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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: December 31, 2019

or

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

Commission File Number: 000-16375



THERMOGENESIS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-3018487

(State of incorporation)

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

2711 Citrus Road Rancho Cordova, California 95742

(Address of principal executive offices) (Zip Code)

(916) 858-5100

(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

<u>Title of each class</u> Common Stock, \$0.001 par value Trading Symbol(s)
THMO

Name of each exchange on which registered
Nasdaq Stock Market, LLC

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X]

No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.). Yes [X] No []

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

Large accelerated filer [] Accelerated filer []	Smaller reporting company [X
Non-accelerated filer [X]	Emerging growth company [

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

As of June 28, 2019, the aggregate market value of the common equity held by non-affiliates of the registrant was approximately \$4,733,000 based on the closing sales price as reported on the NASDAQ Stock Market. As of March 19, 2020, there were 4,561,017 shares of common stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact included in this Annual Report, are forward-looking statements. Reference is made in particular to the description of our plans and objectives for future operations, assumptions underlying such plans and objectives, and other forward-looking statements included in this Annual Report. Such statements may be identified by the use of forward-looking terminology such as "may," "will," "expect," "believe," "estimate," "anticipate," "intend," "continue," "plan," "predict," "seek," "should," "would," "could," "potential," "ongoing," or similar terms, variations of such terms, or the negative of such terms, and include, but are not limited to, statements regarding projected results of operations, capital expenditures, earnings, management's future strategic plans, development of new technologies and services, litigation, regulatory matters, market acceptance and performance of our services, the success and effectiveness of our technologies and services, our ability to retain and hire key personnel, the competitive nature of and anticipated growth in our markets, market position of our services, marketing efforts and partnerships, liquidity and capital resources, our accounting estimates, and our assumptions and judgments. Such statements are based on management's current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by us, all of which are subject to change.

These forward looking statements are not guarantees of future results and are subject to a number of risks, uncertainties and assumptions that are difficult to predict and that could cause actual results to differ materially and adversely from those described in the forward-looking statements, including:

- the sufficiency and source of capital required to fund our operations and in furtherance of our business plan;
- our ability to remain listed on NASDAQ and remain in compliance with its listing standards;
- the global perception of the clinical utility of banked cord blood and the amount of investment in research and development supporting clinical data for additional applications;
- delays in commencing or completing clinical testing of products;
- the success of any collaborative arrangements to commercialize our products;
- our reliance on significant distributors or end users;
- the availability and sufficiency of commercial scale manufacturing facilities and reliance on third party contract manufacturers;
- our ability to protect our patents and trademarks in the U.S. and other countries; and
- uncertainty regarding the impact of the COVID-19 pandemic on our business and operations.

These forward-looking statements speak only as of the date of this Annual Report and we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the expectations with regard thereto or any change in events, conditions, or circumstances on which any such statement is based, except as otherwise required by law. Additional factors that could cause such results to differ materially from those described in the forward-looking statements are set forth in connection with the forward-looking statements.

TRADEMARKS

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

ITEM 1. BUSINESS

ThermoGenesis Holdings, Inc. ("ThermoGenesis Holdings", the "Company", "our", or "we"), formerly known as Cesca Therapeutics Inc.is a pioneer and market leader in the development and commercialization of automated cell processing technologies for the cell and gene therapy field. The company markets a full suite of solutions for automated clinical biobanking, point-of-care applications, and large-scale cell processing and manufacturing for the emerging CAR-T immunotherapy market. Since the 1990's ThermoGenesis Holdings has been a leading provider of automated systems that isolate, purify and cryogenically store units of hematopoietic stem and progenitor cells for the cord blood banking industry. The Company was incorporated in 1986 and is registered in the State of Delaware and headquartered in Rancho Cordova, CA.

ThermoGenesis Holdings has two separately reported business segments: A "Device Segment" and a "Clinical Development Segment." The Device Segment develops and commercializes automated systems that are used for, clinical grade cell-banking, point-of-care applications, and large-scale cell processing. The Clinical Development Segment is developing autologous (utilizing the patient's own cells) cell-based therapeutics that address significant unmet medical needs for the vascular, cardiology and orthopedic markets.

Recent Corporate Name Change

On November 1, 2019, Cesca Therapeutics Inc. changed its corporate name to ThermoGenesis Holdings, Inc. in order to better reflect its new strategic focus on becoming a key solution provider for cell manufacturing tools and services in the cell and gene therapy markets. In conjunction with the name change, the Company began trading under the new Nasdaq ticker symbol, THMO. In addition, the Company changed its CUSIP number to 88362L100.

Our Business Strategy

Our business strategy is to leverage our over 30 years of expertise, our strong intellectual property portfolio and significant know-how in the development and commercialization of automated cell processing technologies for the cell and gene therapy field. The company markets a full suite of solutions for automated clinical biobanking, point-of-care applications, and large scale cell processing and manufacturing for the emerging CAR-T immunotherapy market.

Clinical Bio-Banking

ThermoGenesis is a market leader in the development and commercialization of automated technologies for cell-based therapeutics and bioprocessing. With over 300 BioArchive Systems and 500 AXP® Systems sold, we continue to be the critical supplier of devices and disposables used in the processing of cord blood samples for the largest and most prestigious cord blood banks worldwide. Our Systems are used in 37 countries and greater than 1,000,000 cord blood units have been processed using our technology to date.

