulations and guidance for aseptic processing. Strict QM is enforced to avoid and/or record any process deviations. In 2018 in response to the Letter received by the Company from the FDA, the Company undertook a major reorganization and upgrade of all of its methods, SOPs, processes and facility to upgrade its facility from a registered tissue bank to a Biologic Drug Manufacturer. This update was completed concurrently with the validation and qualification of the Company's new quality management system that was completed, validated and qualified in 2019.

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. 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)
Systems and methods to isolate and expand stem cells from urine	Isolation of stem cells from urine of patients for use in research and therapeutics	US Serial Nos. 62/335,426 and 62/439,106

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

Patent Title	Use of Patent	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®, CELLECT®* and *ATGRAFT™*. We plan to obtain additional registered trademarks for our future products, slogans and themes to be used in our marketing initiatives, including, for example, *ACSelerate-SFM™*, *ACSelerate- LSM™* and *ATCELL™.* The Company has also secured a number of online domain names relevant to its business, including www.americancryostem.com and www.acslaboratories.com.

Market Size and Opportunities

By leveraging and capitalizing on our proprietary Adipose Tissue Processing Platform, our Company is working to address multiple high growth, multi-billion dollar market opportunities prevailing within the Regenerative Medicine, Cosmeceuticals, Medical Tourism and Cell Culture Media markets. The Company regularly reviews independent market research to gauge the market size 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.

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 both print advertising and social media sales campaigns. In addition, we plan to continue to utilize key leaders, and early adopters in the medical community as a marketing resource to enhance awareness of our proprietary, patented products and services and to increase the number of surgeons who join our network, university and private collaboration and consumers who use our products and services.

We plan to continue direct marketing programs focused on reaching plastic and cosmetic surgeons to join our network of providers that 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.

Development of Regional U.S. Markets

Cells on Ice - In August of 2015 the company entered into a contract manufacturing Agreement with Cells On Ice, LLC. (COI) located in Los Angeles, California to process and store adipose tissue and adipose derived cellular samples. COI is a network of physicians interested in the safety and use of adipose tissue and adipose derived cellular samples in regenerative therapies and cellular medicine. The Company has agreed to supply its CELLECT™ collection boxes and provide its ATGRAFT™ and ATCELL™ services under the COI brand for the collection, processing and storage of tissue samples at its NJ facility. Under the agreement, COI will pay the Company for the collection, processing and storage of each sample generated by COI network physicians. COI plans to seek regulatory approval for use of the stored samples in studies and trials utilizing adipose tissue processed into Stromal Vascular Fraction (SVF) and ultimately expanded adipose derived mesenchymal adult stem cells. The Company is incorporating its existing protocols 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 regional relationships to leverage its new products and services through existing cosmetic surgery and regenerative medicine practices. The Company continues to develop and expand its network of physicians seeking to adopt its products and services, initially focusing on surgeons performing liposuction, tissue transfer and regenerative procedures involving the use of adipose tissue. The Company intends to continue expanding its efforts to medical professionals interested in tissue storage and Regenerative Medicine applications utilizing ASDCs and establish itself as a primary source of collection, processing, and preparation of cellular therapies as they are developed and approved for patient use by the FDA.

Development of International Markets

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

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

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

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

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

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.

Health Information Technology Company, LTD (Hong Kong) - On June 30, 2014 the Company granted Health Information Technology Company, LTD ("HIT") exclusive rights to utilize the Company's Standard Operating Procedures (SOP's) to market the Company's ATGRAFT™ tissue storage service for Hong Kong. The Agreement 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 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. The Company and HIT are in discussions concerning renewal and the licensing of additional technology by HIT.

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.

CRYOVIVA (Thailand), Ltd. - 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, Cellect™ tissue collection kit, and ACSelerate – Max™ cell culture medium.

CellSource 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.

Scientific and Medical Advisory Board

We continue to actively recruit and enlist the services of highly qualified peer leaders through our Scientific and Medical Advisory Board to assist us in our industry speaking engagements and education platform. This education platform is designed to focus on physicians, and industry needs and demands as they relate to current and future treatments utilizing our adipose tissue platform and adult stem cell technologies. Additionally, certain members of our advisory board provide assistance and input to management on the oversight of our research relationships, laboratory development and quality management systems. As of September 30, 2019, the following are currently members of our Scientific and Medical Advisory Board:

Dayong Gao, Ph.D. - Dr. Gao is a world-renowned Professor of Mechanical Engineering and Biomedical Engineering at the University of Washington in Seattle. He has been actively engaged in cryopreservation research for more than 20 years, with specific emphasis on fundamental and applied cryobiology, which is the investigation of mechanisms in cryo-injury and cryo-protection with respect to living biological systems at low temperatures; with the development of optimal methods and technologies for the cryopreservation; and with the banking of living cells and tissues for biomedical applications. Dr. Gao has published 175 research papers in prestigious scientific/biomedical journals, with over 250 papers/abstracts in conference proceedings. He has obtained 16 patents, and authored two scientific books and numerous chapters in 17 scientific books. He currently serves on the Editorial Board, as Editor-in-Chief, of six scientific journals, and is the Editor of the Cryopreservation Engineering section of *Biopreservation and Biobanking*. His research in cryobiology and cryopreservation has been funded by the National Institutes of Health, the American Cancer Society, the Bill and Melinda Gates Foundation, the American Heart Association, the Whitaker Foundation, the Washington Research Foundation and the Kentucky Science Foundation, among others. Dr. Gao graduated with B.Sc. degree from the University of Science and Technology in China, and received a Ph.D. in Mechanical Engineering from Concordia University, Montreal, Canada.

Dr. Fredric A. Stern, F.A.C.S. - Dr. Stern is the founder and Medical Director of the Stern Center for Aesthetic Surgery in Bellevue, Washington. Following his education at Columbia University Medical School, Dr. Stern earned his Board Certification in Ophthalmology at the University of Washington, and underwent extensive additional training in oculofacial plastic and laser surgery. In 1987, he joined Virginia Mason Medical Center in Seattle, serving as Director of the Oculoplastic Surgery Division for ten years. While at Virginia Mason, Dr. Stern performed an extensive number of cosmetic laser procedures. He is honored to have been chosen as one of a select group of instructors of the *Botox Cosmetic*® National Education Faculty, as well as the *Radiesse*™ Medical Education Faculty. Dr. Stern is also an instructor for the *Sciton*™ *Laser*. In 2011, he was voted the Best Plastic Surgeon in Western Washington by *KING 5* (NBC affiliate) TV's viewing audience. Dr. Stern is a Fellow of the American College of Surgeons, the American Academy of Facial Plastic and Reconstructive Surgeons, the American Academy of Cosmetic Surgery, and the American Society of Liposuction Surgery, as well as a member of the International Society of Hair Restoration Surgery. In addition, over the past several years, he has appeared on *Northwest Afternoon*, *Evening Magazine*, as well as *KOMO*, *KIRO* and *Q13* news, discussing and demonstrating the latest techniques in facial and eyelid laser cosmetic surgery, *Botox*® and laser-assisted liposuction. He is also an accomplished winemaker & published novelist. Dr. Stern's latest novel is a medical thriller titled, *The Sigma Project*.

Burt D. Ensley, Ph.D. - Dr. Ensley is the Chief Executive Officer and Chairman of Protein Genomics, Inc. He previously served as Chief Executive Officer of Phytotech, Inc. and President of NuCycle Therapy, Inc. prior to their sale. In addition, Dr. Ensley headed the Specialty Chemicals Group at Amgen, Inc. for nearly a decade. He holds a PhD in Microbiology from University of Georgia; is a Fellow of the American Academy of Microbiology; served on the BIO Directorate Board of the National Science Foundation; and is the Board Co-Chair of the University of Arizona's BIO5 Institute. Dr. Ensley holds 19 issued U.S. patents.

Roy D. Mittman, MD, PA. - Dr. Mittman currently serves as a senior partner of Seaview Orthopaedic and Medical Associates (SOMA) located in Ocean, New Jersey. He has assembled a team of highly qualified board certified, fellowship trained physicians to practice at SOMA specializing in general orthopaedics, as well as surgery of the Spine, Hand/Wrist, Knee/Shoulder, Total Joints, Foot and Ankle, Sports Medicine, Pain Management and Osteoporosis. SOMA currently operates six locations committed to providing quality care in Monmouth and Ocean Counties. After earning a Bachelor of Arts degree at John Hopkins University, Dr. Mittman earned his Medical Degree at the Albert Einstein College of Medicine in New York and completed orthopaedic training in 1978 at Montefiore Hospital in New York. He is a member of the New Jersey Orthopaedic Society, Orthopaedic Surgeons of New Jersey, Monmouth County Medical Society and the American College of Sports Medicine.

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

Dr. Rand McClain - Dr. McClain earned his medical degree at Western University and completed his internship at the University of Southern California's Keck School of Medicine Residency Program (U.S.C. California Hospital). Dr. McClain has dedicated over 35 years of his personal and professional life studying nutrition, exercise, herbs and supplements and is also a Master of Acupuncture and Traditional Chinese Medicine. Dr. McClain has participated in professional and elite amateur sport as an individual participant and as well as a member of two U.S. teams and continues to participate competitively. His work is published in peer-reviewed and popular journals and he enjoys sharing and participating in the beneficial changes he helps create in people's lives. Dr. McClain has worked with some of the best and original innovators in Sports, Regenerative Medicine ("Anti-Aging"), Cosmetic and Family Medicine. He also practices as part of the Regenerative Medicine Institute an organization dedicated to advancing cellular treatments, procedures and research in the use of all available avenues to slow or reverse physiological and cosmetic effects of aging. Dr. McClain currently serves as Chief Medical Officer of Live Cell Research, a company dedicated to the discovery and development of products designed to enhance health and quality of life through epigenomic manipulation. Dr. McClain is also a Medical Advisory Board member of American Cryostem Corporation a publicly traded company operating laboratories dedicated to the collection, processing, bio-banking, culturing and differentiation of autologous adipose tissue (fat) and adipose derived stem cells (ADSCs). Dr. McClain is a Board Member of Z.E.N. Foods, a gourmet food delivery and nutrition service company that provides individually designed meal programs in conjunction with health providers and its own registered dietician. Dr. McClain is also proud to be a member of the National Veteran Foundation's Advisory Board.

Corporate Information

Our principal executive offices are located at 1 Meridian Road, Eatontown, New Jersey 07724 and our telephone number is (732) 747-1007. Our website is ***www.americancryostem.com***. We also lease and operate a tissue processing laboratory at Princeton Corporate Plaza in Monmouth Junction NJ. Our laboratory website address is ***www.acslaboratories.com***.

Employees

Currently, we have six (6) employees and continue to use consultants on an as needed basis. As we grow, we will need to attract an unknown number of additional qualified employees, however we could be unsuccessful in attracting and retaining the persons needed.

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.

To date we have generated only minimal operating revenues. Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the fiscal year ended September 30, 2019 with respect to this uncertainty which is included in the 2019 10K. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our Common Stock and we may have a more difficult time obtaining financing.

