AMERICAN CRYOSTEM Corp
Form 10-K
January 16, 2018

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, 2017

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	**26-4574088**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1 Meridian Road, Suite 5

Eatontown, NJ 07724
(Address of principal executive offices)
(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**

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

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

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 x No o

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 x No o

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. o

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 o Accelerated Filer o
Non-Accelerated Filer o Smaller reporting company x

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

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 $0.25 on March 31, 2017 (the last business day of the registrants most recently completed second fiscal quarter) was approximately $ 9,280,427

As of January 10, 2018, the registrant had 45,509,872 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. Contemporaneously with the Asset Purchase Closing, we sold 1,860,000 shares of Common Stock to accredited investors in a private placement at a purchase price of $0.50 per share for aggregate gross proceeds of $930,000.

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 and Tokyo, Japan, 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 jointly developed 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 our products, and data which will help to accelerate the transition from lab research to drug and therapy development and market launch. To this end, we have licensed affiliates operating on our cellular collection-processing and storage platform in Tokyo, Japan, and Hong Kong. Our licensees purchase our CELLECT adipose tissue collection kits and ACSelerate CP storage consumables from us.

Our business strategy is centered on marketing our standardized platform as a complete adipose stem cell (Adult Stem Cells) solution and expanding our research and development through scientific collaborations. We are generating initial 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, wound and burn healing, joint repair and personalized health and beauty care; and (5) building a global network of physicians and affiliated laboratory facilities for the delivery of our products and services.

Our proprietary, patent pending processing platform allows for the collection, preparation and cryo-preservation of adipose tissue without manipulation, bio-generation or the addition of animal-derived products or other chemical materials which require removal from the tissue sample upon retrieval or prior to use. Management believes this core process makes each tissue sample suitable for use in cosmetic grafting procedures or for further processing to adult stem cells for other types of stem cell therapies. Currently, we believe there are numerous therapeutic and orthopedic applications for adipose tissue and adult stem cell treatments identified or in use globally. As of January 1, 2018, a review of clinicaltrials.gov, operated by the US National Institutes of Health (NIH) indicates that there is a significant number of clinical trials registered or completed that are focused on adipose tissue (2387), adult stem cells (5488), adipose derived stem cells (221), mesenchymal stem cells (800), and stromal vascular fraction (83).

Products and Services

American CryoStem is focused on multiple high margin business lines capable of generating sustainable, recurring revenue streams from each of our developed products and services. The Company also incorporates its proprietary and patented or patent pending laboratory products, such as our *ACSelerate*™ 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***® Validated Collection, Transportation, and Storage System and ***ACSelerate***™ Cell Culture Media Products.

To date, we have generated minimal revenue; however, subject to, among other factors, obtaining the requisite financing, management believes that we are well positioned to utilize our developed products and services as the foundation for international distribution through licensees of our technologies and a host of Regenerative Medicine uses and future applications. 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.

The products and services are also designed to become an integral part of generating revenue from current and planned licensing territories, our New Jersey based collection, processing and storage operations (CELLECT®) sale and licensing of our developed laboratory products (ACSelerate™ and research grade ATCELL™), and cellular therapy development activities.

CELLECT® **Validated Collection, Transportation, and Storage System** – An unbreakable "chain of custody" solution for physicians to collect and deliver tissue samples utilizing proprietary and patent pending methods and materials. The CELLECT® service is monitored in real-time and assures the highest cell viability upon laboratory receipt. The CELLECT® system incorporates our ACSelerate–TR™ transport medium into all collection bags which supports the health of the tissue during transport. The CELLECT® kit is an integral part of our validated ATGRAFT™ and ATCELL™ technology to be used by all licensees of our technologies. The CELLECT® service is included in our patent application U.S. Serial No. 13/702,304.