Clinical Bio-Banking Applications:

- **AXP**[®] **System** The innovative AXP System defines a new processing standard for isolating and retrieving over 97% of the stem and progenitor cells from collections of umbilical cord blood in an automated, fully closed, sterile system in 30 minutes. AXP is self-powered, microprocessor-controlled, and contains flow control optical sensors to achieve precise separation.
- **BioArchive** Cryopreservation System The BioArchive Cryopreservation System is the industry's leading, fully automated, robotic, liquid nitrogen controlled-rate-freezing ("CRF") and cryogenic storage system for stem cell samples and clinical products. Using proven, computer-controlled technology, it provides the ultimate performance and protection for today's invaluable cord blood samples and future cell therapeutic products. BioArchive is the preferred system for the highest quality cord blood banks worldwide. A complete technical Master-File has been provided to the U.S. Food and Drug Administration ("FDA") to support those highest quality cord blood banks which have been able to qualify for, and obtain, a Biological License from the FDA to allow their cord blood units to be used to treat patients with blood cancers.

Point-of-Care Application

The PXP® System is our point-of-care device utilizing technology for processing bone marrow concentrate and is highly innovative pairing both speed and performance.

PXP® System – The PXP System is an automated, closed system that harvests a precise volume of cell concentrate from bone marrow aspirates. PXP can generate a concentration of bone marrow in less than 20 minutes, with consistently high MNC and CD34+ stem cell progenitor recovery rates and greater than 98% depletion of contaminating red blood cells ("RBCs"). Processing data is captured using our proprietary DataTrakTM software to assist with Good Manufacturing Practice ("GMP") process monitoring and reporting information.

CAR-TXpress Platform (Large Scale Cell Processing)

With revolutionary cell-based therapies, such as CAR-T (chimeric antigen receptor T-cell) for cancer becoming a reality, developers must address a key challenge: how to manufacture high-quality, clinical-grade cell therapies at commercial scale to provide these groundbreaking treatments to as many patients as possible. Traditional cell processing methodologies are manual and time consuming, presenting an obstacle to large-scale manufactures of adoptive cell therapies.

In contrast, ThermoGenesis Holdings is keeping up with the fast-past field by developing the CAR-TXpressTM Platform designed to automate many of the manual steps involved in cell processing. The CAR-TXpress Platform is a multi-system package that provides a stream-lined solution for cell processing, selection, washing, and cryopreservation. The CAR-TXpress Platform can provide a comprehensive and commercially viable, semi-automated cellular manufacturing and control ("CMC") solution for the development of CAR-T therapeutics.

CAR-TXpress eliminates the use of density gradient media for isolation and replaces magnetic bead-based systems used for selection procedures, thereby dramatically reducing processing time and increasing cell recoveries, in order to significantly reduce the overall manufacturing time and cost and increase the yield/efficiency of high value samples.

CAR-TXpress Processing Applications

• **X-Lab**® **System for Cell Isolation** – a semi-automated, functionally-closed, ficoll-free, system for the rapid isolation of mononuclear cells ("MNCs") from collected units of peripheral blood, cord blood, bone marrow aspirate or leukapheresis. The Company had filed a Device Master File

("MAF") with the FDA for the X-Lab. The MAF contains all the relevant information that the FDA will need to allow principal investigators to include ThermoGenesis Holdings' systems in their investigational new drug applications.

- X-Wash® System for Washing and Reformulation a semi-automated, functionally-closed system that separates, washes, and volume-reduces units of fresh or thawed units of blood, bone marrow, leukapheresis or cell cultures and presents these washed cells in a predetermined small volume. The Company has filed a MAF with the FDA for the X-Wash. The MAF contains all the relevant information that the FDA will need to allow principal investigators to include ThermoGenesis Holdings' systems in their investigational new drug applications.
- **X-BACSTM System for Cell Purification** a semi-automated, functionally-closed system employs a microbubble/antibody reagent to isolate target cells by buoyancy-activated cell sorting ("BACS"). These microbubble/antibody reagents bind to user-selected target cells to increase their buoyancy and provide a complete separation from non-target cells during centrifugation, allowing the harvest of a highly purified population of target cells, with high recovery efficiency and cell viability.
- **BioArchive** for Cryogenic Cellular Product Storage an automated, controlled-rate-freezing, liquid nitrogen freezer intended for the cryopreservation and single-cassette based storage of clinical samples. The BioArchive provides customers who need to store therapeutic cell populations in cryogenic storage (-196°C) with a solution that combines the individualized controlled rate freezing of each sample, robotic storage and retrieval of each sample and real-time chain of custody management.

Cell Manufacturing Services

Through our TotipotentRX subsidiary in Gurgaon, India, we operate an advanced clinical cell manufacturing, processing, testing, and storage facility, compliant with current GMP, Good Tissue Practices ("GTP"), and Good Laboratory Practices ("GLP"). We can support the production of a small, personalized medicine cell prescription or a large-scale batch process. Patient samples, batch samples, and therapeutic aliquots are all labeled in accordance with ISBT 128 and stored in our own cryogenics' facility. In partnership with Fortis Healthcare we also operate commercial service programs supporting bone marrow transplantation (hematopoietic stem cell transplantation) for hematological and oncological disorders.

Recent Key Events and Accomplishments

- *ImmuneCyte Joint Venture formed with Healthbanks Biotech (USA) Inc.* In October 2019, the Company entered into a Joint Venture Agreement with Healthbanks Biotech (USA) Inc., a stem cell bank network (Healthbanks), under which the Company and Healthbanks agreed to form a new company named ImmuneCyte Life Sciences Inc. ("ImmuneCyte"). The joint venture will commercialize ThermoGenesis' proprietary cell processing platform, CAR-TXpressTM, for use in immune cell banking as well as for cell-based contract development and manufacturing services (CMO/CDMO).
- X-Series Supply Agreement. In August 2019, the Company entered into a Supply Agreement with Corning Incorporated ("Corning") in which the Company will distribute its X-Series® cell processing products to Corning who will market them globally. The X-Series products are major components of the Company's CAR-TXpressTM platform, a semi-automated, closed cellular processing platform used for high efficiency cell purification and cell washing. The X-Series products, when used in combination with the Company's proprietary buoyancy activated cell sorting ("BACS") technology, can be applied for both research and commercial manufacturing of

a large variety of cell-based therapeutics, including chimeric antigen receptor-T ("CAR-T") cells. Under the renewable, five-year agreement, the global distributor will be responsible for marketing the X-Series products to customers, worldwide, with the exception of China for the first two years. As per the terms of the agreement, the Company received a \$2 million upfront exclusivity fee, which was paid by the distributor in October 2019.

