

AMERICAN CRYOSTEM Corp  
Form 10-K  
January 15, 2019

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended: September 30, 2018

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

Commission file number: 000-54672

**American CryoStem Corporation**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of incorporation or organization)

**1 Meridian Road, Suite 5**

**26-4574088**

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

**Eatontown, NJ 07724**

(Address of principal executive offices)

**(732) 747-1007**

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value \$0.001**

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large Accelerated Filer  Accelerated Filer   
Non-Accelerated Filer  Smaller reporting company   
Emerging Growth Company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based on a closing price of \$0.87 on March 31, 2018 (the last business day of the registrants most recently completed second fiscal quarter) was approximately \$ 41,930,506

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As of January 11, 2019, the registrant had 48,196,210 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,” 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's R&D efforts are focused on university and private collaborations to discover, develop and commercialize ADSC and laboratory products combined with synergistic technologies to create regenerative medicine applications and new intellectual property.

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.

We are generating revenues through the sale and licensing of our patented products, laboratory tools, and services to capitalize on: (1) ADSC technologies; (2) scientific breakthroughs incorporating ADSCs that have been developing in the fast growing Regenerative and Personalized Medicine industries; (3) providing these growth industries with a standardized ADSC cell processing platform; (4) enhancing the delivery of healthcare through cellular-based therapies and applications which address disease treatment, orthopedic injuries, wound and burn healing, and personalized health and beauty care; and (5) building a global network of physicians and affiliated laboratory facilities for the delivery of our products and services.

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

To date, we have generated minimal revenue; however, subject to, among other factors, obtaining the requisite financing, management believes that we are well positioned to utilize our developed products and services as the foundation for domestic and international distribution through licensees of our technologies, and a host of Regenerative Medicine application uses and future therapy products. In the US we operate an FDA registered facility that generates revenue from; the processing and storage of adipose tissue (ATGRAFT), the processing of adipose tissue into its cellular components for future use (ATCELL) and the production and sale of our CELLECT® 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<sup>SM</sup> 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<sup>TM</sup> and ATCELL<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> procedures may include breast reconstruction, layered augmentation, buttocks enhancement or volume corrections of the hands, feet, face and neck areas that experience significant adipose tissue (fat) volume reduction as we age. ATGRAFT<sup>TM</sup> is processed and stored utilizing our standards so that any stored fat tissue sample may be retrieved in the future and re-processed to create stem cells, “ATCELL<sup>SM</sup>”, for use in Regenerative Medicine applications. The ATGRAFT<sup>TM</sup> service is included in our granted patent “Business Method for Collection, Processing, Cryogenic Storage and Distribution of a Biologic Sample Material” US Patent Number 10,014,079, issued July 3, 2018.



The Company'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, 2014.

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

**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 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.

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

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

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<sup>™</sup> tissue processing and storage technology and the purchase of our CELLECT<sup>®</sup> collection products which include our ACSelerate-TR<sup>™</sup> transport medium. The Company also assisted CellSource in upgrading its facility in Japan and provided training in the ATGRAFT<sup>™</sup> processing and recordkeeping procedures. CellSource began marketing the new services initially within its existing network of clinics throughout Japan and began purchasing its CELLECT<sup>™</sup> and ACSelerate-CP<sup>™</sup> cryoprotectant from the Company in the third quarter

of 2015. Upon execution of the Agreement the Company received an upfront payment and will receive additional minimum annual payments, and consumable product sales revenue - in future years. The 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.

### ***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, Collect™ tissue collection kit, and ACSelerate – Max™ cell culture medium.

### **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 graftment 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.

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

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

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

### ***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.

### ***Rutgers University***

In May of 2012, American CryoStem entered into Material Transfer Agreements with three research scientists at Rutgers University allowing them to utilize the Company's autologous Adipose-Derived Stem Cells (ATCELL™) and patented, serum free, GMP grade cell culture and differentiation mediums (ACSelerate™) for evaluation with the anticipation to implement additional agreements to research, develop and commercialize innovative new cellular therapies targeting incurable diseases, neurological disorders and the \$5 billion global wound care market. During the last quarter of 2015 the Company undertook a review of the collaborative efforts between the Company and Dr. Lee pending the expiration of the agreements in November of 2015. Management believes that potential commercialization of the licensed technologies would require a number of years of additional study and experimentation and substantial investment by the Company. In November of 2015 the Collaboration and Research Agreement and the Licensing Agreement were terminated.

In 2018, The Company began delivering ATCELL samples to Dr. Lee to support his ongoing research into adipose derived stem cells for neural repair. At this time the company cannot assure that any of Dr. Lee's ongoing efforts will result in a commercial product.

### ***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 Collect 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).

In January 2018 the Company 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 has 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 believes that it can complete the laboratory cGMP work to upgrade its facility from a registered tissue bank to a Biologic Drug Manufacturer and submit the IND Application to FDA during Q1-Q2, 2019.

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, SVF, 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.