We expect to incur increased operating expenses for the foreseeable future. The amount of net losses and the time required for us to reach and sustain profitability are uncertain. The likelihood of our success must be considered in light of the problems, expenses, difficulties, and delays frequently encountered in connection with a development stage business, including, but not limited to, uncertainty as to development and the time required for our planned services to become available in the marketplace. There can be no assurance that we will ever generate sufficient revenues or achieve profitability at all or on any substantial basis. These matters raise substantial doubt about our ability to continue as a going concern. If we cease or curtail our development activities, it is highly likely that you would lose your entire investment in our Company.

We will require substantial additional capital to pursue our business plan.

We have incurred negative cash flows since inception from our developmental activities, and at this time as well as for the foreseeable future will finance (until we can generate sufficient revenues, if ever, to cover expenses) our activities and overhead expenses from any revenues we generate and through the issue and sale of debt and/or equity securities. The recoverability of the costs incurred by us to date is highly uncertain and is dependent upon, among other items, achieving commercial production and sales of our services, of which no assurances can be given. Our prospects must be considered in light of the risks, expenses and difficulties which are frequently encountered by companies in the development stage in the emerging Regenerative Medicine industry that we hope to commence operations in.

We have financed our development activities and expenses since inception through the sale of our debt and equity securities. Our capital requirements will depend on many factors, including, among other things, the cost of developing our business and marketing activities, the efficacy and effectiveness of our proposed services, costs (whether or not foreseen), the length of time required to collect accounts receivable we may in the future generate, competing technological and market developments and acceptance. Changes in our proposed business or business plan could materially increase our capital requirements. We cannot assure you that our proposed plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than currently anticipated.

Even if we obtain funding, we still will need to obtain substantial additional financing to, among other things, fund the future development of any services we attempt to undertake and for general working capital purposes. Any additional equity financing, if available, may be dilutive to stockholders and any such additional equity securities may have rights, preferences or privileges that are senior to those of the holders of shares of our Common Stock. Debt financing, if available, will require payment of interest and may involve our granting security interests on our assets and restrictive covenants that could impose limitations on our operating flexibility.

Our ability to obtain needed financing may be impaired by such factors as the capital markets, our capital structure, our development stage, the lack of an active market for shares of our Common Stock, and our lack of profitability, all of which would impact the availability or cost of future financings. We cannot assure prospective investors that we will be able to obtain requisite financing in a timely fashion or at all and, if obtained, on acceptable terms. Our inability to obtain needed financing on acceptable terms would have a material adverse effect on the implementation of our proposed business plan.

Statements concerning our future plans and operations are dependent on our ability to secure adequate funding and the absence of unexpected delays or adverse developments. We may not be able to secure required funding.

The statements concerning future events or developments or our future activities, such as current or planned research and development activities, anticipated products and services, anticipated commercial introduction of products and services, and other statements concerning our future operations and activities, are forward-looking statements that in each instance assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain sufficient funding, or unexpected development or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring which could adversely affect our business, financial condition and results of operations.

We have significant payment obligations under certain Notes due through 2021. Any non-payment of the Notes when due in the absence of an extension of the maturity date would constitute event of default under the Notes, and our financial condition may be adversely affected.

As of September 30, 2019, the Company had issued and outstanding; $226,500 aggregate principal amount of Bridge Notes, which matured, between January through July 2015 and bear interest at the rate of 8% per annum, $83,500 aggregate principal amount of Convertible Notes which matured in September 2014 convertible into shares of Common Stock and the rate of one (1) share of Common Stock for each $0.35 of principal amount and/or interest so converted, $45,000 of 8% convertible notes which matured in September of 2016 and are convertible into shares of Common Stock and the rate of one (1) share of Common Stock for each $0.30 of principal amount and/or interest so converted, $150,000 of 5% convertible notes which mature in Fiscal 2021 convertible into shares of Common Stock at the rate of one (1) share of Common Stock for each $0.33 of principal amount and/or interest so converted, and $155,000 of 8% convertible notes which matured in January 31, 2018 convertible into shares of Common Stock and the rate of one (1) share of Common Stock for each $0.20 of principal amount and/or interest so converted, and $40,000 of 8% convertible notes which matured in January 31, 2018 convertible into shares of Common Stock and the rate of one (1) share of Common Stock for each $0.15 of principal amount and/or interest so converted, and $100,000 aggregate principal amount of Convertible Notes which mature in Fiscal 2020 convertible into shares of Common Stock and the rate of one (1) share of Common Stock for each $0.40 of principal amount and/or interest so converted. No assurances can be given that the Company will have sufficient funds to repay the principal and/or interest on such Bridge Notes when due or on the Convertible Notes such Convertible Notes are converted into Common Stock prior to maturity. In such event, we might be subject to, among other things, non-payment claims of the Note holders, and our financial condition may be adversely affected.

Our limited operating history may make it difficult to evaluate our business and our future viability.

We are in the relatively early stage of operations and have only a limited operating history on which to base an evaluation of our business and prospects. Even if we successfully obtain additional funding, we are subject to the risks associated with development stage companies with a limited operating history, including: the need for additional financing; the uncertainty of research and development efforts; successful commercialization of our products and services; market and customer acceptance of our products and services; unexpected issues with federal or state regulatory authorities; competition from larger organizations; dependence on key personnel; uncertain patent or other intellectual property protection; fluctuations in expenses; and dependence on corporate partners and collaborators. Any failure to successfully address these risks and uncertainties could seriously harm our business and prospects. We may not succeed given the technological, marketing, strategic and competitive challenges we will face. The likelihood of our success must be considered in light of the expenses, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new drug technology, and the competitive and regulatory environment in which we operate or may choose to operate in the future.

Many of our products, services and technologies are in early stages of development.

Processing and cryogenic storage of adipose tissue and stem cells, and application development is in the early stages of development, and there can be no assurance that our business will be successful. Further, potential products based upon individuals' stem cells will require extensive additional research and development before any commercial introduction. There can be no assurance that any future research and development will result in viable products or meet efficacy or regulatory standards.

Cell therapy is a developing field and a significant market for our services has yet to emerge in the US.

Cell therapy and regenerative medicine is a developing field, which we believe few cell therapy products or services approved for and/or commercial use. We are wholly dependent on the acceptance of cell therapy (and specifically stem cells) to develop into a large and profitable industry. We hope to develop services related to the collection, processing, storage of stem cells and application development. We believe the market for stem cell and tissue-based therapies is in its infancy, substantially research oriented and financially speculative and has yet to achieve substantial commercial success. Stem cell products and services may in general be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, lack of acceptance by physicians, hospital and consumers, or other characteristics that may prevent or limit their approval or commercial use. Management believes that the demand for tissue processing and stem cell processing and the number of people who may use cell or tissue-based therapies is difficult, if not impossible, to forecast. Our success is dependent on, among other items, the establishment of a market for our proposed services and our ability to capture a share of this market.

Our proposed services may not attain commercial acceptance absent endorsement by physicians.

Our proposed services will compete against individual adipose tissue and cellular samples derived from alternate sources, such as bone marrow, umbilical cord blood and perhaps embryos. We believe that physicians and hospitals are historically slow to adopt new technologies like ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product performance and/or pricing superiority. Management currently believes physicians' and hospitals' inertia and skepticism to be a significant barrier as we attempt to gain market penetration with our proposed services. Failure to achieve market acceptance of our proposed services would have a material adverse effect on our future prospects.

If we should in the future become required to obtain regulatory approval to market and sell our proposed services we will not be able to generate any revenues until such approval is received.

The medical industry is subject to stringent regulation by a wide range of authorities. We are required to have licenses in two states and have obtained tissue bank licenses to market and support our services in New York and California as well as annual registration with the FDA as a tissue bank. While we believe that, given our proposed business, we are not presently required to obtain additional state and federal regulatory approval to market our services we cannot predict whether regulatory clearance will be required in the future and, if so, whether such clearance will at such time be obtained, whether for the stem cells and/or any other services that we are developing or may attempt to develop. Should such regulatory approval in the future be required, our services may be suspended or may not be able to be marketed and sold in the United States until we have completed the regulatory clearance process as and if implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product or service and would require the expenditure of substantial resources.

If regulatory clearance of a service we propose to provide is granted, this clearance may be limited to those particular states and conditions for which the service is demonstrated to be safe and effective, which would limit our ability to generate revenue.

We cannot ensure that any service developed by us will meet all of the applicable regulatory requirements needed to receive marketing clearance. Failure to obtain regulatory approval will prevent commercialization of our services where such clearance is necessary. There can be no assurance we will obtain regulatory approval of our proposed services that may require it.

Our facilities may require compliance with PHS and FDA regulations and there is no assurance we are in and/or in the future will be in compliance with these protocols or that the PHS or FDA may find deficiencies upon inspection of our facility.

The Company believes that its processing methodologies, and its Monmouth Junction, New Jersey laboratory facilities to be in compliance with all current applicable regulations and guidelines as defined by the United States Public Health Service Act ("**PHS**" or the "**PHS Act**") and the Food and Drug Administration ("**FDA**") regulations and guidance as they relate to the operation of a tissue processing and storage facility.

On January 3, 2018 the Company received a warning letter from the US. FDA concerning its contract manufacturing services provided to Cells on Ice. The FDA has informed the Company through the letter that the FDA has determined that its autologous adipose derived cell product ATCELL is a drug under current FDA regulations and guidance In response to the letter the Company ceased shipment of its ATCELL product within the United States. Since receiving the Warning Letter from the FDA the Company undertook a complete reorganization and remediation of its laboratory facility and operations and an expansion of its existing facility. The Company believes that its effort, new clean room laboratory facility, SOP and Quality Management system upgrades, and filing the IND application (No. 19089) on October 22, 2019 will satisfy the FDA's concerns; no assurance can be given that we are in fact in compliance and/or in the future will be in compliance with these regulations or that upon inspection by PHS and/or FDA that we will not be required to amend our procedures or limit our operations based upon the finding of the inspection.

As and if we evolve from a company primarily involved in the research and development of our technology into one that is also involved in the commercialization of our technology, we may have difficulty managing our growth and expanding our operations.

As and if our business grows, we will in all likelihood need to add employees and enhance our management, systems and procedures. We may need to successfully integrate our internal operations with the operations of various third party service providers to produce and market commercially viable products. We may also need to manage additional relationships with various collaborative partners, suppliers and other organizations. Expanding our business may place a significant burden on our management and operations. We may not be able to implement improvements to our management information and control systems in an efficient and timely manner and we may discover deficiencies in our existing systems and controls. Our failure to effectively respond to such changes may make it difficult for us to manage our growth and expand our operations.

We currently are wholly dependent on John Arnone and Anthony Dudzinski; Conflicts of Interest.

We currently are wholly dependent on John Arnone and Anthony Dudzinski, our only executive officers and directors. Our future performance will depend on the continued services of such persons and our ability to retain such persons and to hire additional qualified persons. The loss of either of Mr. Arnone or Mr. Dudzinski, or both, would materially and adversely affect our proposed business. There are no assurances they will continue to do so. The employment agreements among other terms permit each of Mr. Arnone and Mr. Dudzinski to conduct other business activities outside of their employment with us. Each such employment agreement terminates in October 2020. We have not obtained any “key-man” life insurance policies nor do we presently plan to obtain or maintain any such policies on Mr. Arnone, Mr. Dudzinski or any other of our employees.