American CryoStem is the first tissue bank to globally incorporate through its CELLECT® service the International Blood Banking identification and labeling and product identification coding system. The coding was developed in conjunction with the American Association of Blood Banks (AABB), the American Red Cross and the International Society of Blood Transfusion (ISBT). These groups form the International Council for Commonality in Blood Banking Automation (ICCBBA) and developed the ISBT 128 Standard for machine readable labeling. This labeling system is an acceptable machine readable labeling standard, product description, and bar coding system for FDA Center for Biologics Evaluation and Research under 21 CFR 606.12(c) 13. American CryoStem conforms to this standard in its laboratory facility and all cellular and tissue products produced at the facility carry our W3750 ICCBBA facility identifier allowing any hospital, clinic, laboratory and regulator worldwide to identify the origin and

obtain additional information on any sample produced at an American CryoStem facility. The Company will promote this standard in all laboratories that license or utilize our technology.

ATGRAFT™ **Adipose Tissue Storage Service –** A fat storage solution allowing physicians to provide their patients with multiple tissue and cell storage options. The ATGRAFT™ service, through one liposuction procedure allows individuals to prepare for future cosmetic or regenerative procedures by using their own stored adipose tissue as natural biocompatible filler or the components for cellular therapy application without the trauma of further liposuctions. ATGRAFT™ procedures may include breast reconstruction, layered augmentation, buttocks enhancement or volume corrections of the hands, feet, face and neck areas that experience significant adipose tissue (fat) volume reduction as we age. ATGRAFT™ is processed and stored utilizing our standards so that any stored fat tissue sample may be retrieved in the future and re-processed to create stem cells ATCELL,™ our cell product for use in Regenerative Medicine applications. The ATGRAFT™ service is included in our pending patent application U.S. Serial No. 13/646,647.

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 paid upon sample retrieval, for the thawing, packaging and shipment of the stored samples to the physician or clinic 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.

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

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

The Company believes it will earn additional fees based upon the proposed storage configuration of the final ATCELL™ sample and for future culturing 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™ products and services are incorporated into our pending patent filing US Serial No. 13/646,647.

The Company's ATCELL™ cell lines are processed and cultured in our patented ACSelerate™ cell culture media. All tissue, cells, and research materials made available for sale to research institutions are tested for sterility, disease, lifespan, and population doubling rate (PDL). Additionally, we believe these 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 grade cell types. We believe this research methodology may provide opportunities for the Company's ATCELL™ and ACSelerate™ products to become the building blocks of final developed commercial applications.

The Company intends to support its cell therapy application research, development and collaborative efforts by making ATCELL™ and ATGRAFT™ samples available for research and product development purposes through joint ventures, and university and commercial collaborations. These adipose tissue and cell line samples, we believe will be 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 and the ability to create multiple cell types that have identical genetic profiles. 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 to focus on application development and avoid bench to commercialization delays. The Company is prepared to distribute research samples of its ATCELL™ cell products to users of its ACSelerate™ cell culture media for application development. The Company is investigating new sources of human mesenchymal cell lines for production and distribution to the cellular therapy research market.

***ACSelerate*™ Cell Culture Media Products** – Manufactured patented cell culture media products for growing human stromal cells (including all cells found in human skin, fat and other connective tissue). Certain ACSelerate™ cell culture media lines are available in animal serum free, which may be suitable for human and therapeutic uses or a low serum

version for application development and research purposes. The patented ACSelerate™ cell culture media line was specifically developed to address increasing industry demand for animal serum-free cell culture products and for the acceleration of products from the laboratory to the patient.

The Company entered into a licensing and manufacturing agreement with PeproTech 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. Over the past 26 years the company has grown into a global enterprise with state-of-the-art manufacturing facilities in the US, and offices around the world. With over 2,000 products PeproTech has developed and refined innovative protocols to ensure quality, reliability and consistency. The Company and PeproTech have completed the optimization and scale up manufacturing studies and the licensed medium is marketed under both PeproTech's PeproGrow and the Company's ACSelerate MAX brands.

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, in 2014 the Company filed a continuation of this granted patent with additional claims and improvements, U.S. Serial No. 13/194,900. On November 8, 2016 the Company was granted additional claims from the continuation U.S. Serial No. 13/194,900 issued as a new Patent Serial No. 9,487,755. Prior to the issuance the Company filed a continuation in part (CIP) containing additional claims related to our ongoing media development.