### *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.

## **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:



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<b>Title</b>	<b>Technology</b>	<b>Patent / Application Number</b>
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Covers 12 types of Medium	US Patent No. 7,989,205 Issued August 2, 2011 US Patent No. 9,487,755
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Additional claim Granted for all 12 medium types	Issued November 8, 2016 Continuation of US Patent No. 7,989,205 US Patent Application No. 15/344,805
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Continuation of Granted Patent covering additional improvements	Continuation of US Patent No. 7,989,205 PCT/US15/68350
Human serum for cell culture medium for growth of human adipose stromal cells	A cell culture medium for growth of human adipose stromal cells for human and therapeutic applications	30 month National Phase entry date of June 31, 2017, additional International Filings for China, India, the European Union, Saudi Arabia, Israel, Brazil, Mexico, Australia and New Zealand. US Serial No 13/194,900
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology Covers CELLECT Kit, Transport and Cryopreservation Medium for ATGRAFT and ATCELL Products	Filed June 6, 2010 Patent Application Published December 5, 2013 Claims Granted US Patent No. 10,014,079. Continuation filed upon issuance. Developed Improvement established;
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	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. Developed Improvement established;
Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation	Adipose Tissue Digestion Laboratory Processing Methods	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



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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	China Application No. 2013800391988 Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 14/406,203 imminent (PCT Application filing planned)
Systems and methods to isolate and expand stem cells from urine	Isolation of stem cells from urine of patients for use in research and therapeutics	US Serial Nos. 62/335,426 and 62/439,106

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

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

**Trademarks**

In addition to patents, the Company has registered the following trademarks with the U.S. Patent and Trademark Office: *American CryoStem*<sup>®</sup>, *CELLECT*<sup>®</sup> and *ATGRAFT*<sup>™</sup>. We 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*<sup>™</sup>, *ACSelerate-LSM*<sup>™</sup> and *ATCELL*<sup>™</sup>. The Company has also secured a number of online domain names relevant to its business, including [www.americancryostem.com](http://www.americancryostem.com) and [www.acslaboratories.com](http://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.

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## 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 in response to the Warning Letter issued by the FDA. (See Regulatory Information above)

**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*<sup>®</sup>, *ATGRAFT*<sup>™</sup> and *ATCELL*<sup>™</sup> services in their local market. Strategically, the Company's international licensees will maintain the branding of the Company's services along the lines of the "Intel Inside" branding program.

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

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

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

**Baoxin Asia Pacific Biotechnology (Shenzhen) Co. Ltd.** On July 12, 2018 The Company announced the national launch of CRYO's *ATGRAFT*<sup>™</sup> tissue collection, processing and storage technology by Baoxin Asia Pacific Biotechnology (Shenzhen) Co. Ltd. ("Baoxin") in China. The management team traveled throughout south east China with the management and marketing team of Baoxin to present the *ATGRAFT*<sup>™</sup> platform to leading plastic and cosmetic surgery hospitals in Shenzhen, Nanning, Guangzhou, Guangxi and Changsha. 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.

**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*<sup>™</sup> 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*<sup>™</sup> storage media, *CELLECT*<sup>™</sup> collection and transportation kits as well as other American CryoStem products necessary for clinical adipose tissue processing and storage at the Shenzhen facility. The final master licensing agreement is for a period of 5 years with renewal options and was executed between the parties on September 24, 2014.

In 2017 as part of the Company's transaction with Baoxin, HIT and the Company agreed to transfer certain product and distribution rights granted to HIT under its 2014 agreement to Baoxin. The Company was paid of fee 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, Collect™ 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, 2018, 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 oculo-facial 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*<sup>®</sup> National Education Faculty, as well as the *Radiesse*<sup>™</sup> Medical Education Faculty. Dr. Stern is also an instructor for the *Sciton*<sup>™</sup> 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*<sup>®</sup> 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.

**Alan H. Davis** - Mr. Davis is currently a partner in and the Chief Operating Officer of Novare, LLC. Novare Biologistics was created to meet the need of transporting and storing laboratory materials, including biological samples at required temperature anywhere within the U.S. Over the past 20 years, Mr. Davis has concentrated on business development and sales in biotechnology, manufacturing and software technology. Previously, he was primarily involved in retailing.

**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](http://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](http://www.acslaboratories.com).

### *Employees*

Currently, we have eight (8) 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.

### Item 1A. Risk Factors

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, 2018 with respect to this uncertainty which is included in the 2018 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 March 30, 2020. 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, 2018, 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, 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, laboratory upgrades and filing an IND application 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, 2018, there were 48,196,210 shares of Common Stock (excluding 11,631,500 shares issuable upon exercise of all issued and outstanding stock options and warrants, and 1,680,237 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, 2018, 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, 2018, the Company sold approximately \$4,275,127 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, 2018, we had 11,631,500 of Common Stock issuable upon exercise of all outstanding stock options and warrants, and, 1,680,237 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 leased additional space at the Monmouth Junction facility to accommodate a new Clean Room designed specifically for cellular expansion, medium filling and tissue processing.

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. 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.

PART II

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, 2017	\$1.14	\$0.755
March 31, 2018	\$0.85	\$0.48
June 30, 2018	\$1.03	\$0.85
September 30, 2018	\$0.95	\$0.739

**(b) Holders of Common Equity**

As of September 30, 2018, there were approximately 162 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 2017, the Company issued 91,667 shares and received proceeds of \$13,750.

During fiscal 2017, the Company issued 2,396,548 shares for Convertible Notes exercised at a value of \$468,000.