- Next Generation PXP® 1000 System. In December 2019, the Company completed the development process and submitted a Letter to the Design History File and updated the device listing with the FDA for the PXP®-1000 System. The PXP-1000 is the next generation of ThermoGenesis' automated systems and allows fast, automated and reproducible separation of cellular components from blood in a closed and sterile GMP compliant environment.
- Changed Name and Nasdaq Ticker Symbol. Effective November 1, 2019, the Company changed its name to ThermoGenesis Holdings, Inc. in order to better reflect its new strategic focus on becoming a key solution provider for cell manufacturing tools and services in the cell and gene therapy markets. In conjunction with the name change, the Company began trading under the new Nasdaq ticker symbol, THMO. In addition, the Company changed its CUSIP number to 88362L100.
- Reverse Stock Split. In June 2019, to be compliant with the Nasdaq Listing Compliance requirement, the Company effected a one-for-ten reverse stock split of the Company's common stock, par value \$0.001 per share.
- Launched the AXP II System for Advanced Cord Blood Processing. We completed the commercial launch of the AXP II system for the advanced, isolation, collection and storage of hematopoietic stem cell concentrates from cord blood and peripheral blood. AXP II introduced important enhancements to the AXP device, docking station, and proprietary XpressTRAK® software that together represent a significant advancement in automated cord blood processing. America's largest cord blood bank, CBR® updated to AXP II system.
- Enhanced X-Mini® Release. In April 2019, the Company enhanced its X-Mini CD3 Selection Kit for the research market. The new X-Mini CD3 Selection Kit provides distinct advantages, expanding on the ability of the original X-Mini kit to select the CD3+ target cells from prepared mononuclear cell samples or from a sample of whole blood. Also included in the release of the new kit is the X-Mini Pressor accessory, used in conjunction with the X-Mini selection kits to eliminate the X-BACSTM reagent's buoyancy during the final processing steps.

Sales and Distribution Channels

We market and sell our products through independent distributors, except in North America and India, where we sell direct to end-user customers.

Research and Development

Our research and development activities for 2019 were geared towards expanding the automated platform for the immune-oncology applications while maintaining our bio-banking and point-of-care automation solutions. In 2019, the Company released the enhanced X-Mini CD-3 Selection Kit for the research market and developed an enhanced PXP-1000 system. We also improved our AXP®, and BioArchive® platforms with a focus on both performance improvements and ease of use. Emphasis was also placed on enhancing the capabilities of our contract manufacturing partners and building on our product quality leadership position.

Collectively, research and development expenses were \$2,396,000 and \$3,012,000 for the years ended December 31, 2019 and 2018, respectively. Research and development activities include expenses associated with the engineering, regulatory, scientific and clinical affairs functions.

Manufacturing and Raw Materials

We source components for our products from multiple suppliers that manufacture to our engineering specifications. Our high-volume disposable products are manufactured using contract manufacturers. AXP disposable bagsets are manufactured by Viant Medical and our manual processing bagsets are manufactured by Pall Medical Corporation. We utilize our manufacturing facility in Rancho Cordova, California for production of our low volume, high complexity devices. Additionally, in 2019, the Company completed the construction and qualification of an in-house clean room for the assembly of the X-Series disposable cartridges. We used this facility for the manufacturing of all disposable cartridges in 2019. Various raw materials are used to manufacture our products. The raw materials are generally available from multiple sources. We have not had significant difficulty in obtaining necessary raw materials.

Quality System

Our quality system is compliant with domestic and international standards and is appropriate for the specific devices we manufacture. Our corporate quality policies govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Such policies are intended to ensure that the products we market are safe, effective, and otherwise in compliance with the FDA Quality System Regulation ("QSR") (21 C.F.R. Part 820) and the applicable rules of other governmental agencies.

We and our contract manufacturers are subject to inspections by the FDA and other regulatory agencies to ensure compliance with applicable regulations, codified in the FDA's Quality System Regulations ("QSRs"). Compliance requirements relate to manufacturing processes, product testing, documentation control and other quality assurance procedures. Our facilities have undergone International Organization of Standards ("ISO") 13485:2016 and EU Medical Device Directive ("MDD") (93/42/EEC) inspections and we have obtained approval to CE-Mark our products. We have received our updated certificate demonstrating compliance to this standard under the Medical Device Single Audit Program ("MDSAP").

Regulatory Scheme and Strategy

The development, manufacture and marketing of our cell therapy products, as well as the design and implementation of our clinical trials, are subject to regulation by the FDA as well as the equivalent agencies of other countries including the countries of the European Union and India.

The trials we conduct in India are compliant with the applicable rules of the Indian Council for Medical Research, Ministry of Health Order No. V.25011/375/2010-HR and requisite institutional ethics committee ("IEC") and institutional committee for stem cell research and therapy ("IC-SCRT") approvals. Both the

U.S. and E.U. regulatory agencies are experienced in dealing with and accepting Indian clinical trial data. Good Clinical Practice ("GCP") guidelines necessitates review and approval by an Institutional Review Board ("IRB") before initiation of a study, continuing review of an ongoing study by an IRB, and the documented receipt of a freely given informed consent prior to participation in the study from each subject participant.