Published cell culture research indicates the most widely used cell culture medium for growing and differentiating stem cell cultures for in vitro diagnostics and research contains fetal bovine serum (FBS) and other animal derived products. The use of FBS and other animal products in cellular therapy application development and manufacture raises concerns and generates debates within the scientific and regulatory community relating to potential human/animal cross-contamination. These same concerns may lead to additional expensive and expansive testing and documentation requirements with the FDA during the application and approval process for new cellular therapies manufactured with or containing animal or animal derived products. FDA concerns are evidenced in their Guidance's and Guidelines regarding cellular therapy involving human cells, tissues and products (HCT/Ps) published and maintained by the FDA. Management believes that eliminating or greatly reducing FBS in cellular manufacturing, applications and products can eliminate or ease these scientific and regulatory concerns and may prove to be a winning strategy for cellular therapy application developers seeking FDA approval.

The Company supports its marketing efforts by making ATCELL™ samples available for research purposes and for internal product development through our research programs. We believe these cell lines may be sought after by private researchers and universities for use in pre-clinical trial studies and in-vitro research. We also believe that the Company's ability to provide these materials for these research and development collaborators, partners and other third parties extends the Company's ability to become a primary source of grade materials and services necessary to support approved applications and treatments.

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

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

The Company continues to optimize additional versions of *ACSelerate*™ media through further research and testing to develop versions for differentiation of *ATCELL*™ ADSCs into neural, lung and other specific cell types that may be necessary for use in future applications. Many of these applications are not 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 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 (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 cellular, cell culture, processing and testing products to professional, institutional and commercial clients. The Company operates a separate website (*acslaboratories.com)* to distinguish the sale of commercial and research products from its consumer products and services, which are marketed on its main website (*americancryostem.com*). ACS Laboratories can manufacture 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*® Anti-Aging, Autologous Skin Care Product Line – Under agreement with Personal Cell Sciences Corp. (PCS), we manufacture the key ingredient Autokine-CM® (autologous adipose derived stem cell conditioned medium) for PCS' U-Autologous™ anti-aging topical formulation. Each product is genetically unique to the patient and custom blended, deriving its key ingredients from the individual client's own stem cells. The Company provides its CELLECT® Tissue Collection service to collect the required tissue to manufacture the U-Autologous™ product and processes it under the same Standard Operating Procedures that it developed for the ATGRAFT™ and ATCELL™ cell processing services utilizing ACSelerate™ cell culture media. The Company receives collection, processing and long term storage fees and earns a royalty on all U-Autologous product sales. The utilization of the Company's core services in its contract manufacturing relationships provides opportunities for the Company to promote ATGRAFT™ and ATCELL™ products.

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

International Licensing Program – The Company believes that globally, many jurisdictions outside the US currently permit use of 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, Shenzhen, China and, Tokyo, Japan.

The Company believes it can take advantage of the significant growth of the global cellular therapy market through its international licensing and marketing efforts. A recently published study by Transparency Market Research predicts that the Stem Cell market will grow at a CAGR of 24.2% upon its value of US $26.23 billion in 2013 and will reach an approximate value of US $119.52 billion by 2019. The report, titled "Stem Cells Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2012 - 2018"; which can be found at (http://globenewswire.com/news-release/2014/12/22/693419/10113247/en/Global-Stem-Cells-Market-to-grow-at-a-CAGR-of-

In June of 2015, The Company entered into an initial agreement with CellSource, LTD. ("CellSource") located in Shibuya, Tokyo Japan for the licensing of our AGRAFT™ tissue processing and storage technology and the purchase of our CELLECT® collection products which include our ACSelerate-TR™ transport medium. The Company also assisted CellSource in upgrading its facility in Japan and provided training in the ATGRAFT™ processing and recordkeeping procedures. CellSource began marketing the new services initially within its existing network of clinics throughout Japan and begin purchasing its CELLECT™ and ACSelerate-CP™ cryoprotectant from the Company in the third quarter of 2015. Upon execution of the Agreement the Company received an upfront payment and will receive additional minimum annual payments, and consumable product sales revenue in future years.