During fiscal 2017, the Company issued 2,640,000 shares for Options exercised at a value of \$110,400.

During fiscal 2017, the Company issued 425,000 shares to consultants for services rendered valued at \$175,250.

During fiscal 2017, the Company issued 534,656 shares to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid was \$149,805.

During fiscal 2017, the Company issued 200,000 shares to pay an outstanding legal bill. The value of the stock issued was \$210,000.

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.

*(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 with the following assumptions:

	2018		2017	
Dividend yield	0.00	%	0.00	%
Risk free interest rate	1.95	%	1.25-1.93	%
Volatility	217.20	%	213.01-230.70	%
Share Price	\$0.94		\$0.44	
Term in Years	5		3-5	

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. Using the Black-Sholes valuation method, the Company issued options and recorded salaries and consulting expenses of \$549,588 and \$1,019,998 in fiscal years 2018 and 2017, respectively. For additional information please see Note 8. Option Issuances to the Financial Statements contained herein.

**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 neg 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.

### **Fiscal 2018 Operations**

In Fiscal 2018, The Company's Total Revenue decreased to \$1,103,417 in Fiscal 2018 versus \$1,865,364 in Fiscal 2017, due mainly to ceasing shipment of our ATCELL product in the US. Accounts Receivable increased to \$271,318 in Fiscal 2018 from \$171,860 in Fiscal 2017 due to increased fees receivable from International Licensees. In 2018 Licensing Fees and Royalties increased to \$449,019 from \$124,535 in Fiscal 2017. Short term liabilities decreased to \$1,772,296 in Fiscal 2018 from \$1,922,100 in Fiscal 2017 due to conversions of convertible notes. Long term debt decreased to \$107,189 in 2018 from \$108,651 in 2017. Cost of Sales decreased to \$296,993 in Fiscal 2018 from \$554,514 in Fiscal 2017 due to lower processing activities associated with ATCELL™. The Company saw an increase in professional fees to \$171,563 in Fiscal 2018 from \$72,990 in Fiscal 2017 due to increased use of consultants associated with the Company's laboratory remediation and IND preparation activities. Research and Development increased to \$341,516 in 2018 from \$87,210 in 2017 due to 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, 2018, the Company had a cash balance of \$68,320 and accounts receivable of \$217,318. Our sources of funds in 2018 were tissue processing and storage fees, international product sales, consulting and licensing fees, and financing activities. In Fiscal 2018 we used \$174,474 net cash for Operations, and \$524,974 in investment activities including the Investment in Baoxin Asia Pacific Biotechnology (Shenzhen) Co. Ltd., Patent Development, and the purchase of Laboratory equipment and furniture associated with the ongoing remediation and upgrade of our Monmouth Junction, NJ facility. Additionally, the Company generated \$357,425 from financing activities including option exercises and the issuance of convertible notes.

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, 2018.

## **Off Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

## **Critical Accounting Policies**

We prepare financial statements in conformity with U.S. generally accepted accounting principles (“GAAP”), which requires us to make estimates and assumptions that affect the amounts reported in our combined and consolidated financial statements and related notes. We periodically evaluate these estimates and assumptions based on the most recently available information, our own historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from those estimates. Some of our accounting

policies require higher degrees of judgment than others in their application. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

### **Basis of Presentation**

Our financial statements are presented on the accrual basis of accounting in accordance with generally accepted accounting principles in the United State of America, whereby revenues are recognized in the period earned and expenses when incurred.

### **Management's Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

### **Long-Lived Assets**

We review and evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, we compare the assets' carrying amounts against the estimated undiscounted cash flows to be generated by those assets over their estimated useful lives. If the carrying amounts are greater than the undiscounted cash flows, the fair values of those assets are estimated by discounting the projected cash flows. Any excess of the carrying amounts over the fair values are recorded as impairments in that fiscal period.

### **Statement of Cash Flows**

For purposes of the statement of cash flows, we consider all highly liquid investments (i.e., investments which, when purchased, have original maturities of three months or less) to be cash equivalents.

## **Fair Value of Financial Instruments**

Our financial instruments consist of cash and cash equivalents. The fair value of cash and cash equivalents approximates the recorded amounts because of the liquidity and short-term nature of these items.

## **Recent Accounting Pronouncements**

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

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

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

**Related Party Transactions.**

At September 30, 2018, the Company was indebted to a company that is majority owned by the Company's two chief executive officers for \$107,189.

The advances 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-12 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 2018. There were no disagreements with our Accountants on Accounting or Financial Disclosure for Fiscal 2018.

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, 2018, 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, 2017. 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, 2017, 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.

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## 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	61	Chairman and Chief Executive Officer	2011
Anthony F. Dudzinski	56	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 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, 2018, 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	<b>Option Awards<sup>1</sup></b>	Total Compensation
John S. Arnone	2018	\$ 59,500	\$ 120,000	N/A	N/A	\$ 0	\$ 179,500
President and CEO	2017	\$ 63,500	\$ 105,000	N/A	N/A	\$ 211,300	\$ 379,800
Anthony F. Dudzinski	2018	\$ 59,500	\$ 120,000	N/A	N/A	\$ 0	\$ 179,500
Chief Operating Officer	2017	\$ 61,500	\$ 105,000	N/A	N/A	\$ 211,300	\$ 377,800

<sup>1</sup>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, 2017 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.