Mssrs. Arnone and Dudzinski collectively beneficially own in excess of 50.1% of our issued and outstanding voting stock and as a result have the ability to directly and/or indirectly make all decisions for us.

Mr. Arnone owns the majority of the issued and outstanding voting stock of Personal Cell Sciences Corporation, a Florida corporation (“ PCS”). PCS is in the cosmetic business and has entered into a contract manufacturing and royalty agreement with us to manufacture conditioned medium. We also receive a royalty of 10% of the gross sales of any autologous products sold by PCS containing the conditioned medium that we manufacture. Mr. Arnone is also the CEO of Regenerative BioTherapy Corp. Regenerative BioTherapy Corp, a Florida corporation which entered into a licensing Agreement with the Company in September of 2014. The licensing agreement Permits Regenerative BioTherapy the use of the Company’s Standard Operating Procedures, Quality Management and General Operations procedures and process for the Company’s product lines and IP; to construct and operate a laboratory and treatment facility in the Caribbean. We may in the future seek to expand our business relationship with, and/or acquire PCS and/or Regenerative BioTherapy Corp. Management cannot assure you that any such business relationship or acquisition, if consummated, would be on terms favorable to us.

We may be unable to protect our intellectual property from infringement by third parties, and third parties may claim that we are infringing on their intellectual property, either of which could materially and adversely affect us.

We intend to rely on patent protection, trade secrets, technical know-how and continuing technological innovation to protect our intellectual property, and we expect to require any employees, consultants and advisors that we may hire or engage in the future to execute confidentiality and assignment of inventions agreements in connection with their employment, consulting or advisory relationships. There can be no assurance, however, that these agreements will not be breached or that we will have adequate remedies for any such breach.

Despite our efforts to protect our intellectual property, third parties may infringe or misappropriate our intellectual property or may develop intellectual property competitive with ours. Our competitors may independently develop similar technology or otherwise duplicate our proposed processes or services. As a result, we may have to litigate to enforce and protect our intellectual property rights to determine their scope, validity or enforceability. Intellectual property litigation is particularly expensive, time-consuming, diverts the attention of management and technical personnel and could result in substantial cost and uncertainty regarding our future viability. The loss of intellectual property protection or the inability to secure or enforce intellectual property protection would limit our ability to produce and/or market our services in the future and would likely have an adverse effect on any revenues we may in the future be able to generate by the sale or license of such intellectual property.

We may be subject to costly litigation in the event our future services or technology infringe upon another party's proprietary rights. Third parties may have, or may eventually be issued, patents that would be infringed by our technology. Any of these third parties could make a claim of infringement against us with respect to our technology. We may also be subject to claims by third parties for breach of copyright, trademark or license usage rights. Any such claims and any resulting litigation could subject us to significant liability for damages or injunctions precluding us from utilizing our technology or services or marketing or selling any products or services under the same. An adverse determination in any litigation of this type could require us to design around a third party's patent, license alternative technology from another party or otherwise result in limitations in our ability to use the intellectual property subject to such claims.

Risks Related to Our Common Stock

We are authorized to issue 300,000,000 shares of Common Stock and 50,000,000 shares of "blank check" preferred stock, the issuance of which could, among other things, reduce the proportionate ownership interests of current shareholders.

We are authorized to issue 300,000,000 shares of Common Stock and 50,000,000 shares of "blank check" preferred stock. As of September 30, 2019, there were 49,387,918 shares of Common Stock issued (excluding 8,761,500 shares issuable upon exercise of all issued and outstanding stock options and warrants, and shares issuable on the conversion of all outstanding Convertible Notes, and no shares of preferred stock were issued and outstanding). Our board of directors has the ability, without seeking shareholder approval, to issue additional shares of Common Stock and/or to designate, establish the terms and conditions of, and issue shares of preferred stock for such consideration, if any, as the board of directors may determine. Any such shares of preferred stock could have dividend, liquidation, conversion, voting or other rights, which could adversely affect the voting power or other rights of the holders of shares of Common Stock. In the event of such issuance, the preferred stock could, among other items, be used as a method of discouraging, delaying or preventing a change in control of our Company, which could have the effect of discouraging bids for our Company and thereby prevent security-holders from receiving the maximum value for their shares of our Common Stock.

Our Common Stock is currently traded on the OTC pink sheets and is subject to additional trading restrictions as a "penny stock," which could adversely affect the liquidity and price of such stock. If our Common Stock remains subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

Our Common Stock currently trades on the OTC pink sheets. The OTC pink sheets may be viewed by investors as a less desirable, and less liquid, marketplace. As a result, an investor may find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our Common Stock.

Because our Common Stock is not listed on any national securities exchange, such shares will also be subject to the regulations regarding trading in "penny stocks," which are those securities trading for less than $5.00 per share, and that are not otherwise exempted from the definition of a penny stock under other exemptions provided for in the applicable regulations. The following is a list of the general restrictions on the sale of penny stocks:

- Before the sale of penny stock by a broker-dealer to a new purchaser, the broker-dealer must determine whether the purchaser is suitable to invest in penny stocks. To make that determination, a broker-dealer must obtain, from a prospective investor, information regarding the purchaser's financial condition and investment experience and objectives. Subsequently, the broker-dealer must deliver to the purchaser a written statement setting forth the basis of the suitability finding and obtain the purchaser's signature on such statement.
- A broker-dealer must obtain from the purchaser an agreement to purchase the securities. This agreement must be obtained for every purchase until the purchaser becomes an "established customer."
- The Exchange Act requires that before effecting any transaction in any penny stock, a broker-dealer must provide the purchaser with a "risk disclosure document" that contains, among other things, a description of the penny stock market and how it functions and the risks associated with such investment. These disclosure rules are applicable to both purchases and sales by investors.
- A dealer that sells penny stock must send to the purchaser, within 10 days after the end of each calendar month, a written account statement including prescribed information relating to the security.

These requirements can severely limit the liquidity of securities in the secondary market because fewer brokers or dealers are likely to be willing to undertake these compliance activities. As a result of our Common Stock not being listed on a national securities exchange and the rules and restrictions regarding penny stock transactions, an investor's ability to sell to a third party and our ability to raise additional capital may be limited. We make no guarantee that market-makers will make a market in our Common Stock, or that any market for our Common Stock will continue.

Our two (2) principal stockholders control us, and your interests as a stockholder may conflict with the interests of those persons.

Based on the number of outstanding shares of our Common Stock held by our stockholders as of September 30, 2019, our two (2) directors, executive officers and their respective affiliates beneficially owned in excess of 50.1% of our outstanding shares of Common Stock. As a result, those stockholders have the ability to control, among other items, the outcome of all matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our Common Stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, and/or (iii) discouraging a potential acquirer from attempting to obtain acquire us. The control held over us by such 2 persons may adversely affect the trading price of our Common Stock due to investor's awareness of conflicts of interest.

Our stockholders may experience significant dilution as a result of any additional financing using our securities.

We will need to raise significant additional capital in order to maintain and continue our operations. To the extent that we raise additional funds by issuing equity securities or securities convertible into or exercisable for equity securities, our stockholders may experience significant dilution and we may issue securities with better terms than those offered hereby.

We have not paid dividends on our Common Stock in the past and do not expect to pay dividends on our Common Stock for the foreseeable future. Any return on investment may be limited to the value of our Common Stock.

No cash dividends have been paid on our Common Stock, and we do not expect to pay cash dividends on our Common Stock in the foreseeable future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our Common Stock may be less valuable because a return on a stockholder's investment will only occur if our stock price appreciates.

A sale of a substantial number of shares of our Common Stock may cause the price of our Common Stock to decline and may impair our ability to raise capital in the future.

Our Common Stock is currently traded on the OTC pink sheets, and there have been and may continue to be periods when it could be considered "thinly-traded," meaning that the number of persons interested in purchasing our Common Stock at or near bid prices at any given time may be relatively small or non-existent. Finance transactions resulting in a large amount of newly issued shares that become readily tradable or other events that cause stockholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of Common Stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our Common Stock in the public market, the market price of our Common Stock could decline. Sales of a substantial number of shares of our Common Stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

The Company may not have complied with various state securities laws in connection with prior issuances/sales of its securities.

Since April 2011, the date of the closing of the Asset Purchase, through September 30, 2019, the Company sold approximately $4,705,127 gross amount of its equity and debt securities. In connection with such sales, the Company may have violated various state securities laws. If the Company was determined by a court, FINRA or regulatory body with the required jurisdiction to have violated such laws, any such violation could result in the Company being required to offer rescission rights to each such prior purchase from the Company to rescind such purchases and pay to the prior purchaser an amount of funds equal to the purchase price paid by such prior investors plus interest from the date of any such purchase. No assurances can be given the Company will, if it is required to offer such purchasers rescission right, have sufficient funds to pay the prior purchasers the amount required. In addition, if the Company violated one or more securities laws of a state in connection with prior offers and/or sales of its securities, each such state could bring an enforcement, regulatory and/or other legal action against the Company which, among other things, could result in the Company having to pay substantial fines, not being able to sell securities in such states in the future and/or having a determination made by any such states against the Company that the Company failed to comply with such states' securities laws, which could result in the Company, among other untoward effects including those set forth above, not being able to have its Common Stock be eligible for continued quotation on the OTC pink sheets and/or other trading markets and/or mediums that the Common Stock is then trading and/or eligible for quotation on and/or in the future seeks to be quoted or traded on.

As a "thinly-traded" stock, large sales can place downward pressure on our stock price.

Our stock experiences periods when it could be considered "thinly traded." Financing transactions resulting in a large number of newly issued shares that become readily tradable, or other events that cause current shareholders to sell shares, could place further downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a shareholder who desires to sell a large number of shares to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

Shares eligible for future sale may adversely affect the market for our Common Stock.

As of September 30, 2019, we had 8,761,500 of Common Stock issuable upon exercise of all outstanding stock options and warrants, and, 2,134,784 shares issuable on the conversion of outstanding Convertible Notes. If and when these securities are exercised or converted into shares of our Common Stock, the number of our shares of Common Stock outstanding will increase. Such increase in our outstanding shares, and any sales of such shares into the public market, could have a material adverse effect on the market for our Common Stock and the market price of our Common Stock.

In addition, from time to time, certain of our shareholders may be eligible to sell all or some of their shares of Common Stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated shareholders (or shareholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock and (ii) non-affiliated shareholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Description of Property

We currently rent office space at 1 Meridian Road, Eatontown, NJ 07724 for our corporate offices, and we rent laboratory space in Monmouth Junction, New Jersey. During 2018, the Company constructed a new Clean Room designed specifically for cellular expansion, medium filling and tissue processing at the Monmouth Junction space.