We have a quality and regulatory compliance management system that meets the requirements of the ISO 13485: 2003 standard, the FDA's QSRs, the EU MDD, Canadian Medical Device Regulations (SOR 98-282), and all other applicable local, state, national and international regulations.

Medical Devices. The FDA regulates medical devices to ensure their safety and efficacy under the Federal Food Drug and Cosmetic Act ("FD&C"). Medical devices are defined by language within the FD&C Act which essentially states that a product is considered a medical device if it is intended to provide a diagnosis or basis for treatment. Once a company determines that its product is a medical device, it is required to comply with a number of federal regulations. These include the following:

- 510(k) clearance or Premarket Approval Application ("PMA") approval from the FDA, prior to commercialization (unless the device is classified as "exempt");
- Registration of the company and listing of the medical device with the FDA (within 30 days prior to commercialization);
- Establishment and adherence to the FDA's labeling requirements; and
- Establishment and adherence to the FDA's Quality Systems and Medical Device Reporting regulations.

The FDA classifies medical devices into three groups: Class I, II or III. These are stratified from lowest to highest safety risk, and regulatory controls increase based on Class.

Class I Devices

Some of our products are considered to pose little or no risk when used as directed and have been deemed by the FDA to be "exempt" from FDA approval or clearance processes prior to commercialization. While pre-marketing FDA review is not mandatory for Exempt Class I medical devices, the manufacturer's compliance with QSR is nevertheless a requirement.

Class II Devices

Several of our products, including the BioArchive and the AXP are categorized as U.S. Class II medical devices and require premarket notification, also known as a section 510(k) clearance, prior to commercialization. Data submitted as part of a 510(k) process must demonstrate a device is "substantially equivalent" with a predicate device that is already on the market. Once 510(k) clearance has been secured, the new medical device may be marketed for its intended use and distributed in the U.S.

Class III Devices

If a product is considered a Class III device, the FDA approval process is more stringent and time-consuming, and includes the following:

- Extensive pre-clinical laboratory and animal testing;
- Submission and approval of an Investigational Device Exemption ("IDE") application prior to the conduct of a clinical study;
- Human clinical studies (or trials) to establish the safety and efficacy of the medical device for the intended use: and
- Submission and approval of a PMA application to the FDA.

Pre-clinical testing typically involves in vitro laboratory analysis and in vivo animal studies to obtain information related to such things as product safety, feasibility, biological activity and reproducibility. The results of pre-clinical studies are submitted to the FDA as part of an IDE application and are reviewed by the Agency before human clinical trials can begin.

Higher risk clinical trials conducted inside the U.S. are subject to FDA IDE regulation (21 C.F.R. Part 812), or an Investigational New Drug ("IND") application (21 C.F.R. Part 312). Clinical trials conducted outside the U.S., and the data collected therefrom are allowed in accordance with applicable FDA requirements. The FDA or the sponsor may suspend a clinical trial at any time if either believes that study participants may be exposed to an unacceptable health risk.

For certain Class III devices, data generated during product development, pre-clinical studies, and human clinical studies must be submitted to the FDA as a PMA application in order to secure approval for commercialization in the U.S. The FDA may deny the approval of a PMA application if applicable regulatory criteria are not satisfied and, in some cases, may mandate additional clinical testing. Product approvals, once obtained, can be withdrawn if compliance with regulatory standards is not maintained or if safety concerns arise after the product reaches the market. The FDA might also require post-marketing testing and surveillance programs to monitor the safety and efficacy of a medical device and has the power to forbid or limit future marketing of the product based on the results of such programs.

Other U.S. Regulatory Information

Medical device manufacturers must register with the FDA and submit their manufacturing facilities to biennial inspections to ensure compliance with applicable regulations. Failure to comply with FDA requirements can result in withdrawal of marketing clearances, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production or loss of distribution rights. In addition, device manufacturing facilities in the state of California must be registered with the California State Food and Drug Branch of the California Department of Public Health and submit to an annual inspection by the State of California to ensure compliance with applicable state regulations. We are also subject to a variety of environmental laws as well as workplace safety, hazardous material, and controlled substances regulations.

Also, federal transparency requirements, sometimes referred to as the "Sunshine Act" under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to

report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

Changes in these laws at all levels of government are frequent and could increase our cost of doing business. If we fail to comply, even inadvertently, with any of these requirements, we could be required to alter our operations, refund payments to the government, lose our licensure or accreditation, enter into corporate integrity, deferred prosecution or similar agreements with state or federal government agencies, and become subject to significant civil and criminal penalties.

International Regulatory Requirements

International regulatory requirements differ somewhat from those of the U.S. In the EU, a single regulatory approval process has been created and approval is represented by CE-Marking. To be able to affix the CE-Mark to our medical devices and distribute them in the EU, we must meet minimum standards for safety and quality (known as the essential requirements) and comply with one or more conformity rules. A notified body assesses our quality management system and compliance with the Medical Device Directive. Marketing authorization can be revoked by the applicable governmental agency or notified body in the event of an unsuccessful quality system annual audit.

In India, the regulatory body having oversight of medical devices, therapies, and cell banking is the Central Drugs Standard Control Organization ("CDSCO"), and specifically the Drugs Controller General India office. Our marketing and facilities licenses are subject to revocation by the applicable state Drug Controller in Haryana or DCGI.

Patents and Proprietary Rights

We believe that patent protection is important for our products and current and proposed business. We currently have over 30 issued patents globally. The patent positions can be uncertain because they involve interpretation of complex factual information and an evolving legal environment. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. There can be no assurance that any of our pending patent applications will actually result in an issued patent. Furthermore, there can be no assurance that any existing or future patent will provide significant protection or commercial advantage, or that any existing or future patent will not be circumvented by a more basic patent. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent or the first to file a patent application for the subject matter covered by each of our pending U.S. and foreign patent applications.