Product Development

Our strategic approach to product development is to design, develop and launch new products and services that utilize our existing products and services, i.e. the use of the CELLECT® collection materials by contracted companies to collect fresh tissue for their product. Management believes that allowing other biotech companies to utilize portions of our platform will provide the Company with additional opportunities to produce near term cash flow, strong recurring revenue streams, strong international licensing partners and complementary scientific data. We focus on developing products, services and applications that require tissue collection and processing as the initial requirement to produce cellular therapies and products. These products and services may include adipose tissue and stem cell sample processing and storage as a form of personal *"bio-insurance",* adipose tissue (fat) storage for cosmetic fat engraftment procedures, and the creation of topical applications and ingredients used by other companies in the wound care and cosmetic industries as well as cellular applications and bio-materials development.

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

Collaboration / Partnering Opportunities / Acquisitions

PeproTech, Inc.

On April 4, 2016 the Company entered into an Agreement with PeproTech, Inc of Rocky Hill, NJ. Under the Agreement PeproTech will manufacture, market and distribute the Company's ACSelerate – Max cell growth medium. The Company and PeproTech completed the optimization and scale up manufacturing studies and the licensed medium is marketed under both PeproTech's PeproGrow and the Company's ACSelerate MAX brands. PeproTech 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 licensing partners. Additionally, the Company and PeproTech are discussing the licensing of additional American CryoStem patented media and products for production and distribution by PeproTech, any additional media licensed to PeproTech will undergo similar optimization and scale up production testing prior to being released for sale.

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.

Protein Genomics and Formation of Autogenesis Corporation

In 2012, American CryoStem entered into a Memorandum of Understanding (MOU) outlining our initial collaborative efforts with Protein Genomics, Inc. (PGEN) to test and develop new products by combining certain components of our respective intellectual property and patented products. We have provided PGEN and its research partner, Development Engineering Sciences (DES), with Adipose Derived Stem Cells (ATCELL ™) and our patented cell culture mediums (ACSelerate™) for testing with PGEN's patented products designed for the wound healing market.

In fiscal 2013 we entered into a formal joint venture with Protein Genomics through the incorporation of Autogenesis, Corp. as required by the 2012 MOU. Each company (CRYO and PGen) initially has an equal ownership interest. All products capable of being commercialized, as well as any new intellectual property, resulting from the ongoing scientific collaboration will be wholly-owned by Autogenesis. During 2013 and 2014, the collaborative efforts

resulted in successful initial “proof of concept” combining PGEN’s unique biomaterial and the Company’s ATCELL™ and ACSelerate™ products. Management believes the preliminary results showed successful healing of full depth wounds on the backs of immune deficient mice.

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.

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 network of physicians interested in the development and use of adipose tissue and adipose derived cellular samples in regenerative therapies and cellular medicine. The Company has agreed to distribute its Cellect collection boxes and provide its ATGRAFT™ and ATCELL™ processing services 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 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. 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.

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

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

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. To ensure delivery of the highest quality services, we incorporate these SOPs, which are designed to provide a basis for accreditation by the American Association of Blood Banks (AABB), the American Association of Tissue Banks (AATB) and the Foundation for the Accreditation of Cellular Therapy (FACT-JACIE). We have consistently endeavored to ensure that our processes, methodologies and procedures remain among the highest standards in the global tissue collection, processing and storage market. To this end, we have equipped ourselves with state-of-the-art quality processing and testing equipment, which we believe helps to ensure that every sample collected and processed is sterile (free from adventitious agents), viable and capable of significant cellular growth and expansion.

Quality Management

The Company's quality management program attempts to ensure that during processing and testing of each adipose tissue or SVF sample, the appropriate quality management tests and processing methodologies are performed and the data is collected, recorded and reviewed by the laboratory management team.

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.