Item 3. 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. On August 5, 2019, the Company was served with a civil complaint by Focus Search Group, LLC in Massachusetts. The complaint made claims for certain consulting fees due totaling approximately $61,500, which included claims for interest legal and other fees. The matter was resolved by settlement between the two parties. We settled the debt for $35,632. 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 4. Mine Safety Disclosures

Not applicable.

Item 5. Market for Common Equity and Related Stockholder Matters

(a) Market Information

Our common stock is listed on the OTC pink sheets under the symbol “CRYO” The following table shows the reported high and low closing prices per share for our common stock for each quarterly period as noted. The over-the-counter market quotations set forth for our common stock reflect interdealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter ended	High	Low
December 31, 2018	$ 0.75	$ 0.37
March 31, 2019	$ 0.64	$ 0.38
June 30, 2019	$ 0.50	$ 0.19
September 30, 2019	$ 0.50	$ 0.18

(b) Holders of Common Equity

As of September 30, 2019, there were approximately 167 holders of record of our common stock. This figure does not take into account those shareholders whose certificates are held in the name of broker-dealers or other nominees.

(c) Dividend Information

We have never paid any cash dividends on our common shares, and we do not anticipate that we will pay any dividends with respect to those securities in the foreseeable future. Our current business plan is to retain any future earnings to finance the expansion development of our business.

(d) Sales of Unregistered Securities

During fiscal 2018, the Company issued 3,072,976 shares for Convertible Notes exercised at a value of $540,500

During fiscal 2018, the Company issued 1,145,000 shares for Options exercised at a value of $165,500.

During fiscal 2018, the Company issued 80,000 shares to consultants for services rendered valued at $64,050.

During fiscal 2018, the Company issued 118,461 shares to pay interest due to holders of the bridge notes and convertible notes. The value of the interest paid was $62,232.

During fiscal 2018, the Company issued 219,290 shares to pay an outstanding legal bill. The shares issued were valued at $186,396.

During fiscal 2018, the Company issued 35,013 shares to build a “clean room” at the laboratory. The shares issued were valued at $33,262.

During fiscal 2018, the Company issued 115,890 for nine months of rent from May 2018 through January 2019. The shares issued were valued at $110,096.

The Company issued shares of common stock to pay a consulting bill valued at $27,500 in Fiscal 2019.

The Company issued shares of common stock for consulting services valued at $25,000 in Fiscal 2019.

The Company issued shares of common stock to pay interest expense on the convertible notes and bridge notes of $50,391 in fiscal year 2019.

(e) ***Securities Authorized For Issuance Under Equity Compensation Plans***

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. For purposes of determining the option value at issuance, the fair value of each option granted is measured at the date of the grant by the option pricing model.

The fair values generated by option pricing model may not be indicative of the future values, if any, that may be received by the option holder.

The Company normally issues options to its key personnel and consultants at the end of each fiscal year. The Company did not issue any options for Fiscal Year 2019.

Using the Black-Sholes valuation method, the Company issued options and recorded salaries and consulting expenses of $549,588 in fiscal year 2018.

The fair value of the options issued in Fiscal 2018 was calculated using the following assumptions:

	2018
Dividend yield	0.00%
Risk free interest rate	1.95%
Volatility	217.20%
Share Price	$ 0.94
Term in Years	5

Transfer Agent

Our transfer agent is Olde Monmouth Stock Transfer Co., Inc. located at 200 Memorial Parkway, Atlantic Highlands, New Jersey 07716. Its contact phone is 732-872-2727.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This annual report on Form 10-K and other reports filed by American CryoStem Corporation (the "Company") from time to time with the U.S. Securities and Exchange Commission (the "SEC") contain or may contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used in the filings, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks contained in the "Risk Factors" section of the this Annual Report on Form 10-K., relating to the Company's industry, the Company's operations and results of operations, and any businesses that the Company may acquire. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP and does not require management's judgment in its application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result. The following discussion should be read in conjunction with our consolidated financial statements and notes thereto appearing elsewhere in this report.

Background

We were 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 our common stock, par value $0.001 per share, to ACS (the "Asset Purchase"). We filed a Current Report on Form 8-K with the Securities and Exchange Commission on April 27, 2011 disclosing the Asset Purchase and certain related matters including, but not limited to, the appointment of our present officers and directors as well as the resignation by the former chief executive officer and sole director. Our fiscal year ends September 30 of each calendar year.

Overview

American CryoStem Corporation, which we refer to as "we," "us," "our" and "our Company," is a developer, marketer and global licensor of patented adipose tissue-based cellular technologies and related proprietary services with a focus on processing, commercial bio-banking and application development for adipose (fat) tissue and autologous adipose-derived regenerative cells (ADRCs). We maintain a strategic portfolio of intellectual property and patent applications that form our Adipose Tissue Processing Platform, which supports and promotes a growing pipeline of biologic products and processes, services and international licensing opportunities. Through our ACS Laboratories division, we operate an FDA registered, human tissue processing, cryopreservation, and cell culture and differentiation media development facility in Monmouth Junction, New Jersey.

Our growth strategy is centered on expanding our research and development through scientific collaborations to fully capitalize on (1) scientific breakthroughs that have been rapidly shaping the fast growing Regenerative and Personalized Medicine industries; (2) to provide these growth industries with a standardized cell processing platform and, (3) to enhance the delivery of healthcare through cellular-based therapies and applications which address disease treatment, wound and burn healing, joint repair and management, and personalized health and beauty care.

Through our ACS Laboratories division, our Company operates its FDA registered, human tissue processing, cryopreservation and cell culture and differentiation media development facility in Monmouth Junction, New Jersey. On a mission to fulfill the pressing need to set a global gold standard for end-to-end collection, processing, tracking and storage, American CryoStem has spent nearly eight years designing and constructing the necessary framework capable of replicating its protocols in markets around the world.

American CryoStem continues to focus on expanding and securing additional licensing arrangements with qualified partners around the world to institute and operate its turnkey laboratories that are properly equipped for processing and storing adipose tissue and ADSCs for use in Regenerative and Personalized Medicine applications.

Cash Requirements

We will require additional capital to fund marketing, operational expansion, processing staff training, as well as for working capital. We are attempting to raise sufficient funds would enable us to satisfy our cash requirements for a period of the next 12 to 24 months. In order to finance further market development with the associated expansion of operational capabilities for the time period discussed above, we will need to raise additional working capital. However, we cannot assure you we can attract sufficient capital to enable us to fully fund our anticipated cash requirements during this period. In addition, we cannot assure you that the requisite financing, whether over the short or long term, will be raised within the necessary time frame or on terms acceptable to us, if at all. Should we be unable to raise sufficient funds we may be required to curtail our operating plans if not cease them entirely. As a result, we cannot assure you that we will be able to operate profitably on a consistent basis, or at all, in the future.

In order to move our Company through its next critical growth phase of development and commercialization and to ensure we are in position to support our research collaborations and market penetration strategies, Management continues to seek new investment into the Company from existing and new investors with particular emphasis on identifying the best deal structure to attract and retain meaningful capital sponsorship from both the retail and institutional investing communities, while limiting dilution to our current shareholders. Management also focuses its efforts on increasing sales and licensing revenue and reducing expenses. On May 11, 2018 the Company entered into an agreement with Gramatan LLC under which Gramatan will provide the Company with advisory services and assistance with business and strategic development and raising additional capital. The Company terminated the agreement on January 14, 2019.

Fiscal 2019 Operations

In Fiscal 2019, The Company's Total Revenue decreased to $321,647 versus $1,103,417 in Fiscal 2018, due mainly to ceasing shipment of our ATCELL product in the US. Accounts Receivable increased to $330,154 in Fiscal 2019 from $217,318 in Fiscal 2018 due to increased fees receivable from International Licensees. In 2019 Licensing Fees and Royalties decreased to $44,757 from $449,019 in Fiscal 2018. Consulting Fees increased to $225,000 in Fiscal 2019 from $75,000 in 2018. Short term liabilities increased to $1,292,206 in Fiscal 2019 from $1,112,110 in Fiscal 2018 due to increases in liabilities to contractors, consultants and professionals along with debt discounts maturing and long term debt becoming current. Long term debt increased to $1,239,716 in 2019 from $854,761 in 2018. Cost of Sales decreased to $31,876 in Fiscal 2019 from $296,992 in Fiscal 2018 due to reduced processing activities associated with ATCELL™. The Company saw a decrease in professional fees to $101,619 in Fiscal 2019 from $171,536 in Fiscal 2018. Research and Development decreased to $224,792 in 2019 from $341,516 in 2018 due to completion of certain activities associated with laboratory remediation, validation, and IND preparation expenses associated with the Company's ATCELL™ product.

Going Concern

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

We have suffered recurring losses from operations since our inception. In addition, we have yet to generate an internal cash flow from our business operations or successfully raised the financing required to expand our business. As a result of these and other factors, our independent auditor has expressed substantial doubt about our ability to continue as a going concern. Our future success and viability, therefore, are dependent upon our ability to generate capital financing. The failure to generate sufficient revenues or raise additional capital may have a material and adverse effect upon us and our shareholders.

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

Liquidity and Capital Resources

As of the fiscal year ended September 30, 2019, the Company had a cash balance of $23,800 and accounts receivable of $330,154. Our sources of funds in 2019 were tissue processing and storage fees, international product sales, consulting and licensing fees, and financing activities. In Fiscal 2019, we used $496,957 of net cash for Operations, and $49,902 in investment activities, including Patent Development, and the purchase of Laboratory equipment and furniture associated with the ongoing upgrade of our Monmouth Junction, NJ facility. Additionally, the Company generated $502,339 from financing activities, which included option exercises, issuance of convertible notes, issuance of common stock and an infusion of capital from an affiliate. The Company also paid down a portion of its Capital Lease.

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

There was no significant impact on the Company's operations as a result of inflation for the fiscal year ended September 30, 2019.

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.

Related Party Transactions

The Company was indebted to a company that is majority owned by the Company's two officers in the amount of $205,355 for Fiscal 2019 and $107,189 for Fiscal 2018. The advances are unsecured, and carry no interest rate and are collectible at the discretion of the company's two officers/directors. The officers/directors do not anticipate collecting this in Fiscal 2020.

The Company was indebted to a company that is wholly owned by the Company's Chief Executive Officer $3,080 for Fiscal 2019 and $1,831 for Fiscal 2018. The advances are unsecured, carry no interest rate and are collectible at the discretion of the company's two officers/directors. The balance due at September 30, 2019 has been paid in full.

The Company was indebted to the Company's Chief Executive Officer in the amount of $5,165 for Fiscal 2019. The advances are unsecured, and carry no interest rate and are collectible at the discretion of the company's two officers/directors. The balance due at September 30, 2019 of $5,165 was paid in full in Fiscal 2020.

The company paid Mr. Arnone consulting fees of $5,000 in Fiscal 2019 and $59,500 in Fiscal 2018. The company paid Mr. Dudzinski consulting fees of $5,000 in Fiscal 2019 and $59,500 in Fiscal 2018.

The advances are determined by actual cash received by the Company, are due on demand, are unsecured, and carry no interest rate.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We do not hold any derivative instruments and do not engage in any hedging activities.