If a third-party files a patent application relating to an invention claimed in our patent application, we may be required to participate in an interference or derivation proceeding conducted by the U.S. Patent and Trademark Office to determine who owns the patent. Such proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

Agreements

The following are certain material agreements involving our business in effect as of December 31, 2019:

Healthbanks Biotech (USA) Inc.

On November 26, 2019 the Company entered into a joint venture agreement with HealthBanks Biotech (USA) Inc. (the "JV Agreement") to form a new company called ImmuneCyte Life Sciences, Inc. ("ImmuneCyte") to commercialize the Company's proprietary cell processing platform, CAR-TXpressTM, for use in immune cell banking as well as for cell-based contract development and manufacturing services

(CMO/CDMO). Under the terms of the JV Agreement, ImmuneCyte will initially be owned 80% by HealthBanks Biotech and 20% by ThermoGenesis. ImmuneCyte will be among the first immune cell banks in the U.S. and offer customers the ability to preserve younger, healthier and uncontaminated immune cells for future potential use in dendritic and chimeric antigen receptor ("CAR-T") cell therapies, in a GMP compliant processing environment. The Company's principal contribution to ImmuneCyte will be a supply agreement under which ImmuneCyte will have the exclusive right to purchase the Company's proprietary cell processing equipment in the immune cell banking business and a non-exclusive right to purchase it for other cell-based contract development and manufacturing ("CMO/CDMO") services at a price equal to 115% of the Company's cost. The Company will also contribute to ImmuneCyte intellectual property and trademarks relating to the Company's clinical development assets as a result of the Company's decision to discontinue its clinical development program. Healthbanks contributed to ImmuneCyte a paid-up, royalty free license to use its proprietary business management system, customer relationship management software, and laboratory information statement, and it will also make available a \$1,000,000 unsecured, non-convertible line of credit to ImmuneCyte to provide initial operating capital. Healthbanks is a subsidiary of Boyalife Group, Inc. (USA), the owner of Boyalife Asset Holding II, Inc., which is the largest stockholder of the Company, and is owned by Dr. Xiaochun (Chris) Xu, the Company's Chief Executive Officer and Chairman of our Board of Directors.

Corning Incorporated

On August 30, 2019, the Company entered into a Supply Agreement with Corning (the "Supply Agreement"). The Supply Agreement has an initial term of five years with automatic two-year renewal terms, unless terminated by either party in accordance with the terms of the Supply Agreement (collectively, the "Term"). Pursuant to the Supply Agreement, the Company has granted to Corning exclusive worldwide distribution rights for substantially all X-Series® products under the CAR-TXpress™ platform (the "Products") manufactured by its subsidiary, ThermoGenesis Corp., for the duration of the Term, subject to certain geographical and other exceptions. In addition, the Company has granted Corning rights of first refusal for the exclusive worldwide distribution of certain future products developed or introduced by the Company relating to cell isolation or cell selection, including any such products substantially related or similar to the Products (the "ROFR Products"). As consideration for the exclusive worldwide distribution rights for the Products and ROFR Products, Corning has agreed to pay a \$2,000,000 fee, in addition to any amounts payable throughout the Term for the Products and any ROFR Products. The Supply Agreement also contains an option, exercisable by Corning at any time following January 1, 2021, to become the manufacturer for all or any portion of the Products.

IncoCell Tianjin Ltd

On March 12, 2018, ThermoGenesis Corp. entered into a License Agreement (the "IncoCell Agreement") with IncoCell Tianjin Ltd., a wholly-owned subsidiary of Boyalife Group ("IncoCell"). Boyalife Group is an affiliate of the Company's Chief Executive Officer and Chairman of our Board of Directors, and Boyalife (Hong Kong) Limited. Under the terms of the IncoCell Agreement, ThermoGenesis Corp. granted IncoCell an exclusive license to use the ThermoGenesis Corp. X-Series® products in the conduct of IncoCell's contract manufacturing and development operations in the People's Republic of China, Japan, South Korea, Taiwan, Hong Kong, Macau, Singapore, Malaysia, Indonesia and India (the "IncoCell Territories").

Pursuant to the terms of the IncoCell Agreement, ThermoGenesis Corp. granted IncoCell an exclusive license to purchase and use, at a discounted purchase price, X-Series cellular processing research devices, consumables, and kits for use in the conduct of contract manufacturing and development services in the IncoCell Territories. In exchange, ThermoGenesis Corp. is entitled to a percentage of IncoCell's gross contract development revenues, including any potential upfront payments, future milestones or royalty payments, during the term of the IncoCell Agreement. The term of the Agreement is ten years, provided that either party may terminate the Agreement earlier upon ninety (90) days' prior notice to the other party. The Company recorded revenue of \$83,000 related to product sales under this agreement for the year ended December 31, 2019, and \$14,000 for the year ended December 31, 2018. The Company recorded no

revenue under the contract development portion of the Agreement for the years ended December 31, 2019 and 2018.

CBR Systems, Inc. ("CBR")

Effective May 15, 2017 we entered into a Manufacturing and Supply Agreement with CBR which replaced the prior December 31, 2013 Sale and Purchase Agreement in which we agreed to supply CBR with the AXP cord blood processing system and disposables. The term of the Manufacturing and supply Agreement is for three years and will automatically renew in one-year increments unless either party provides written notice of its intention not to renew six months prior to the end of the term.