**Item 12. Security Ownership of Certain Beneficial Owners and Management**

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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	<b>Percent of Class<sup>1</sup></b>	
<b>Directors and Named Executive Officers <sup>2</sup>:</b>			
John S. Arnone <sup>3</sup>	26,630,000	51.26	%
Anthony Dudzinski <sup>4</sup>	26,030,000	50.10	%
All directors and named executive officers as a group (2 persons)			
<b>Other 5% or Greater Beneficial Owners</b>			
ACS Global, Inc.	21,000,000	43.57	%

<sup>1</sup>*Beneficial ownership is calculated based on 48,196,210 shares of Common Stock issued and outstanding as of September 30, 2018, 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.*

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

<sup>3</sup>*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 21,000,000 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 4,000,000 options (of which 3,750,000 are vested) to purchase the Company’s Common Stock of which 1,000,000 expire on September 24, 2019 and 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.*

<sup>4</sup>*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 21,000,000 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 4,000,000 options (of which 3,750,000 are vested) to purchase the Company’s Common Stock of which 1,000,000 expire on September 24, 2019, and 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 January 11, 2018, there were 48,196,210 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 2018:

Option Awards					
Name	Number of securities underlying unexercised options (#) Exercisable	<b>Number of securities underlying unexercised options (#) Unexercisable</b>	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	\$ 0.25	9/28/2019
	1,000,000	0	1,000,000	\$ 0.20	9/20/2020
	1,000,000	0	1,000,000	\$ 0.30	9/20/2021
	750,000	250,000	1,000,000	\$ 0.40	7/10/2022
Anthony Dudzinski	1,000,000	0	1,000,000	\$ 0.25	9/28/2019
	1,000,000	0	1,000,000	\$ 0.20	9/20/2020
	1,000,000	0	1,000,000	\$ 0.30	9/20/2021
	750,000	250,000	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, 75,000 have expired, and 3,070,000 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 2018.

### 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 and approved Fruci & Associates retention for the Fiscal 2018 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, 2018 were \$22,500 and \$22,500 for the fiscal year ended September 30, 2017. 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 for professional services rendered, other than as stated under the captions Audit Fees.

***Tax Fees***

There were no other fees billed Fruci & Associates 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 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)

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
31.1	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Chief Operating Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>Certification of American CryoStem Corporation's Chief Executive Officer and Chief Operating Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
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

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## **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 15, 2019 By: */s/ John S. Arnone*  
John S. Arnone  
President, CEO and Chairman of the Board

Dated: January 15, 2019 By: */s/ Anthony F. Dudzinski*  
Anthony F. Dudzinski  
COO, Treasurer, Secretary and Director

**EXHIBIT INDEX**

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PART F/S

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AUDITED FINANCIAL STATEMENTS

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of American CryoStem Corp.

### **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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended September 30, 2018, 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.



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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 15, 2019

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**American CryoStem Corporation****Consolidated Balance Sheets****As of September 30, 2018 and 2017**

	30-Sep-18	30-Sep-17
<b>ASSETS</b>		
Current Assets:		
Cash	\$68,320	\$410,342
Accounts Receivable - net of allowance for bad debt	217,318	171,860
Other Receivable	790	—
Prepaid Expenses	48,931	33,333
Inventory	33,698	27,704
Total Current Assets	369,057	643,239
Other Assets:		
Other Receivable	159	—
Investment in Autogenesis - at cost	1,000	1,000
Investment in Baoxin - at cost	300,000	—
Security Deposit	13,540	13,540
Patents and Patents Development - net of accumulated amortization	337,962	299,057
Fixed Assets - net of accumulated depreciation	244,707	52,357
Total Assets	\$1,266,425	\$1,009,193
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable & Accrued Expenses	\$473,869	\$223,205
Legal & Accounting Payable	30,573	162,545
Bridge Notes Payable	226,500	226,500
Convertible Notes Payable	323,500	864,000
Equipment Lease Payable	31,001	—
Deferred Revenues	26,667	25,664
Total Current Liabilities	1,112,110	1,501,914
Long Term Liabilities:		
Convertible Note Payable - Net of Debt Discount	25,000	—
Equipment Lease Payable	62,386	—
Accrued Executive Salaries	660,186	420,186
Payable to Related Party (ACS Global Inc.)	107,189	108,651
Total Liabilities	1,966,871	2,030,751
Commitments and Contingencies	0	0
Shareholders' Deficit:	0	0

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Preferred Stock - \$.0001 par value, 50,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2018 and 2017		
Common Stock - \$.001 par value, 300,000,000 shares authorized, 48,196,210 shares issued and outstanding at September 30, 2018 and 43,409,580 issued and outstanding at September 30, 2017	48,197	43,410
Additional Paid in Capital	13,388,034	11,581,197
Accumulated Deficit	(14,136,677)	(12,646,165)
Total Shareholders' Deficit	(700,446 )	(1,021,558 )
Total Liabilities & Shareholders' Deficit	\$1,266,425	\$1,009,193

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

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## American CryoStem Corporation