Item 8. Financial Statements

Our financial statements are contained in pages F-1 through F-18 which appear at the end of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

The Company's Accountants (Fruci & Associates) are unchanged for Fiscal 2019. There were no disagreements with our Accountants on Accounting or Financial Disclosure for Fiscal 2019.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure and Control 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 September 30, 2019, and concluded that the disclosure controls and procedures were effective as a whole.

(b) Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with Generally Accepted Accounting Principles ("GAAP").

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance of such reliability and may not prevent or detect misstatements. Also, projection of any evaluation of effectiveness to future periods is subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has conducted, with the participation of our Chief Executive Officer and our Principal Accounting Officer, an assessment of the effectiveness of our internal control over financial reporting as of September 30, 2019. Management's assessment of internal control over financial reporting used the criteria set forth in SEC Release 33-8810 based on the framework established by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control over Financial Reporting – Guidance for Smaller Public Companies* (2013). Based on this evaluation, Management concluded that our system of internal control over financial reporting was effective as of September 30, 2019, based on these criteria.

(c) 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.

(d) Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for smaller reporting companies.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The following table and biographical summaries set forth information, including principal occupation and business experience, about our directors and executive officers at September 30, 2018:

Name	Age	Position	Officer and/or Director Since
John Arnone	62	Chairman and Chief Executive Officer	2011
Anthony F. Dudzinski	57	Chief Operating Officer and Director	2011

John Arnone – Chairman and Chief Executive Officer

Mr. Arnone has been the Chairman of American CryoStem since 2008 and Chief Executive Officer since 2011. Mr. Arnone is also Chairman and CEO of Personal Cell Sciences, Inc., a private Company that markets the U-Autologous line of skin care products. Prior to his involvement in the life sciences/biotechnology industries, he spent 25 years in the investment banking/financial services industry as an investment banker and a proactive investor. Over a 25 year period and holding six NASD licenses, Mr. Arnone founded, managed and operated two general securities broker-dealers based in New York specializing in strategic planning, corporate structure, financial planning and new business development. Over the years, he has provided advisory and business management services as a founder, officer, director and/or shareholder to both mid-level and development stage private and public companies. Mr. Arnone also co-founded and operated a global entertainment distribution corporation with 120 employees, and under his guidance the Company was voted medium wholesaler of the year in the music industry (1997, 1998 and 2000) by the National Association of Recording Merchants. Mr. Arnone is a co-founder and Director of DigiTrax Entertainment Inc. a Artificial Intellegence based music company located in Knoxville, Tennessee. Mr. Arnone holds a degree in Business Administration and a Bachelors of Art in Economics from Kean University in New Jersey.

Anthony F. Dudzinski – Chief Operating Officer and Director

Mr. Dudzinski is a founder of American CryoStem as well as its Chief Operating Officer. He is primarily focused on building and maintaining the Company's operational and laboratory infrastructure and their compliance with current regulations. Mr. Dudzinski has been in the life sciences and biotechnology sector for more than eight years and has more than 25 years of experience in areas of senior management with a variety of public and private companies. Beginning in the securities industry with a focus on regulatory compliance and operations, he combined this experience with the biotechnology industry while building new investment vehicles focused on life sciences and biotechnology companies in 2004. Mr. Dudzinski's past positions include Chief Executive Officer, President, Chief Operating Officer and Director of small and medium-sized organizations, including a publicly traded company with approximately 300 employees. He was also the President and Chief Operating Officer of a privately operated, registered broker-dealer with more than 175 sales associates. In addition to this experience, he was a founder and Chief Executive Officer of a number of publicly available exchange traded funds; and the Founder, Chairman and Chief Operating Officer of a target date fund complex and a registered investment company.

Compliance with Section 16(A) of the Exchange Act

Section 16(a) of the Exchange Act requires the Company's directors, executive officers and persons who beneficially own 10% or more of a class of securities registered under Section 12 of the Exchange Act to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Directors, executive officers and greater than 10% stockholders are required by the rules and regulations of the SEC to furnish the Company with copies of all reports filed by them in compliance with Section 16(a).

Based solely on our review of certain reports filed with the Securities and Exchange Commission pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, the reports required to be filed with respect to transactions in our common stock during the fiscal year ended September 30, 2019, were timely.

Code of Ethics

We have not adopted a Code of Ethics.

Item 11. Executive Compensation

The following table sets forth compensation information for services rendered by certain of our executive officers in all capacities during the last two completed fiscal years. The following information includes the dollar value of base salaries and certain other compensation, if any, whether paid or deferred.

Summary Compensation Table

Name and Position(s)	Year	Salary($)	Accrued Salary($)	Bonus	Stock Awards	Option Awards[1]	Total Compensation
John S. Arnone	2019	$ 5,000	$ 120,000	N/A	N/A	$ 0	$ 125,000
President and CEO	2018	$ 59,500	$ 120,000	N/A	N/A	$ 0	$ 179,500
Anthony F. Dudzinski	2019	$ 5,000	$ 120,000	N/A	N/A	$ 0	$ 125,000
Chief Operating Officer	2018	$ 59,500	$ 120,000	N/A	N/A	$ 0	$ 179,500

[1]This column represents the aggregate grant-date fair value of the awards computed in accordance with FASB ASC Topic 718. These amounts represent the accounting value for these awards and do not necessarily correspond to the actual value that may be realized by the named executive officer. The assumptions used in the calculation of these amounts for the fiscal year ended September 30, 2019 are described in the Notes to our financial statements included in this Annual Report.

We do not anticipate increasing the annual salaries paid to our officers until we have adequate funds to do so.

Compensation of Directors

We do not compensate any of our directors for their services as directors other than stock for their time. However, we do reimburse our directors for expenses incurred in attending board meetings and issue stock for their time. During Fiscal 2019 and 2018 the Company did not issue any stock to directors for their time or reimburse any expenses to the Directors.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our Common Stock by: (i) each person who, to our knowledge, beneficially owns 5% or more of our Common Stock and (ii) each of our directors and officers. Unless otherwise indicated, each of the stockholders listed below has sole voting and investment power over its shares of Common Stock beneficially owned.

Name and Address of Beneficial Owner	Number of Shares	Percent of Class [1]
Directors and Named Executive Officers [2]:		
John S. Arnone [3]	24,880,000	50.04%
Anthony Dudzinski [4]	24,280,000	49.16%
All directors and named executive officers as a group (2 persons)		
Other 5% or Greater Beneficial Owners		
ACS Global, Inc.	20,000,000	40.50%

[1]*Beneficial ownership is calculated based on 49,387,918 shares of Common Stock issued and outstanding as of September 30, 2019, together with securities exercisable or convertible into shares of Common Stock within sixty (60) days of the date hereof for each stockholder. Beneficial ownership is determined in accordance with Rule 13d-3 of the Commission. The number of shares of Common Stock beneficially owned by a person includes shares of Common Stock issuable upon conversion of securities and subject to options or warrants held by that person that are currently convertible or exercisable or convertible or exercisable within sixty (60) days of the date hereof. The shares of Common Stock issuable pursuant to those convertible securities, options or warrants are deemed outstanding for computing the percentage ownership of the person holding such convertible securities, options or warrants but are not deemed outstanding for the purposes of computing the percentage ownership of any other person. The above calculations include an adjustment as required to include all vested options granted to John Arnone and Anthony Dudzinski.*

[2]*Unless otherwise specified, the address for the directors and officers is c/o American CryoStem Corporation at 1 Meridian Road, Eatontown, NJ 07724.*

[3]*Mr. Arnone presently owns 18,250,000 shares of Common Stock of ACS Global and has the right to receive an additional 12,000,000 such shares upon the conversion of Series C Preferred Stock of ACS Global owned by him. As a result, he beneficially owns 37.27% percent of the ACS Global Common Stock. Mr. Arnone is also an officer and a director of ACS Global. Consequently, Mr. Arnone is a control person of ACS Global and may as such be deemed to "beneficially own" the 20,000,000 shares of Common Stock owned by ACS Global. Mr. Arnone, however, disclaims beneficial ownership of all such shares. Mr. Arnone also holds, 1,880,000 shares of the Company's common shares and 3,000,000 options (of which 3,000,000 are vested) to purchase the Company's Common Stock 1,000,000 which expire on September 20, 2020, and 1,000,000 expire on September 20, 2021 and 1,000,000 expire on July 10, 2022.*

[4]*Mr. Dudzinski presently owns 6,020,000 shares of ACS Global Common Stock and has the right to receive an additional 12,000,000 such shares upon the conversion of ACS Global preferred stock owned by him. As a result, he beneficially owns 22.20% percent of the ACS Global Common Stock. Mr. Dudzinski is also an officer and a director of ACS Global. Consequently, Mr. Dudzinski is a control person of ACS Global and may as such be deemed to "beneficially own" the 20,000,000 shares of Common Stock owned by ACS Global. Mr. Dudzinski, however, disclaims beneficial ownership of all such shares. Mr. Dudzinski also holds 1,280,000 shares of the Company's Common Stock and 3,000,000 options (of which 3,000,000 are vested) to purchase the Company's Common Stock of which 1,000,000 which expire on September 20, 2020, and 1,000,000 expire on September 20, 2021 and 1,000,000 that expire on July 10, 2022.*

Description of Securities

We are authorized to issue 300,000,000 shares of Common Stock, par value $0.001 per share and 50,000,000 shares of preferred stock, par value $0.001 per share. As of September 30, 2019 there were 49,387,918 shares of Common Stock and no shares of preferred stock issued and outstanding.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information with respect to the outstanding equity awards to our named executive officers during fiscal 2019:

Option Awards

Name	Number of securities underlying unexercised options (#) Exercisable	Number of securities underlying unexercised options (#) Unexercisable	Equity incentive plan awards: Number of securities underlying unexercised options (#)	Option exercise price ($)	Option expiration date
John S. Arnone	1,000,000	0	1,000,000	$ 0.20	9/20/2020
	1,000,000	0	1,000,000	$ 0.30	9/20/2021
	1,000,000	0	1,000,000	$ 0.40	7/10/2022
Anthony Dudzinski	1,000,000	0	1,000,000	$ 0.20	9/20/2020
	1,000,000	0	1,000,000	$ 0.30	9/20/2021
	1,000,000	0	1,000,000	$ 0.40	7/10/2022

Option Plans

On September 18, 2011 our Board of Directors approved the “American CryoStem Corporation Incentive Stock Option Plan” (the “2011 Plan”). Under the Plan, officers, directors, employees and consultants to the Company may be granted options to purchase shares of the Company’s common stock, par value $0.001 per share. There are 3,000,000 shares of common stock reserved for issuance under the Plan. The Plan is administered under the authority of the Stock Option Plan Committee (the “Committee”). The Company issued 2,910,000 of the Options available under the 2011 Plan in Fiscal 2012. To date 2,185,000 options from the 2011 Plan have been exercised, 725,000 have expired, and a total of 0 remain outstanding.