In June 2010, we entered into a License and Escrow Agreement in order to alleviate CBR's concerns about potential long-term supply risk. We are the sole supplier of critical devices and disposables used in the processing of cord blood samples in CBR's operations. Under the License and Escrow Agreement, we granted CBR a perpetual, non-exclusive, royalty-free license to certain intellectual property necessary for the manufacture of AXP® devices and disposables. The license is for the sole and limited purpose of ensuring continued supply of the AXP and related disposables for use by CBR. The licensed intellectual property is held in escrow and available to CBR only in the event of a default under the License and Escrow Agreement. Effective May 15, 2017 we entered into a Sixth Amended and Restated Technology License and Escrow Agreement with CBR. This amendment, among other things, changes the circumstances that constitute a "Default" thereunder and conditions the circumstances under which CBR may, upon a default by the Company, purchase licensed products directly from the Company's manufacturers and suppliers. The events or conditions of default include: a cash balance coupled with short-term investments net of debt or borrowed funds that are payable within one year of less than \$2,000,000 (amended to \$1,000,000 in March 2020) at any month end or we fail to provide products pursuant to the Manufacturing and Supply Agreement. We were in compliance with the License and Escrow Agreement at December 31, 2019.

Boyalife W.S.N.

On August 21, 2017, our subsidiary, ThermoGenesis Corp. entered into an International Distributor Agreement with Boyalife W.S.N., a Chinese corporation and affiliate of the Company. Under the terms of the agreement, Boyalife W.S.N. was granted the exclusive right, subject to existing distributors and customers (if any), to develop, sell to, and service a customer base for ThermoGenesis Corp. AXP (AutoXpress®) System and BioArchive System in the People's Republic of China (excluding Hong Kong and Taiwan), Singapore, Indonesia, and the Philippines (the "Territories"). The agreement replaced our prior distribution agreement with Golden Meditech, which expired in August 2017 and had granted similar exclusive distribution rights in the Territories. Boyalife W.S.N. is an affiliate of Dr. Xiaochun Xu, our Chief Executive Officer and Chairman of our Board of Directors, and Boyalife (Hong Kong) Limited, our largest stockholder. Boyalife W.S.N,'s rights under the agreement include the exclusive right to distribute AXP Disposable Blood Processing Sets and use rights to the AutoXpress System, BioArchive System and other accessories used for the processing of stem cells from cord blood in the Territories. Boyalife W.S.N. is also appointed as the exclusive service provider to provide repairs and preventative maintenance to ThermoGenesis Corp. products in the Territories. The term of the agreement is for three years with ThermoGenesis Corp. having the right to renew the agreement for successive two-year periods at its option.

Employees

As of December 31, 2019, we and our subsidiaries had 50 employees, 45 of whom were employed in the U.S. and 5 of whom were employed in India. We also utilize temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are covered by a collective bargaining agreement, nor have we experienced any work stoppage.

Foreign Sales and Operations

See Note 12 of our Notes to Consolidated Financial Statements for information on our sales and operations outside of the U.S.

Where you can Find More Information

We are required to file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other information, including our proxy statement, with the Securities and Exchange Commission ("SEC"). The public can obtain copies of these materials by accessing the SEC's website at http://www.sec.gov. In addition, as soon as reasonably practicable after these materials are filed with or furnished to the SEC, we will make copies available to the public free of charge through our website, http://www.thermogenesis.com. The information on our website is not incorporated into, and is not part of, this Annual Report on Form 10-K or our other filings with the SEC.

ITEM 1A. RISK FACTORS

An investment in our common stock is subject to risks inherent to our business. The material risks and uncertainties that management believes affect us are described below. Before making an investment decision, you should carefully consider the risks and uncertainties described below together with all of the other information included or incorporated by reference in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are not aware of or focused on or that we currently deem immaterial may also impair our business operations. This Annual Report is qualified in its entirety by these risk factors.

If any of the following risks actually occur, our financial condition and results of operations could be materially and adversely affected. If this were to happen, the value of our common stock could decline significantly, and you could lose all or part of your investment.

Risks Related to Our Structure and Business

A third party owns 20% of our subsidiary, CARTXpress Bio, Inc. (CARTXpress Bio), and holds certain minority investor rights therein. These rights could limit or delay our ability to take certain major actions relating to CARTXpress Bio. In January 2019, ThermoGenesis Corp. contributed its X-Series business into a newly formed subsidiary of ThermoGenesis Corp., CARTXpress Bio. Pursuant to the terms of a reorganization and share exchange agreement, ThermoGenesis Holdings acquired a 20% equity ownership in ThermoGenesis Corp. from Bay City Capital Fund V, L.P. and certain of its affiliates ("Bay City"). In exchange, Bay City acquired a 20% ownership in CARTXpress Bio. As a result of these transactions, ThermoGenesis Corp. became a wholly-owned subsidiary of ThermoGenesis Holdings, and ThermoGenesis Corp. owns 80% of the outstanding equity of CARTXpress Bio, while Bay City owns the remaining 20% of the outstanding equity of CARTXpress Bio. While we continue to indirectly own 80% of the outstanding capital stock of CARTXpress Bio, Bay City was granted certain minority investor rights in CARTXpress Bio. These rights include board representation rights, a right of first refusal over sales of CARTXpress Bio. stock by us, co-sale rights with respect to any sale of CARTXpress Bio stock by us, certain piggyback and Form S-3 registration rights in the event that CARTXpress Bio becomes a publicly traded company at any time in the future and other rights as detailed in the Investors' Rights Agreement. In addition, the board of directors of CARTXpress Bio is comprised of three persons, two of whom are designated by us and one of whom is designated by Bay City. The foregoing minority investor rights in CARTXpress Bio could limit or delay our ability or flexibility to take certain major actions or make major decisions relating to CARTXpress Bio that might be beneficial to our stockholders, unless such actions or decisions have the consent or support of Bay City. Accordingly, the minority investor rights in CARTXpress Bio could have a negative impact on the market price of our common stock.