Intellectual Property

From the Company's formation, our strategy has been to invest time and capital in intellectual property protection. This strategy is intended to strengthen our Company's foundation in any defensive or offensive legal challenge. In addition, we are developing our IP portfolio to ensure and enhance our business flexibility and allow us to gain favorable terms in potential future collaborative partnerships with third parties. Our intellectual property portfolio currently includes two issued U.S. patents (No. 7,989,205, and Serial No. 9,487,755, *Cell Culture Media Kits and Methods of Use*); and has additional pending patent applications which are detailed in the following chart:

Title	Technology	Application #
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Covers 12 types of Medium	US Patent No. 7,989,205 Issued August 2, 2011
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Additional claim Granted for all 12 medium types	US Patent No. 9,487,755 Issued November 8, 2016 Continuation of US

		Patent No. 7,989,205
Cell culture media, Kits, and Methods of Use	ACS cell culture media line Continuation of Granted Patent covering additional improvements	US Patent Application No. 15/344,805 Continuation of US Patent No. 7,989,205
Human serum for cell culture medium for growth of human adipose stromal cells	A cell culture medium for growth of human adipose stromal cells for human and therapeutic applications	PCT/US15/6835030 month National Phase entry date of June 31, 2017
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology Covers CELLECT Kit, Transport and Cryopreservation Medium for ATGRAFT and ATCELL Products	US Serial No 13/194,900 Filed June 6, 2010 Patent Application Published December 5, 2013
A Business Method for Collection, Cryogenic Storage and Distribution of a Biological Sample Material	Company Core Tissue Collection Processing and Storage Methodology Continuation covering Improvements	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/194,900 imminent (PCT Application filing planned)
Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation	Adipose Tissue Digestion Laboratory Processing Methods	U.S. Serial No. 13/646,647 filed October 6, 2011

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Systems and Methods for the Digestion of Adipose Tissue Samples Obtained From a Client For Cryopreservation	Adipose Tissue Digestion Laboratory Processing Methods	Developed Improvement established; Divisional, Continuation-In-Part claiming priority to US Serial No. 13/646,900 imminent (PCT Application filing planned)
Compositions and Methods for collecting, Washing, Cyroprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures”	Company Adipose Tissue Storage Platform for Cosmetic Procedures Covers the core processing adipose tissue for ATGRAFT adipose tissue dermal filler product	U.S. Serial No. 14/406,203 National Phase entry date of December 5, 2014 based on PCT/US2013/044621 European Union Application No. EPI3800847.9 China Application No. 2013800391988
Compositions and Methods for “Collecting, Washing, Cyroprocessing, Recovering and Return of Lipoaspirate to Physicians for Autologous Adipose Transfer Procedures”	Company Adipose Tissue Storage Platform for Cosmetic Procedures Covers additional claims related to ATGRAFT process not included in original application	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 and62/439,106

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

Patent Title	**Use of Patent**	**Application #**
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

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Trademarks

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

The Company has also secured a number of online domain names relevant to its business, including www.americancryostem.com and www.acslaboratories.com.

Market Size and Opportunities

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

Medical Tourism, Global Wellness Tourism

As stated by the Global Wellness Institute; The global wellness economy, which encompasses 10 diverse sectors chart was worth an estimated $3.7 trillion in 2015.
https://static1.squarespace.com/static/54306a8ee4b07ea66ea32cc0/t/58862a472994ca37b8416c61/1485187660666/GWI_Well
2017_FINALweb.pdf

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Cell Culture Market

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

According to MarketsandMarkets, the global cell culture market was valued at an estimated $14,772 million in 2013. This market is expected to grow at a CAGR of 10.71% between 2013 and 2018, to reach $24,574 million in 2018. The cell culture media, sera, and reagents market consists of six segments, namely, contamination detection kits, cryoprotective agents, lab reagents, media, serum, and other reagents. Of these, the serum product segment had the largest share of the cell culture media, sera, and reagents market in 2013, whereas the media product segment is expected to grow at the highest CAGR between 2013 and 2018.

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.

Physician Network

The Company continues to develop regional relationships to leverage its new products and services through existing cosmetic surgery and regenerative medicine practices. The Company continues to develop and expand its network of physicians seeking to adopt its products and services, initially focusing on surgeons performing liposuction, tissue transfer and regenerative procedures involving the use of adipose tissue. The Company intends to continue expanding its efforts to medical professionals interested in tissue storage and Regenerative Medicine applications utilizing ASDCs and establish itself as a primary source of collection, processing, and preparation of cellular therapies as they are developed and approved for patient use by the FDA.