On May 1, 2013 our Board of Directors approved the 2013 American CryoStem Corporation Incentive Stock Option Plan (the “2013 Plan)”. Under the Plan, officers, directors, employees and consultants to the Company may be granted options to purchase shares of the Company’s common stock, par value $0.001 per share. There are 5,000,000 shares of common stock reserved for issuance under the Plan. The Plan is administered under the authority of the Stock Option Plan Committee (the “Committee”). During 2013 the Company granted a total of 3,740,000 at a weighted average price of $0.18 to certain employees, advisory board members and consultants. To date 2,175,000 Options issued under the plan have been exercised, 1,565,000 have expired, and 0 remain outstanding.

On September 21, 2014 our Board of Directors approved the 2014 American CryoStem Corporation Incentive Stock Option Plan (the “2014 Plan”). Under the Plan, officers, directors, employees and consultants to the Company may be granted options to purchase shares of the Company’s common stock, par value $0.001 per share. There are 4,000,000 shares of common stock reserved for issuance under the Plan. The Plan is administered under the authority of the Stock Option Plan Committee (the “Committee”). During 2014 the Company granted a total of 3,495,000 at a weighted average price of $0.21 to certain employees, advisory board members and consultants. To date 350,000 Options issued under the plan have been exercised, 3,145,000 have expired, and 0 remain outstanding.

On September 20, 2015 our Board of Directors approved the 2015 American CryoStem Corporation Incentive Stock Option Plan (the “2015 Plan”). Under the Plan, officers, directors, employees and consultants to the Company may be granted options to purchase shares of the Company’s common stock, par value $0.001 per share. There are 4,000,000 shares of common stock reserved for issuance under the Plan. The Plan is administered under the authority of the Stock Option Plan Committee (the “Committee”). During 2015 the Company granted a total of 3,550,000 at a weighted average price of $0.21 to certain employees, advisory board members and consultants. To date 150,000 Options issued under the plan have been exercised, 0 have expired, and 3,400,000 remain outstanding.

On September 20, 2016 our Board of Directors approved the 2016 American CryoStem Corporation Incentive Stock Option Plan (the “2016 Plan”). Under the Plan, officers, directors, employees and consultants to the Company may be granted options to purchase shares of the Company’s common stock, par value $0.001 per share. There are 4,000,000 shares of common stock reserved for issuance under the Plan. The Plan is administered under the authority of the Stock Option Plan Committee (the “Committee”). During 2016 the Company granted a total of 3,050,000 at a weighted average price of $0.21 to certain employees, advisory board members and consultants. To date no Options issued under the plan have been exercised, 0 have expired, and 3,050,000 remain outstanding.

On July 10, 2017 our Board of Directors approved the 2017 American CryoStem Corporation Incentive Stock Option Plan (the "2017 Plan"). Under the Plan, officers, directors, employees and consultants to the Company may be granted options to purchase shares of the Company's common stock, par value $0.001 per share. There are 4,000,000 shares of common stock reserved for issuance under the Plan. The Plan is administered under the authority of the Stock Option Plan Committee (the "Committee"). During 2017 the Company granted a total of 2,770,000 at a weighted average price of $0.40 to certain employees, advisory board members and consultants. To date 20,000 Options issued under the plan have been exercised, 0 have expired, and 2,750,000 remain outstanding.

Our current Board of Directors serves as the Committee. The Plan further provides for the Committee to set the terms of any Options granted at the time of the grant and terminates ten years for its effective date and is subject to final shareholder approval.

On September 18, 2011, our Board of Directors approved the Annual Bonus Performance Plan for Executive Officers. To promote the success of our Company by providing to participating executives bonus incentives that qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code of 1986 as amended. The plan provides for the granting of up to an aggregate amount of bonuses awarded to all Participants of up to 10% of our income before taxes. The plan shall be administered by a Committee currently consisting of our Board of Directors. No bonuses have been granted under this plan during fiscal 2019.

Item 13. Certain Relationships and Related Transactions

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. (formerly known as American CryoStem Corporation) a Nevada corporation ("ACS Global"), in exchange for 21,000,000 shares of our Common Stock. At the time of the acquisition, John Arnone, our Chairman of the Board, CEO and President was a director and the secretary of ACS Global and Anthony Dudzinski, one of our directors and our Chief Operating Officer, Treasurer and Secretary was a director, president and secretary of ACS Global. In addition, Mr. Arnone owns 18,250,000 shares of Common Stock of ACS Global and has the right to receive an additional 12,000,000 such shares upon the conversion of Series C Preferred Stock of ACS Global owned by him and Mr. Dudzinski owns 6,020,000 shares of ACS Global Common Stock and has the right to receive an additional 12,000,000 such shares upon the conversion of ACS Global preferred stock owned by him. As a result, assuming the conversion of such preferred stock, Mr. Arnone and Mr. Dudzinski would have been deemed to be the beneficial owners of approximately 37.27 % and 22.20% of the Common Stock of ACS Global, respectively. Further, Mr. Arnone and Mr. Dudzinski, as control persons of ACS Global may be deemed to beneficially own the 21,000,000 shares of our Common Stock issued to ACS Global in the acquisition. Each of Mr. Arnone and Mr. Dudzinski disclaim such beneficial ownership.

Mr. Arnone remains a Director and Secretary of ACS Global and Mr. Dudzinski remains as a Director, President and Treasurer of ACS Global. Mr. Arnone is also the Chairman and CEO of Personal Cell Sciences, Inc.

Director Independence

Using the definition of "independent" using the rules of The Nasdaq Stock Market, we have determined that neither John Arnone nor Anthony Dudzinski are independent.

Item 14. Principal Accountant Fees and Services

The Company's Board of Directors and management annually reviews its audit needs and the qualifications of its current auditor. During fiscal 2018 the Company reviewed the services, qualification and retainer agreement of its current Auditor, Fruci & Associates II, PLLC and approved Fruci & Associates II, PLLC retention for the Fiscal 2019 audit and for review of its quarterly filing requirements for Fiscal 2019.

Audit Fees

The aggregate fees billed by Fruci & Associates II, PLLC, for professional services rendered for the audit of our annual financial statements for fiscal year ended September 30, 2019 were $24,500 and $22,500 for the fiscal year ended September 30, 2018. Fruci & Associates billed the Company a total of $11,250 for the review of the Company's quarterly reports ($3,750 per quarter).

Audit-Related Fees

There were no other fees billed by Fruci & Associates II, PLLC for professional services rendered, other than as stated under the captions Audit Fees.

Tax Fees

There were no other fees billed Fruci & Associates II, PLLC for professional services rendered, other than as stated under the captions Audit Fees.

All Other Fees

There were no other fees billed by Fruci & Associates II, PLLC for professional services rendered, other than as stated under the captions Audit Fees, Audit-Related Fees, and Tax Fees.

PART IV

Item 15. Exhibits

(a)

Exhibit No.	**Description**
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Operating Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of American CryoStem Corporation's Chief Executive Officer and Chief Operating Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation
101.DEF	XBRL Taxonomy Extension Definition
101.LAB	XBRL Taxonomy Extension Label
101.PRE	XBRL Taxonomy Extension Presentation

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

AMERICAN CRYOSTEM CORPORATION

Dated: January 14, 2020

By: */s/ John S, Arnone*
John S. Arnone
President, CEO and Chairman of the Board

Dated: January 14, 2020

By: */s/ Anthony F. Dudzinski*
Anthony F. Dudzinski
COO, Treasurer, Secretary and Director

PART F/S

INDEX TO FINANCIAL STATEMENTS

AUDITED FINANCIAL STATEMENTS

FRUCI & ASSOCIATES II
A Professional Limited Liability Company

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of American CryoStem Corp. and Subsidiaries ("the Company") as of September 30, 2019 and 2018, and the related consolidated statements of operations, changes in shareholders' deficit, and cash flows for each of the years in the two-year period ended September 30, 2019, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended September 30, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred significant losses since inception. This factor raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Fruci & Associates II, PLLC

We have served as the Company's auditor since 2017.

Spokane, Washington
January 14, 2020

AMERICAN CRYOSTEM CORPORATION
CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018

American CryoStem Corporation
Consolidated Balance Sheets
As of September 30, 2019 and 2018

ASSETS	**30-Sep-19**	**30-Sep-18**
Current Assets:		
Cash	$ 23,800	$ 68,320
Accounts Receivable - net of allowance for bad debt	330,154	217,318
Other Receivable - Related Parties	—	790
Prepaid Expenses	—	48,931
Inventory	25,855	33,698
Total Current Assets	379,809	369,057
Other Assets:		
Other Receivable	—	159
Investment in Autogenesis - at cost	—	1,000
Investment in Baoxin - at cost	300,000	300,000
Security Deposit	13,540	13,540
Patents and Patents Development - net of accumulated amortization	362,490	337,962
Fixed Assets - net of accumulated depreciation	238,078	244,707
Total Assets	$ 1,293,917	$ 1,266,425
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable & Accrued Expenses	$ 321,738	$ 307,214
Legal & Accounting Payable	97,235	65,561
Consultants Payable	189,227	131,667
Bridge Notes Payable	226,500	226,500
Convertible Notes Payable	398,500	323,500
Equipment Lease Payable	35,673	31,001
Deferred Revenues	23,333	26,667
Total Current Liabilities	1,292,206	1,112,110
Long Term Liabilities:		
Convertible Notes Payable - Net of Debt Discount	102,288	25,000
Equipment Lease Payable	26,722	62,386
Accrued Executive Salaries	900,186	660,186
Payable to Related Parties	210,520	107,189
Total Liabilities	2,531,922	1,966,871
Commitments and Contingencies	0	0
Shareholders' Deficit:		
Preferred Stock - $.0001 par value, 50,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2019 and 2018	0	0
Common Stock - $.001 par value, 300,000,000 shares authorized, 49,387,918 shares issued and outstanding at September 30, 2019 and 48,196,210 issued and outstanding at September 30, 2018	49,389	48,197
Additional Paid in Capital	13,931,500	13,388,034
Accumulated Deficit	(15,218,894)	(14,136,677)
Total Shareholders' Deficit	(1,238,005)	(700,446)
Total Liabilities & Shareholders' Deficit	$ 1,293,917	$ 1,266,425

See the notes to the financial statements.

American CryoStem Corporation
Consolidated Statements of Operations
For the Years Ended September 30, 2019 and 2018

	30-Sep-19	30-Sep-18
Revenues		
Tissue Processing & Storage	$ 26,367	$ 570,908
Product Sales	25,523	8,490
Licensing Fees & Royalties	269,757	449,019
Consulting Fees	—	75,000
Total Revenues	321,647	1,103,417
Less Cost of Revenues	(31,876)	(296,992)
Gross Margin	289,771	806,425
Operating Expenses		
Research & Development	224,792	341,516
Laboratory Expense	156,512	179,476
Sales & Marketing	33,754	70,630
Professional Fees	101,619	171,536
Stock Compensation Expense	125,403	613,638
General & Administrative	598,726	669,847
Total Operating Expenses	1,240,806	2,046,643
Net Loss from Operations	(951,035)	(1,240,218)
Other Income (Expenses):		
Interest Income	160	—
Exchange Rate(Loss)	(3,407)	(17,804)
Gain/(Loss) on Settlements	14,812	(96,437)
(Loss) on Sale of Assets	(5,883)	—
Foreign Taxes	(4,117)	(32,303)
Penalties	(2,579)	(3,836)
Interest Expense	(66,516)	(74,914)
Interest Expense (beneficial conversion feature-debenture)	(63,652)	(25,000)
Net Loss before Provision for Income Taxes	(1,082,217)	(1,490,512)
Provision for Income Taxes	—	—
Net Loss	$ (1,082,217)	$ (1,490,512)
Basic & Fully Diluted Net Income (Loss) per Common Share:	$ (0.02)	$ (0.03)
Weighted Average of Common Shares Outstanding - Basic & fully diluted	48,915,644	46,216,368

See the notes to the financial statements.