Our largest stockholder has significant influence over us which could limit your ability to influence the outcome of key transactions, including a change of control, and could negatively impact the market price of our common stock by discouraging third party investors. As of December 31, 2019, approximately 24% of our outstanding common stock is owned by Boyalife Asset Holding II, Inc ("Boyalife"). In addition, pursuant to the terms of the Amended Nomination Agreement we entered into with Boyalife in April 2018, Boyalife has the right to designate a number of members of our board of directors that is in proportion to the "Boyalife Ownership Percentage", which is Boyalife and its affiliates' combined percentage ownership of outstanding common stock, treating as outstanding any shares of common stock underlying convertible securities that are immediately exercisable by Boyalife and its affiliates' (including under the debt facility) without any further payment. The Amended Nomination Agreement will terminate according to its terms when and if the Boyalife Ownership Percentage falls below 20%.

Boyalife is 100% owned by Dr. Xiaochun Xu, our Chief Executive Officer and Chairman of our Board of Directors. As a result of their ownership and ability to designate members of our Board of Directors, Boyalife (including Dr. Xu) is able to exercise significant influence over all matters affecting us, including the election of directors, formation and execution of business strategy and approval of mergers, acquisitions and other significant corporate transactions, which may have an adverse effect on our stock price and ability to execute our strategic initiatives. Boyalife and/or Dr. Xu may have conflicts of interest and interests that are not aligned with those of other investors in all respects. As a result of the concentrated ownership of our common stock, Dr. Xu may be able to control matters requiring stockholder approval, including the election of directors, the adoption of amendments to our certificate of incorporation and bylaws, and approval of a sale of our Company, and other significant corporate transactions. This concentration of ownership may delay or prevent a change in control and may have a negative impact on the market price of our common stock by discouraging third party investors from investing or making tender offers for our shares.

In addition, Boyalife is a material creditor of our company. We are a party to a revolving debt facility with Boyalife which has a maximum borrowing availability of \$10,000,000 and an outstanding balance as of December 31, 2019 of \$8,713,000 in principal and \$1,869,000 in accrued interest. In February 2020, Boyalife converted \$3.0 million of the outstanding balance of the convertible note into an aggregate of 1.67 million shares of our common stock. The debt facility matures on March 6, 2022, with accrued interest due annually on the last day of each calendar year. Because this debt facility is secured by all of our shares in our ThermoGenesis Corp. subsidiary, an event of default under the debt facility would have a material adverse impact on our interest in ThermoGenesis Corp. if the lender under the debt facility elected to foreclose on such security interest.

We utilize debt financing from outside the U.S. and an inability to obtain funds when requested could adversely impact operations. We use debt financing for working capital and other cash requirements. Our ability to use this funding source may be impacted by reasons such as default or foreign government policies that restrict or prohibit transferring funds. In the event that we were not able to obtain funds as needed, it could result in delays to project funding or non-compliance with cash-based covenants.

We may seek to enter into collaborative arrangements to develop and commercialize products which may not be successful. We may seek to enter into collaborative arrangements to develop and commercialize some of our potential products and product candidates both in North America and international markets. There can be no assurance that we will be able to negotiate collaborative arrangements on favorable terms or at all or that current or future collaborative arrangements will be successful.

A significant portion of revenue is derived from customers outside the United States. We may lose revenues, market share, and profits due to exchange rate fluctuations and political and economic changes related to its foreign business. For the year ended December 31, 2019, sales to customers outside the U.S. comprised approximately 48% of revenues. This compares to 50% for the year ended December 31, 2018. Our foreign

business is subject to economic, political and regulatory uncertainties and risks that are unique to each area of the world. Fluctuations in exchange rates may also affect the prices that foreign customers are willing to pay and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial position and results.

The loss of a significant distributor or end user customer may adversely affect financial condition and results of operations. Revenues from our largest customer comprised 28% of revenues for the year ended December 31, 2019. Revenues from our largest distributor comprised 11% of revenues for the year ended December 31, 2019. The loss of a large customer or distributor may significantly decrease revenues.

We may be exposed to liabilities under the foreign corrupt practices act and any determination that we violated these laws could have a material adverse effect on our business. We are subject to the Foreign Corrupt Practices Act ("FCPA"), and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute, for the purpose of obtaining or retaining business. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

Adverse results of legal proceedings could have a material adverse effect on us. We are subject to, and may in the future be subject to, a variety of legal proceedings and claims that arise out of the ordinary conduct of our business. Results of legal proceedings cannot be predicted with certainty. Irrespective of their merits, legal proceedings may be both lengthy and disruptive to our operations and may cause significant expenditure and diversion of management attention. We may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on a portion of our business operations or a material adverse effect on our financial condition and results of operations.

Risks Related to Our Operations

We do not have commercial-scale manufacturing capability and have minimal commercial manufacturing experience. We operate GMP manufacturing facilities for device production; however, they are not of sufficient size for large commercial production. We do not have experience in large scale manufacturing, and currently rely on third-party contract manufacturers for a significant portion of our device production. We expect to depend on these contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay production of our current or future products, depriving us of potential product revenues and resulting in additional losses.

We have limited sales, marketing and distribution capabilities which may limit our ability to significantly increase sales quickly. We have limited internal capabilities in the sales, marketing, and distribution areas. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities internally or make arrangements with current collaborators or others to perform such activities or that such effort will be successful. If we decide to market any of our new products directly, we must either partner, acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, divert the attention of our management and key personnel, and have a negative impact on further product development efforts.