## Consolidated Statements of Operations

## For the Years Ended September 30, 2018 and 2017

	30-Sep-18	30-Sep-17
Revenues		
Tissue Processing & Storage	\$570,908	\$1,364,373
Product Sales	8,490	76,456
Licensing Fees & Royalties	449,019	124,535
Consulting Fees	75,000	300,000
Total Revenues	1,103,417	1,865,364
Less Cost of Revenues	(296,992 )	(554,514 )
Gross Margin	806,425	1,310,850
Operating Expenses		
Research & Development	341,516	87,210
Laboratory Expense	179,476	234,215
Sales & Marketing	70,630	30,621
Professional Fees	171,536	72,990
Consulting Expense - Stock or Options Granted	613,638	1,085,998
General & Administrative	669,847	819,898
Total Operating Expenses	2,046,643	2,330,932
Net Income (Loss) from Operations	(1,240,218 )	(1,020,082 )
Other Income (Expenses):		
Other Income/Expense	—	2,000
Exchange Rate Gain / (Loss)	(17,804 )	
Loss on Settlement	(96,437 )	(113,617 )
Foreign Taxes	(32,303 )	
Penalties	(3,836 )	—
Interest Expense	(74,914 )	(90,308 )
Interest Expense (beneficial conversion feature-debenture)	(25,000 )	—
Net Income (Loss) before Provision for Income Taxes	(1,490,512 )	(1,222,007 )
Provision for Income Taxes	—	—
Net Income (Loss)	\$(1,490,512 )	\$(1,222,007 )
Basic & Fully Diluted Net Income (Loss) per Common Share:	\$(0.03 )	\$(0.03 )
Weighted Average of Common Shares Outstanding - Basic & fully diluted	46,216,368	37,973,803

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

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## American CryoStem Corporation

## Consolidated Statements of Cash Flows

For the Years Ended September 30, 2018 and 2017

	30-Sep-18	30-Sep-17
Operating Activities:		
Net Loss	\$(1,490,512)	\$(1,222,007)
Adjustments to reconcile net loss items not requiring the use of cash:		
Bad Debt Recovery	707	84,544
Loss on Settlement of Legal Bill	96,437	113,617
Impairment Expense (write off laboratory software development)	—	123,000
Consulting Fees - Stock for Services/Options Granted	613,638	1,019,998
Depreciation & Amortization Expense	26,981	37,480
Interest Expense - Beneficial Conversion Feature	25,000	—
Decrease (increase) in operating assets		
Accounts Receivable	(46,165 )	(191,069 )
Prepaid Expense	94,498	(33,333 )
Inventory	(5,994 )	(3,006 )
Other Receivable - Related Parties	(949 )	10,880
Increase (decrease) in operating liabilities		
Deferred Revenue	1,003	(2,850 )
Salaries Payable	233,288	—
Accounts Payable and Accrued Expenses	277,595	395,397
Net Cash Provided (Used) by Operations	(174,473 )	332,651
Investing activities:		
Patents Development	(44,242 )	(44,535 )
Investment in Baoxin	(300,000 )	—
Purchase of Laboratory Equipment & Furniture	(180,732 )	(28,142 )
Net cash used by investing activities	(524,974 )	(72,677 )
Financing activities:		
Issuance of Common Shares	—	13,750
Options exercised	165,500	110,400
Issuance of Convertible Note	100,000	—
Payment of Convertible Note	—	(2,500 )
Proceeds from Capital Lease	102,790	
Paid down Capital Lease	(9,403 )	
Payable to related party	(1,462 )	(8,533 )
Net cash provided by financing activities	357,425	113,117
Net change in cash	(342,022 )	373,091
Cash and equivalents, beginning of year	410,342	37,251

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Cash and equivalents, end of year	\$68,320	\$410,342
Supplemental disclosures of cash flow information:		
Interest paid during the period	\$10,235	\$—
Income taxes paid during the period	\$—	\$—

See the notes to the financial statements.

See Note 15 for non-cash transactions.

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**American CryoStem Corporation****Consolidated Statement of Changes in Shareholders' Deficit****For the Years Ended September 30, 2018 and 2017**

	Common Shares	Par Value	Additional Paid in Capital	Accumulated Deficit	Total Deficit
Balance at September 30, 2016	37,121,709	\$37,122	\$9,440,282	\$(11,424,158)	\$(1,946,754)
Issuance of common shares	91,667	92	13,658		13,750
Convertible notes exercised	2,396,548	2,397	465,603		468,000
Options exercised	2,640,000	2,640	107,760		110,400
Shares issued for services	425,000	425	174,825		175,250
Shares issued to pay interest due	534,656	534	149,271		149,805
Issued shares to pay legal bill	200,000	200	209,800		210,000
Issuance of options			1,019,998		1,019,998
Net loss				(1,222,007 )	(1,222,007)
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
Issued shares 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 )

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



## **American CryoStem Corporation**

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

**September 30, 2018 and 2017**

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

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

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

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

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

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

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

The Consolidated Financial Statements for the year ended September 30, 2018 should be read in conjunction with the Company's Form 10K for the year ended September 30, 2018.