American CryoStem Corporation
Consolidated Statements of Cash Flows
For the Years Ended September 30, 2019 and 2018

	30-Sep-19	30-Sep-18
Operating Activities:		
Net loss	$ (1,082,217)	$ (1,490,512)
Adjustments to reconcile net loss items not requiring the use of cash:		
Bad Debt Expense	10,935	707
Interest Paid with Common Stock	50,391	—
Bill Paid with Common Stock	27,500	—
Loss on Settlement of Legal Bill	—	96,437
Stock Compensation	125,403	613,638
Depreciation & Amortization Expense	32,002	26,981
Interest Expense- Beneficial Conversion Feature	63,652	25,000
Loss on Investment	1,000	—
Changes in operating assets and liabilities		
Accounts receivable	(123,771)	(46,165)
Other Receivable - Related Parties	949	(949)
Prepaid expense	48,931	94,498
Inventory	7,843	(5,994)
Accounts Payable and Accrued Expenses	103,759	277,595
Salaries Payable	240,000	233,288
Deferred Revenue	(3,334)	1,003
Net cash used by operations	(496,957)	(174,473)
Investing activities:		
Patents development	(29,855)	(44,242)
Investment in Baoxin	—	(300,000)
Purchase of lab equipment & furniture	(20,047)	(180,732)
Net cash used by investing activities	(49,902)	(524,974)
Financing activities:		
Issuance of common shares	280,000	—
Options exercised	—	165,500
Issuance of convertible note	150,000	100,000
Proceeds form Capital lease	—	102,790
Pay down Capital Lease	(30,992)	(9,403)
Payable to related party	103,331	(1,462)
Net cash provided by financing activities	502,339	357,425
Net change in cash	(44,520)	(342,022)
Cash balance at beginning of the period	68,320	410,342
Cash balance at end of the period	$ 23,800	$ 68,320
Supplemental disclosures of cash flow information:		
Interest paid during the period	$ 11,357	$ 10,235
Income taxes paid during the period	—	—

See the notes to the financial statements.
See Note 17 for non-cash transactions.

American CryoStem Corporation
Consolidated Statement of Changes in Shareholders' Deficit
For the Years Ended September 30, 2019 and 2018

	Common Shares	Par Value	Paid in Capital	Accumulated Deficit	Total Deficit
Balance at September 30, 2017	43,409,580	$ 43,410	$ 11,581,197	$ (12,646,165)	$ (1,021,558)
Convertible notes exercised	3,072,976	3,073	537,427		540,500
Options exercised	1,145,000	1,145	164,355		165,500
Shares issued for services	80,000	80	63,970		64,050
Shares issued to pay interest due	118,461	119	62,113		62,232
Shares issued to pay legal bill	219,290	219	186,177		186,396
Issued convertible debenture			100,000		100,000
Issuance of options			549,588		549,588
Purchase prepaid rent	115,890	116	109,980		110,096
Purchase leasehold improvement	35,013	35	33,227		33,262
Net loss				(1,490,512)	(1,490,512)
Balance at September 30, 2018	48,196,210	$ 48,197	$ 13,388,034	$ (14,136,677)	$ (700,446)
Issuance of common shares	950,003	950	279,050		280,000
Shares issued to pay bill	100,000	100	27,400		27,500
Shares issued to pay interest due	91,705	92	50,299		50,391
Shares issued for services provided	50,000	50	24,950		25,000
Stock Compensation Expense			100,403		100,403
Issued convertible note - Beneficial Conversion Feature			61,364		61,364
Net loss				(1,082,217)	(1,082,217)
Balance at September 30, 2019	49,387,918	$ 49,389	$ 13,931,500	$ (15,218,894)	$ (1,238,005)

See the notes to the financial statements.

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.

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.

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.

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

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. 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 X, "Revenue Recognition" for additional information.

Reclassification – Some of the balances for Fiscal 2018 have been reclassified. None of these reclassifications affect the presentation of the Company's financial Position or results of operations.

Advertising – Advertising Cost are expensed as they are incurred. Advertising Costs were $998 for Fiscal 2019 and $5,100 for Fiscal 2018, which is in Sales and Marketing Expenses within the Consolidated Statements of Operations.

Bad Debt Expense - The Company provides, through charges to income or loss, a charge for bad debt expense, which is based upon management's evaluation of numerous factors. These factors include economic conditions prevailing, a predictive analysis of the outcome of the current portfolio by client, and prior credit loss experience of each client. The Company uses the information from this analysis to develop an estimate of bad debt reserve based upon the amount of accounts receivable by client at the balance sheet date. The Allowance for Doubtful Accounts was $10,865 at September 30, 2019 and $0 at September 30, 2018.

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

Inventory was composed of Raw Materials and Finished Goods, which was valued at $25,855 at September 30, 2019 and $33,698 at September 30, 2018.

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

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

Office Equipment	5 years
Lab Equipment & Furniture	7 years
Lab Software	5 years
Leasehold Improvements	15 years

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

The Company follows the accounting requirements associated with uncertainty in income taxes using the provisions of Financial Accounting Standards Board (FASB) ASC 740, Income Taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not the positions will be sustained upon examination by the tax authorities. It also provides guidance for derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of September 30, 2019 and September 30, 2018, the Company has no uncertain tax positions that qualify for either recognition or disclosure in the financial statements. All tax returns from fiscal years 2015 to 2018 are subject to IRS and State of New Jersey audit.

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

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 No. 2016-02 which supersedes ASC 840, *Accounting for Leases*. The new guidance requires the recognition of lease assets and lease liabilities for operating leases with lease terms of more than twelve months. Presentation of leases within the consolidated statements of operations and consolidated statement of cash flows will be generally consistent with current lease accounting guidance. The amended ASU is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. The Company believes the accounting change would not have a material effect on the financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which was an updated standard on revenue recognition. The ASU provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies that report using the International Financial Reporting Standards or U.S.GAAP. The main purpose of the ASU is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also enhances disclosures about revenue, providing guidance for transactions not previously addressed comprehensively and improves the guidance for multiple-element arrangements. The FASB deferred approval of the ASU to effective date for periods beginning after December 15, 2017. The Company has implemented this accounting change which does not 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 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, 2019, we adopted ASC 606 applying the modified retrospective transition method to all contracts that were not completed as of October 1, 2019. 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.

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.

NOTE 3. Revenue Recognition (continued)

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, Pepro-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 years ended September 30, 2019 and 2018.

	Years Ended September 30	
	2019	2018
Licensing & Other Fees		
Baoxin	$ 225,000	$ 400,000
Cell Source	43,333	40,000
Pepro-Tech	—	5,659
CryoViva	—	75,000
Personal Cell Sciences	1,424	3,360
Total	$ 269,757	$ 524,019
Product Sales		
Baoxin	$ 19,683	$ 8,490
CryoViva	5,840	—
Total	$ 25,523	$ 8,490

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

NOTE 3. Revenue Recognition (continued)

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 13,941,500 shares of Common Stock issuable upon exercise of all outstanding stock options and warrants for Fiscal Years 2019 and 2018, respectively; and, 2,134,784 and 1,680,237 shares issuable on the conversion of outstanding Convertible Notes for Fiscal Years 2019 and 2018, respectively.

Net Loss per share for the Fiscal Years is computed below:

	2019	2018
Net Gain (Loss)	$ (1,082,217)	$ (1,490,512)
Weighted average shares outstanding, basic and diluted	48,915,644	46,216,368
Basic & fully diluted net loss per common share	$ (0.02)	$ (0.03)

NOTE 5. Fixed Assets

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

	September 30, 2019	September 30, 2018
Laboratory Equipment	$ 386,579	$ 416,879
Laboratory Leasehold Improvements	110,286	84,608
Laboratory Furniture	1,841	1,841
Office Equipment	23,988	23,988
Office Leasehold Improvements	2,650	2,650
Office Furniture	1,812	1,812
Accumulated Depreciation	(289,078)	(287,071)
Net Property and Equipment	$ 238,078	$ 244,707

Depreciation expense for Fiscal Years 2019 and 2018 is $26,675 and $21,644 respectively.

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 Fiscal Year 2019 was $5,327 and $5,337 for Fiscal 2018.

Patents still in the application process have not been amortized. The unamortized costs of patents in the application process are $288,882 for Fiscal 2019 and $291,027 for Fiscal 2018. Amortizable Patent Costs $96,000 at Fiscal Year Ended 2019 and $64,000 at Fiscal Year Ended 2018. The following is the amortization expense for these patents for the next 5 years:

Fiscal 2020	$ 5,647
Fiscal 2021	$ 5,647
Fiscal 2020	$ 5,647
Fiscal 2020	$ 5,647
Fiscal 2020	$ 5,647

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.

NOTE 6. Patent & Patents Filings (continued)

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. EPl3800847.9 and China Application No. 2013800391988.

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

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

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

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

NOTE 7. Debt

The following table describes the Company's debt outstanding as of September 30, 2019:

Debt	Carrying Value	Maturity	Rate
Bridge Notes	$ 226,500	Demand	8.00%
Convertible Notes @ 40 cents	$ 100,000	Fiscal 2020	8.00%
Convertible Notes @ 35 cents	$ 83,500	Demand	8.00%
Convertible Notes @ 33 cents	$ 150,000	Fiscal 2021	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%
Capital Lease	$ 62,395	Fiscal 2021	14.00%

The convertible notes are exercisable at any time and have exercise prices ranging from $0.15 to $0.40 with the amount of shares exercisable based on the face value of the convertible note. The holders of the bridge notes also have an option to purchase shares of the Company at $0.05 per share with the number of shares dependent upon the face value of the bridge note. As of the date of this report, 36,500 of these options remain outstanding.

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

As a result of the issue, the Company recognized interest expense of $100,000 as a beneficial conversion feature of the debenture which has been amortized over the life of the note. The Interest Expense due to the Beneficial Conversion Feature for the Years Ended September 30, 2019 and 2018 were $50,000 and $25,000.

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.

NOTE 7. Debt (continued)

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 Year Ended September 30, 2019 was $13,652.

NOTE 8. Common Stock Issuances

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

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

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

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

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

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

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

During fiscal 2019, the Company issued 950,003 shares and received $280,000. The share prices were determined by agreement with the purchasers, based upon the current market price less a discount for purchasing restricted securities.

During fiscal 2019, the Company issued 50,000 shares to a consultant for services rendered valued at $25,000. The share price used was the market value price per share on the date issued.