Development of International Markets

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

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

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

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

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

Health Information Technology Company, LTD (Hong Kong)

On June 30, 2014 the Company granted Health Information Technology Company, LTD (“HIT”) exclusive rights to utilize the Company’s Standard Operating Procedures (SOP’s) to market the Company’s ATGRAFT™ tissue storage service for Hong Kong. The Agreement calls for upfront fees, royalties and the purchase by HIT of certain consumables manufactured by the Company. The Company and HIT have reached further agreement to extend their relationship on a non exclusive basis to include HIT’s cord blood laboratory located in Shenzhen, Guangdong Province, one of China’s most successful Special Economic Zones.. HIT will also purchase CRYO ACSelerate™ storage media, CELLECT™ collection and transportation kits as well as other American CryoStem products necessary for 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. During 2017 the Company entered into additional agreements with HIT to allow for the transfer of their rights to an affiliated Company Boaxin in Shenzhen China.

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. According to Allied Market Research, World Regenerative Medicines Market Currently, North America dominates the global Regenerative Medicine market due to heavy investment in development of regenerative products.. However, the growing focus on research and development in Japan and South Korea makes Asia-Pacific the fastest growing region at a CAGR of 30.9% during 2014-2020.

Scientific and Medical Advisory Board

To expand our Scientific, R&D and product marketing efforts 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, 2017, 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, FACS**
Dr. Stern is the founder and Medical Director of the Stern Center for Aesthetic Surgery in Bellevue, Washington. Following his education at Columbia University Medical School, Dr. Stern earned his Board Certification in Ophthalmology at the University of Washington, and underwent extensive additional training in oculofacial plastic and laser surgery. In 1987, he joined Virginia Mason Medical Center in Seattle, serving as Director of the Oculoplastic Surgery Division for ten years. While at Virginia Mason, Dr. Stern performed an extensive number of cosmetic laser procedures. He is honored to have been chosen as one of a select group of instructors of the *Botox Cosmetic*® National Education Faculty, as well as the *Radiesse*™ Medical Education Faculty. Dr. Stern is also an instructor for the *Sciton*™ *Laser*. In 2011, he was voted the Best Plastic Surgeon in Western Washington by *KING 5*

(NBC affiliate) TV's viewing audience. Dr. Stern is a Fellow of the American College of Surgeons, the American Academy of Facial Plastic and Reconstructive Surgeons, the American Academy of Cosmetic Surgery, and the American Society of Liposuction Surgery, as well as a member of the International Society of Hair Restoration Surgery. In addition, over the past several years, he has appeared on *Northwest Afternoon*, *Evening Magazine*, as well as *KOMO*, *KIRO* and *Q13* news, discussing and demonstrating the latest techniques in facial and eyelid laser cosmetic surgery, *Botox*® and laser-assisted liposuction. He is also an accomplished winemaker & published novelist. Dr. Stern's latest novel is a medical thriller titled, *The Sigma Project*.

· **Burt D. Ensley, Ph.D.**

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

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

· **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, Rejuvenative, Regenerative ("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.