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

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

*Revenue Recognition* – The Company recognizes tissue storage revenue from the processing of adipose tissue into usable stem cells once all the procedures have been performed and the client sample has been stored in the Company's cryogenic storage tank. Product Sales revenues are recognized when the product has shipped. Storage revenues for stored client samples are recognized on an annual basis on the anniversary date of the storage. Royalties from the licensing of the Company's assets and Consulting Fees are recognized when earned and collection is reasonably assured. Management evaluated its various revenues to determine whether there are different operating segments based upon their respective source of revenue. Management determined at this time that all types of revenue currently represent one segment.

## American CryoStem Corporation

### Notes to the Consolidated Financial Statements

#### September 30, 2018 and 2017

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

*Reclassification* – Some of the balances for Fiscal 2017 have been reclassified. None of these reclassifications affect the presentation of the Company’s financial position or results of operations.

*Advertising* – Advertising Cost are reported as they are incurred. Advertising Costs were \$5,100 for Fiscal 2018 and \$5,084 for Fiscal 2017, which is in Sales and Marketing Expenses within the Consolidated Statements of Operations.

*Bad Debt Expense* - The Company provides, through charges to income or loss, a charge for bad debt expense, which is based upon management’s evaluation of numerous factors. These factors include economic conditions prevailing, a predictive analysis of the outcome of the current portfolio by client, and prior credit loss experience of each client. The Company uses the information from this analysis to develop an estimate of bad debt reserve based upon the amount of accounts receivable by client at the balance sheet date. The Allowance for Doubtful Accounts was \$0 at September 30, 2018 and \$23,436 at September 30, 2017.

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

Inventory was composed of Raw Materials and Finished Goods, which was valued at \$33,698 at September 30, 2018 and \$27,704 at September 30, 2017.

*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, 2018 and September 30, 2017, the Company has no uncertain tax positions that qualify for either recognition or disclosure in the financial statements. All tax returns from fiscal years 2014 to 2017 are subject to IRS and State of New Jersey audit.

*Recently Issued Accounting Pronouncements*

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

## American CryoStem Corporation

### Notes to the Consolidated Financial Statements

September 30, 2018 and 2017

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

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 evaluated the impact of this pronouncement and does not expect the accounting change to have a material effect on our financial statements.

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

#### Note 2. Going Concern

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

The Company plans to continue to fund its operations through fundraising activities in fiscal 2019 to fund future operations and business expansion.

#### Note 3. Loss per Share

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The Company applies ASC 260, "Earnings *per Share*" to calculate loss per share. In accordance with ASC 260, basic and fully diluted net loss per share has been computed based on the weighted average of common shares outstanding during the years. The dilutive effects of the convertible notes and the options outstanding are not included in the calculation of loss per share since their inclusion would be anti-dilutive.

The Company had 11,631,500 and 13,941,500 shares of Common Stock issuable upon exercise of all outstanding stock options and warrants for Fiscal Years 2018 and 2017, respectively; and, 1,680,237 and 4,503,214 shares issuable on the conversion of outstanding Convertible Notes for Fiscal Years 2018 and 2017, respectively.

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

	<b>2018</b>	<b>2017</b>
Net Gain (Loss)	\$(1,490,513 )	\$(1,222,007 )
Weighted average shares outstanding, basic and diluted	46,216,368	37,973,803
Basic & fully diluted net loss per common share	\$(0.03 )	\$(0.03 )

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**American CryoStem Corporation****Notes to the Consolidated Financial Statements****September 30, 2018 and 2017****Note 4. Fixed Assets**

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

	September 30, 2018	September 30, 2017
Laboratory Equipment	\$ 416,879	\$ 278,027
Laboratory Leasehold Improvements	84,608	10,666
Laboratory Furniture	1,841	642
Office Equipment	23,988	23,988
Office Leasehold Improvements	2,650	2,650
Office Furniture	1,812	1,812
Accumulated Depreciation	(287,071 )	(265,428 )
Net Property and Equipment	\$ 244,707	\$ 52,357

Depreciation expense for Fiscal Years 2018 and 2017 is \$21,644 and \$35,486 respectively.

In 2017, management determined that its lab software asset development was obsolete and decided to write off the asset to its consolidated statement of operations.

**Note 5. Patent & Patents Filings**

The patent and patents development are recorded at cost and are being amortized on a straight line basis over a period of seventeen years. The company capitalizes Legal and Administrative Fees incurred in the process of filing for its patents. The Company has only been amortizing the patents issued. Amortization Expense for Fiscal Year 2018 was \$5,337 and \$1,994 for Fiscal 2017.

Patents still in the application process have not been amortized. The unamortized costs of patents in the application process are \$291,027 for Fiscal 2018 and \$276,887 for Fiscal 2017.

The following is a description of the Company's patent assets:

On August 2, 2011, the Company was awarded U.S. Patent No. US 7,989,205 B2, titled Cell Culture Media, Kits, and Methods of Use. The Patent is for cell culture media kits for the support of primary culture of normal non-hematopoietic cells of mesodermal origin suitable for both research and clinical applications. The Company filed and maintains a continuation (U.S. Serial No. 13/194,900) and additional claims were granted on November 8, 2016 under patent Number 9,487,755. The Company filed an additional continuation on November 7, 2016 as part of our overall patent strategy and to cover expanded modifications of the original patent grant, US Patent Application No. 15/344,805.