During fiscal 2019, the Company issued 91,706 shares to pay interest due to holders of the bridge notes and convertible notes. The value of the interest paid was $50,391. The share prices were determined by the aggregate market price for the week in which the shares were issued.

During fiscal 2019, the Company issued 100,000 shares to pay an outstanding consulting bill. The shares issued were valued at $27,500. The share prices were determined by agreement with the consultant based on the value of the services provided.

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 instructs the transfer agent to issue the requisite number of shares underlying the option exercise.

NOTE 9. Option Issuances (continued)

Using the Black-Sholes valuation method, the Company issued options and recorded salaries and consulting expenses of $549,588 in fiscal year 2018. The Company did not issue any options for Fiscal Year 2019.

The fair value of the options issued in Fiscal 2018 was calculated using the following assumptions:

	2018
Dividend yield	0.00%
Risk free interest rate	1.95%
Volatility	217.20%
Share Price	$ 0.94
Term in Years	5

The following is a summary of common stock options outstanding at September 30, 2019:

	Amount	Exercise Price Range	Weighted Average Exercise Price	Weighted Average Remaining Term (Years)
Outstanding at September 30, 2017	14,776,500	$0.05 - $0.40	$ 0.25	2.75
Granted	500,000	$0.01		
Exercised	(1,145,000)	$0.01 - $0.40		
Expired	(1,825,000)	$0.15 - $0.40		
Forfeited	—			
Outstanding at September 30, 2018	12,306,500	$0.05 - $0.40	$ 0.26	2.31
Granted	—			
Exercised	—			
Expired	(3,220,000)	$0.25 - $0.35		
Forfeited	(325,000)	$0.20 - $0.40		
Outstanding at September 30, 2019	8,761,500	$0.05 - $0.40	$ 0.26	1.85

All outstanding stock options at September 30, 2019 are vested and exercisable.

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 are valued using level 3 of the fair value hierarchy.

NOTE 11. Commitments & Contingencies

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

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

The least was amended for six months from February 1, 2019 to July 31, 2019: for a rent of $7,732 per month. The Company continued on a month to month basis for August 1 to September 30, 2019 at a rent of $7,732 per month.

The lease was amended again, reducing the amount of space by 1,628 square feet. The current terms are 722 square feet of laboratory space from October 1, 2019 to March 31, 2020 for a rent of $2,389 per month.

Total minimum lease payments under this lease are $14,334 for Fiscal 2020.

These remaining lease payments are due in cash.

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

	2020	31,800
	2021	18,550
Total minimum lease payments		$50,350

Rent Expense was $158,047 for Fiscal 2019 and $148,261 for Fiscal 2018.

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

	2020	42,235
	2021	28,157
Total minimum lease payments		$ 70,392
Less amounts representing interest		(7,997)
Present value of net minimum lease payments		$ 62,395

Depreciation expense for the leased equipment for Fiscal 2019 was $18,362 and $6,094 for Fiscal 2018.

NOTE 12. Litigation

On August 5, 2019, the Company was served with a civil complaint by Focus Search Group, LLC in Massachusetts. The complaint made claims for certain consulting fees due totaling approximately $61,000. The matter was resolved by settlement between the two parties. There is no other litigation or anticipated litigation as of the date of these financial statements. Legal Expenses are expensed as incurred.

NOTE 13. Concentration of Credit

The Company received approximately 91% of its revenues in Fiscal 2019 from three clients, Baoxin, Cell Source and Cryoviva; and approximately 83% in Fiscal 2018 from two clients, Cells on Ice and Baoxin. The Company also had accounts receivable from Baoxin of $328,154 at September 30, 2019 and $208,490 at September 30, 2018.

The Company's accounts receivable from non-US countries was approximately 96% for Fiscal 2019 and 96% for Fiscal 2018. The Company received approximately 86% of its revenues in Fiscal 2019 and 47% of its revenues in Fiscal 2018 from non-US countries.

NOTE 14. Investments

During fiscal year 2014, the Company invested $1,000 in a joint venture. The joint venture is called Autogenesis Corporation and was incorporated in the state of Florida. The Company and its two chief executives own 50% of Autogenesis. Autogenesis was formed for the purpose of developing a wound healing protocol. The Company has no further obligations to Autogenesis and the joint venture is responsible for its own funding. Autogenesis has no material business operations since its inception. For Fiscal 2019 the Company has written off its investment in Autogenesis.

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 September 30, 2019 and 2018. 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 Fiscal 2019.

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

NOTE 15. Related Party Transactions

The Company was indebted to a company that is majority owned by the Company's two officers in the amount of $205,355 for Fiscal 2019 and $107,189 for Fiscal 2018. The advances are unsecured, and carry no interest rate and are collectible at the discretion of the company's two officers/directors. The officers/directors do not anticipate collecting this in Fiscal 2020.

The Company was indebted to a company that is wholly owned by the Company's Chief Executive Officer $3,080 for Fiscal 2019 and $1,831 for Fiscal 2018. The advances are unsecured, carry no interest rate and are collectible at the discretion of the company's two officers/directors. The balance due of $3,080 and $1,831 at September 30, 2019 has been paid in full in Fiscal 2020.

The Company was indebted to the Company's Chief Executive Officer in the amount of $5,165 for Fiscal 2019. The advances are unsecured, and carry no interest rate and are collectible at the discretion of the company's two officers/directors. The balance due at September 30, 2019 of $5,165 was paid in full in Fiscal 2020.

The company paid Mr. Arnone consulting fees of $5,000 in Fiscal 2019 and $59,500 in Fiscal 2018. The company paid Mr. Dudzinski consulting fees of $5,000 in Fiscal 2019 and $59,500 in Fiscal 2018.

NOTE 16. Income Taxes

Provision for income taxes is comprised of the following:

	Sept 30, 2019	Sept 30, 2018
Net loss before provision for income taxes	$ (1,082,217)	$ (1,490,512)
Current tax expense:		
Federal	$ 0	$ 0
State	0	0
Total	$ 0	$ 0
Less deferred tax benefit:		
Tax loss carry forwards	$ (8,111,635)	$ (7,029,418)
Allowance for recoverability	8,111,635	7,029,418
Provision for income taxes	$ 0	$ 0

A reconciliation of provision for income taxes at the statutory rate to provision for income taxes at the Company's effective tax rate is as follows:

Statutory U.S. federal rate	21.0%	24.5%
Statutory state and local income tax	10%	10%
Less allowance for tax recoverability	-31.0%	-34.5%
Effective rate	0%	0%

NOTE 16. Income Taxes (continued)

The effective tax rate for the years ended September 30, 2019 and 2018 required the recording of any impact of the Tax Cuts and Jobs Act (the "Tax Act"), enacted on December 22, 2017 by the U.S. government. The Tax Act made broad and complex changes to the U.S. tax code that affect our fiscal years ended September 30, 2019 and 2018, including, but not limited to, (1) reducing the U.S. federal corporate tax rate and (2) requiring a one-time transition tax on certain un-repatriated earnings of foreign subsidiaries that is payable over eight years.

The Tax Act reduced the federal corporate tax rate to 21.0% effective January 1, 2018. In accordance with Section 15 of the Internal Revenue Code, we will utilize a blended rate of 24.5% for our fiscal 2018 tax year, by applying a prorated percentage of the number of days prior to and subsequent to the January 1, 2018 effective date. For Fiscal 2019, we used the new federal corporate rate of 21.0%.

The Deemed Repatriation Transition Tax (the "Transition Tax") is a tax on previously untaxed accumulated earnings and profits ("E&P") of certain of our foreign subsidiaries. Since there were no accumulated earnings and profits in 2018, we determined that the "Transition Tax" did not affect the Company. We have no "Transition Tax liability" for Fiscal 2019.

Note 17. Non-Cash Transactions

As an addendum to the consolidated statements of cash flows, the following non-cash transactions occurred in fiscal years 2019 and 2018:

The Company issued shares of common stock to pay legal bills valued at $186,396 in Fiscal 2018.

The company entered into a Capital Lease to purchase equipment in Fiscal 2018. The balance due on the lease is $70,392.

The Company issued shares of common stock for the conversion of notes in the amount of $540,500 in Fiscal 2018.

The Company issued common stock in Fiscal 2018 to build a "Clean Room" at the Laboratory Facility valued at $33,262.

NOTE 18. Subsequent Events

The Company has made a review of material subsequent events from September 30, 2019 through the date of issuance of this report.

On October 3, 2019 the Company closed a new investment from JSJ Investments in the form of a convertible note. The note is for a principal amount of $168,000 plus 10% interest and is convertible at the rate of $0.48 per share for the initial 180 days and at a 30% discount to the average of the three lowest trading prices during the 10 trading days prior to the date of conversion and is subject to standard equitable adjustment for stock splits, stock dividends, or rights offering by the Company relating to the Company's securities or the securities of any subsidiary of the Company, combinations, recapitalization, reclassifications, extraordinary distributions and similar events.

On December 13, 2019 an investor purchased 500,000 shares of common stock at $0.20 per share for a total investment of $100,000. The share price was determined by agreement with the purchaser, based upon the current market price less a discount for purchasing restricted securities.

On December 27, 2019 two investors purchased 375,000 shares of common stock at $0.20 per share for a total investment of $75,000. The share price was determined by agreement with the purchasers, based upon the current market price less a discount for purchasing restricted securities.

EXHIBIT 31.1

Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer

I, John S. Arnone, certify that:

1. I have reviewed this annual report on Form 10-K 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 presented in this report;

4. The registrant's other certifying officer(s) and I are 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. The registrant's other certifying officer(s) and 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 involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: January 14, 2020

/s/ John S. Arnone
John S. Arnone,
President, CEO and Chairman of the Board

EXHIBIT 31.2

Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer

I, Anthony F. Dudzinski, certify that:

1. I have reviewed this annual report on Form 10-K 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 presented in this report;

4. The registrant's other certifying officer(s) and I are 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. The registrant's other certifying officer(s) and 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 involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: January 14, 2020

/s/ Anthony F. Dudzinski
Anthony F. Dudzinski,
COO, Treasurer, Secretary and Director

EXHIBIT 32.1

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

In connection with the Annual Report of American CryoStem Corporation (the "**Company**") on Form 10-K for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), each of the undersigned, John S. Arnone, President, CEO and Chairman of the Board of the registrant and Anthony F. Dudzinski, COO, Treasurer, Secretary and Director of the registrant, certifies, pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that:

1. The Report on Form 10-K fully complies with the requirements of Sections 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certificate is being made for the exclusive purpose of compliance by the Chief Executive Officer and the Treasurer of the Company with the requirements of Section 906 of the Sarbanes-Oxley Act of 2002, and may not be disclosed, distributed or used by any person or for any reason other than as specifically required by law.

Date: January 14, 2020

By: */s/ John S. Arnone*
Name: John S. Arnone
Title: President, CEO and Chairman of the Board

Date: January 14, 2020

By: */s/ Anthony F. Dudzinski*
Name: Anthony F. Dudzinski
Title: COO, Treasurer, Secretary and Director