· **Dr. Richard Goldfarb, FACS**

Dr. Richard Goldfarb established the Center for SmartLipo with the vision of bringing patients advanced treatments and techniques to help patients restore and maintain a more youthful appearance. He has formed a team of specialists, each with a unique strength in treating the various parts of your face and body. Included are Aesthetic Laser and Liposuction Specialists, Facial Plastic Surgeons, a Plastic and Reconstructive Surgeon, and a Medical Weight Loss team. As a group, they are unequaled in their ability to provide you with comprehensive consultative and treatment options to achieve your aesthetic goals.Dr. Goldfarb graduated from University of Health Sciences / Finch University, The Chicago Medical School with top honors in Surgery. He completed his surgical training at Northeastern Ohio College of Medicine. He did additional training in cosmetic surgery at the University of Pennsylvania, Department of Plastic Surgery and Yale University. He has over 30 years of General and Vascular Surgery experience, and has become a Cosmetic Surgery Specialist. In view of his advanced training and skills, Dr. Goldfarb is highly sought after to lecture and train physicians internationally on numerous cosmetic laser and surgery topics. He is the Medical Director, International and National trainer for Selphyl, and National and International trainer/lecturer for the Silhouette Lift Procedure. Dr. Goldfarb pioneered the technique to combine Silhouette Lift with fat transfer and SelphylÂ® for total facial rejuvenation (“The Goldfarb Procedure”). He is on the Board of Directors, and lectures and trains physicians for the National Society of Cosmetic Physicians and Surgeons. He is a faculty member and lecturer for THE Aesthetics Show, a training organization for physicians in the field of laser and aesthetic medicine and cosmetic surgery. Doctors visit the Center for SmartLipo from all over the world on a regular basis to learn state-of-the-art cosmetic treatments and techniques from Dr. Goldfarb and his team. The American Society of Lasers in Medicine, American Academy of Liposuction Surgery, and American Academy of Cosmetic Surgery all count him as a member. Dr. Goldfarb is board certified and a Fellow of the American College of Surgeons, in addition to the American Society of Laser Medicine and Surgery.

Corporate Information

Our principal executive offices are located at 1 Meridian Road, Eatontown, New Jersey 07724 and our telephone number is (732) 747-1007. Our website is ***www.americancryostem.com***. We also lease and operate a tissue processing laboratory in Mount Laurel, New Jersey at the Burlington County College Science Incubator located on the Burlington County College campus. Our laboratory website address is ***www.acslaboratories.com***.

Employees

Currently, we have ten 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, 2017 with respect to this uncertainty which is included in the 2017 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 January 31, 2018. 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, 2017, 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, $86,000 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 $467,500 of 8% convertible notes which mature 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 $265,500 of 8% convertible notes which mature 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 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 has developed its processing methodologies, and its Monmouth Junction, New Jersey laboratory facilities which the Company believes may be required 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. While we believe such facilities are in compliance with such regulations, 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.

Mr. Arnone owns the majority of the issued and outstanding voting stock of Personal Cell Science, 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. 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 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, 2017, there were 43,409,580 shares of Common Stock (excluding 13,941,500 shares issuable upon exercise of all issued and outstanding stock options and warrants, and 4,503,214 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 OTCIQ 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 OTCIQ. The OTCIQ 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, 2017, 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 OTCIQ, 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, 2017, the Company sold approximately $4,004,627 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 OTCIQ 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, 2017, we had 13,941,500 of Common Stock issuable upon exercise of all outstanding stock options and warrants, and, 4,503,214 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.

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 OTCIQ 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, 2016	$0.48	$0.20
March 31, 2017	$0.32	$0.23
June 30, 2017	$0.55	$0.25
September 30, 2017	$1.08	$0.40

(b) Holders of Common Equity

As of September 30, 2017, 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 year 2016, the Company issued 707,500 shares of common stock and received proceeds of $144,501.

During fiscal year 2016, option holders exercised their options and received 709,500 shares of common stock. The Company received proceeds of $55,476 upon exercise.

During fiscal year 2016, the Company issued 425,000 shares of common stock to consultants for services rendered valued at $95,750.

During fiscal year 2016, the Company issued 50,000 shares of common stock for a security deposit on its new lab location in Princeton, New Jersey. The value of the deposit is $10,450.

During fiscal year 2016, the Company issued 557,591 shares of common stock to pay for interest due to holders of the bridge notes and convertible notes. The value of the interest paid is $168,763.

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

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

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

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

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

During fiscal year 2017, the Company issued 534,656 shares of common stock to pay $149, 805 in interest due to holders of the bridge notes and convertible notes. The fair value of the common stock issued at the date of issuance was used to value the transactions.

(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:

	FY 2017		FY 2016	
Dividend yield	0.00	%	0.00	%
Risk free interest rate	1.25	%	0.25	%
Volatility	181.12	%	202.70	%

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 recorded salaries and consulting expense of $$1,085,988 and $603,364 in fiscal years 2017 and 2016, respectively.

During fiscal year 2017, the Company issued 2,770,000 options to employees and other professionals. As a result, the Company recorded labor expense of $1,019,.998, in its statement of operations.

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