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

claims for improvements that it has developed since the original patent filing,

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

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

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

Compositions and Methods for Collecting, Washing, Cryopreserving, Recovering and Return of Lipoaspirates to Physician for Autologous Adipose Transfer Procedures PCT/US13/44621 filed June 6, 2013 with a priority date of June 7, 2013. Additionally, this patent has been filed European Union Application No. EPI3800847.9 and China Application No. 2013800391988.

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

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**American CryoStem Corporation**

**Notes to the Consolidated Financial Statements**

**September 30, 2018 and 2017**

**Note 5. Patent & Patents Filings (continued)**

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

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

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

**Note 6. Debt**

The following table describes the Company's debt outstanding as of September 30, 2018:

Debt	Carrying Value	Maturity	Rate
Bridge Notes	\$ 226,500	Demand	8.00 %
Convertible Notes @ 40 cents	\$ 100,000	Fiscal 2020	8.00 %
Convertible Notes @ 35 cents	\$ 83,500	Demand	8.00 %
Convertible Notes @ 30 cents	\$ 45,000	Demand	8.00 %
Convertible Notes @ 20 cents	\$ 155,000	Demand	8.00 %
Convertible Notes @ 15 cents	\$ 40,000	Demand	8.00 %
Capital Lease	\$ 93,387	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 Year Ended September 30, 2018 was \$25,000.

**Note 7. Common Stock Issuances**

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

During fiscal 2017, the Company issued 2,396,548 shares for Convertible Notes exercised at a value of \$468,000.

During fiscal 2017, the Company issued 2,640,000 shares for Options exercised at a value of \$110,400.

During fiscal 2017, the Company issued 425,000 shares to consultants for services rendered valued at \$175,250.

During fiscal 2017, the Company issued 534,656 shares to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid was \$149,805.

During fiscal 2017, the Company issued 200,000 shares to pay an outstanding legal bill. The value of the stock issued was \$210,000.

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 an 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.

**American CryoStem Corporation**

**Notes to the Consolidated Financial Statements**

**September 30, 2018 and 2017**

**Note 7. Common Stock Issuances (continued)**

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.

**Note 8. Option Issuances**

The Company applies ASC 718, “Accounting for Stock-Based Compensation” to account for its option issues. Accordingly, all options granted are recorded at fair value using a generally accepted option pricing model at the date of the grant. The Company uses the Black-Sholes option pricing model to measure the fair values of its option grants. For purposes of determining the option values at issuance, the fair value of each option granted is measured at the date of the grant by the option pricing model using the parameters of the volatility of the Company’s share prices and the risk free interest rate. The options vest annually at the anniversary dates of the option grants, 50% the first year, 25% the second year and 25% the third year. Forfeitures are recognized as they occur. The number of options changed for 2017 but there is no material effect to Additional Paid-In Capital and the Accumulated Deficit as of 9/30/2018.

The Company normally issues options to its key personnel and consultants at the end of each fiscal year or as may be included in retainer or employment agreements. The Company prepares an option agreement for each option grant that includes the date of the grant, the vesting schedule, the expiration date and other terms of the granted options. The Company’s option plan calls for the immediate expiration and cancellation of the granted options in the event of the termination of employment or the contract associated with the original option grant except for certain circumstances including retirement or disability. The Company’s method for exercising options is to require delivery of the executed option agreement with the payment of the option price to the Company by the option holder. Upon receipt and confirmation of payment of the exercise price by Company management, the Company prepares board minutes and issues instructions to the Company’s transfer agent to issue the requisite number of shares underlying the option exercise. Using the Black-Sholes valuation method, the Company issued options and recorded salaries and consulting expenses of \$549,588 and \$1,019,998 in fiscal years 2018 and 2017, respectively and there is approximately \$100,000 of unrecognized expense due to unvested options.

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The fair value of the options issued in Fiscal 2018 and 2017 was calculated using the following assumptions:

	2018		2017	
Dividend yield	0.00	%	0.00	%
Risk free interest rate	1.95	%	1.25-1.93	%
Volatility	217.20%		213.01-230.70%	
Share Price	\$0.94		\$0.44	
Term in Years	5		3-5	

The following is a summary of common stock options outstanding at September 30, 2018:

	Amount	Exercise Price Range	Weighted Average Exercise Price	Weighted Average Remaining Term (Yrs)
Outstanding, September 30, 2016	14,871,500	\$0.05 - \$0.40	\$ 0.22	3.17
Granted	2,770,000	\$0.40		
Exercised	(2,640,000 )	\$0.01 - \$0.35		
Expired	(225,000 )	\$0.01 - \$0.35		
Forfeited	—			
Outstanding, 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, September 30, 2018	12,306,500	\$0.05 - \$0.40	\$ 0.26	2.31
Exercisable, September 30, 2018	11,631,500	\$0.05 - \$0.40	\$ 0.28	2.31

There were 675,000 unvested stock options as of September 30, 2018. The aggregate intrinsic value based on the closing share price as of September 30, 2018 is \$5,671,235.

## American CryoStem Corporation

### Notes to the Consolidated Financial Statements

September 30, 2018 and 2017

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

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

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

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

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

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

The Company valued financial instruments at cost for Fiscal 2018 and Fiscal 2017. There are no items subject to accounting under the fair value hierarchy.

#### Note 10. Commitments & Contingencies

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

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

Minimum lease payments under this lease are as follows:

2019	15,460
Total minimum lease payments	\$ 15,460

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:

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

Rent Expense was \$148,261 for Fiscal 2018 and \$94,854 for Fiscal 2017.

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

2019	42,235
2020	42,235
2021	28,157
Total minimum lease payments	\$112,628
Less amounts representing interest	(19,241 )
Present value of net minimum lease payments	\$93,387

Depreciation expense for the leased equipment for Fiscal 2018 was \$6,094.

The Company is not party to any litigation against it and is not aware of any litigation contemplated against it as of September 30, 2018.

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## **American CryoStem Corporation**

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

#### **September 30, 2018 and 2017**

#### **Note 11. Concentration of Credit**

The Company received approximately 83% of its revenues in Fiscal 2018 from two clients, Cells on Ice and Boaxin; and 83% and 2017 from Cells on Ice, a network of physicians through which we market our services under the Cells on Ice brand, and ProStemCell, our licensee located in Hong Kong. The Company also had accounts receivable from Boaxin of \$208,490 for the year ended September 30, 2018 and from Health Innovative Technologies of \$100,000 for the year ended September 30, 2017.

#### **Note 12. Investments**

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

During the first quarter of 2018, the Company invested \$300,000 in Baoxin Ltd., a Chinese company that is involved in tissue storage and processing in Baoxin, China. Baoxin is not a publically traded corporation and the investment is carried at cost at September 30, 2018. The Company annually reviews its investments for impairment and has determined that no impairment of its investment is necessary for Fiscal 2018.

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

#### **Note 13. Related Party Transactions**

The Company was indebted to a company that is majority owned by the Company's two officers in the amount of \$107,189 for Fiscal 2018 and \$108,651 for Fiscal 2017. 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 2019. The Company has accrued salaries for Mr. Arnone and Mr. Dudzinski and we do not foresee paying the accrued amounts until the Company has adequate funds to do so.

The company paid Mr. Arnone consulting fees of \$59,500 in Fiscal 2018 and \$63,500 in Fiscal 2017. The company paid Mr. Dudzinski consulting fees of \$59,500 in Fiscal 2018 and \$61,500 in Fiscal 2017.

**Note 14. Income Taxes**

Provision for income taxes is comprised of the following:

	Sept 30, 2018	Sept 30, 2017
Net loss before provision for income taxes	\$ (1,490,512 )	\$ (1,222,007 )
Current tax expense:		
Federal	\$ 0	\$ 0
State	0	0
Total	\$ 0	\$ 0
Less deferred tax benefit:		
Tax loss carry forwards	\$ (7,029,418 )	\$ (5,538,905 )
Allowance for recoverability	7,029,418	5,538,905
Provision for income taxes	\$ 0	\$ 0

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**American CryoStem Corporation**  
**Notes to the Consolidated Financial Statements**  
**September 30, 2018 and 2017**

**Note 14. Income Taxes (continued)**

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	24.5	%	34	%
Statutory state and local income tax	10	%	10	%
Less allowance for tax recoverability	(34.5)	%	(44)	%
Effective rate	0	%	0	%

The effective tax rate for the year ended September 30, 2018 was significantly impacted by recording the impact of the Tax Cuts and Jobs Act (the "Tax Act"), enacted on December 22, 2017 by the U.S. government. The Tax Act makes broad and complex changes to the U.S. tax code that affect our fiscal year ended September 30, 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 reduces 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.

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 is no accumulated earnings and profits, we have determined that the "Transition Tax" does not affect the Company. We have no "Transition Tax liability.

On December 22, 2017, the SEC issued Staff Accounting Bulletin ("SAB 118"), which provides guidance on accounting for tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Act for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate to be included in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provision of the tax laws that were in effect immediately before the enactment of the Tax Act. While we are able to make reasonable estimates of the impact of the reduction in corporate rate and the deemed repatriation transition tax, the final impact of the Tax Act may differ from these estimates, due to, among other things, changes in our interpretations and assumptions, additional guidance that may be issued by the I.R.S., and actions we may take. We are continuing to gather additional information to determine the final impact.

Our subsidiaries are located in foreign jurisdictions Hong Kong and China with minimal operations. The Company intends to engage local accounting and tax preparation professionals to handle all local tax matters.

**Note 15. Non-Cash Transactions**

As an addendum the consolidated statements of cash flows, the following non-cash transactions occurred in fiscal years 2018 and 2017:

The Company issued shares of common stock to pay a legal bill valued at \$186,396 in 2018 and \$210,000 in 2017.

The Company issued shares of common stock to pay interest expense on the convertible notes and bridge notes of \$62,232 and \$149,805 in fiscal years 2018 and 2017, respectively.

The Company issued shares of common stock for the conversion of notes in the amount of \$540,500 and \$460,000 in fiscal years 2018 and 2017, respectively.

The Company issued shares of common stock in 2018 for nine months of rent at the Laboratory Facility, for the months from May 2018 through January 2019 valued at \$110,096.

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

**Note 16. Subsequent Events**

The Company has made a review of material subsequent events from September 30, 2018 through the date of issuance of this report. There are no subsequent events to report as of the issuance of this report.