Our inability to protect our patents, trademarks, trade secrets and other proprietary rights could adversely impact our competitive position. We believe that our patents, trademarks, trade secrets and other proprietary rights are important to our success and our competitive position. Accordingly, we commit substantial

resources to the establishment and protection of our patents, trademarks, trade secrets and proprietary rights. We use various methods, including confidentiality agreements with employees, vendors, and customers, to protect our trade secrets and proprietary know-how for our products. We currently hold patents for products, and have patents pending in certain countries for additional products that we market or intend to market. However, our actions to establish and protect our patents, trademarks, and other proprietary rights may be inadequate to prevent imitation of our products by others or to prevent others from claiming violations of their trademarks and proprietary rights by us. If our products are challenged as infringing upon patents of other parties, we may be required to modify the design of the product, obtain a license, or litigate the issues, all of which may have an adverse business effect on us.

We may be subject to claims that our products or processes infringe the intellectual property rights of others, which may cause us to pay unexpected litigation costs or damages, modify our products or processes or prevent us from selling our products. Although it is our intention to avoid infringing or otherwise violating the intellectual property rights of others, third parties may nevertheless claim that our processes and products infringe their intellectual property and other rights. Our strategies of capitalizing on growing international demand as well as developing new innovative products across multiple business lines present similar infringement claim risks both internationally and in the U.S. as we expand the scope of our product offerings and markets. We compete with other companies for contracts in some small or specialized industries, which increase the risk that the other companies will develop overlapping technologies leading to an increased possibility that infringement claims will arise. Whether or not these claims have merit, we may be subject to costly and time-consuming legal proceedings, and this could divert management's attention from operating our business. In order to resolve such proceedings, we may need to obtain licenses from these third parties or substantially re-engineer or rename our products in order to avoid infringement. In addition, we might not be able to obtain the necessary licenses on acceptable terms, or at all, or be able to re-engineer or rename our products successfully.

We commercially, in co-branding with Fortis Healthcare, bank and store private cord blood stem cells in our TotipotentRX GMP facility. We could be subject to unexpected litigation costs or damages for loss of one or more family owned units of cord blood or if one of the cord blood units we store causes bodily injury. We face an inherent business risk of exposure to product liability claims if our products or product candidates are alleged or found to have caused injury or cannot be used for some reason within our control and are found to result in injury or death. While we believe that our current liability insurance coverage is adequate for our present clinical and commercial activities, we may not be able to maintain insurance on acceptable terms or at all. If we are unable to obtain insurance or any claims against us substantially exceed our coverage, then our business could be adversely impacted.

We may not be able to protect our intellectual property in countries outside the United States. Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. This is particularly relevant to us as a significant amount of our current and projected future sales are outside of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

Any failure to achieve and maintain the high design and manufacturing standards that our products require may seriously harm our business. Our products require precise, high-quality manufacturing. Achieving precision and quality control requires skill and diligence by our personnel as well as our vendors. Our

failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business. Additionally, the large amount of AXP disposable inventory certain distributors and end-users maintain may delay the identification of a manufacturing error and expand the financial impact. A manufacturing error or defect, or previously undetected design defect, or uncorrected impurity or variation in a raw material component, either unknown or undetected, could affect the product. Despite our very high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we or our vendors are unable to manufacture our products in accordance with necessary quality standards, our business and results of operations may be negatively affected.

Our revenues and operating results may be adversely affected as a result of our required compliance with the adopted EU directive on the restriction of the use of hazardous substances in electrical and electronic equipment, as well as other standards around the world. A number of domestic and foreign jurisdictions seek to restrict the use of various substances, a number of which have been or are currently used in our products or processes. For example, the EU Restriction of Hazardous Substances in Electrical and Electronic Equipment ("RoHS") Directive now requires that certain substances, which may be found in certain products we have manufactured in the past, be removed from all electronics components. Other countries, such as China, have enacted or may enact laws or regulations similar to RoHS. Eliminating such substances from our manufacturing processes requires the expenditure of additional research and development funds to seek alternative substances for our products, as well as increased testing by third parties to ensure the quality of our products and compliance with the RoHS Directive. While we have implemented a compliance program to ensure our product offerings meet these regulations, there may be instances where alternative substances will not be available or commercially feasible, or may only be available from a single source, or may be significantly more expensive than their restricted counterparts. Therefore, we have focused our compliance efforts on those products and geographical areas in which we have the highest revenue potential. Our failure to comply with past, present and future similar laws could result in reduced sales of our products, substantial product inventory write-offs, reputation damage, penalties and other sanctions, any of which could harm our business and operating results.

Our products may be subject to product recalls which may harm our reputation and divert our managerial and financial resources. The FDA and similar governmental authorities in other countries have the authority to order the mandatory recall of our products or order their removal from the market if the governmental entity finds our products might cause adverse health consequences or death. The FDA may also seize product or prevent further distribution. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects (including labeling defects). In the past, we have initiated voluntary recalls of some of our products and we could do so in the future. Any recall of our products may harm our reputation with customers, divert managerial and financial resources and negatively impact our profitability.

We are dependent on our suppliers and manufacturers to meet existing regulations. Certain of our suppliers and manufacturers are subject to heavy government regulations, including FDA QSR compliance, in the operation of their facilities, products and manufacturing processes. Any adverse action by the FDA against our suppliers or manufacturers could delay supply or manufacture of component products required to be integrated or sold with our products. Although we attempt to mitigate this risk through inventory held directly or through distributors, and audit our suppliers, there are no assurances we will be successful in identifying issues early enough to allow for corrective action or transition to an alternative supplier, or in locating an alternative supplier or manufacturer to meet product shipment or launch deadlines. As a result, our sales, contractual commitments and financial forecasts may be significantly affected by any such delays.

Dependence on suppliers for custom components may impact the production schedule. We obtain products and custom components from a limited number of suppliers. If the supplier raises the price or discontinues

production, we may have to find another qualified supplier to provide the item or re-engineer the item. In the event that it becomes necessary for us to find another supplier, we would first be required to qualify the quality assurance systems and product quality of that alternative supplier. Any operational issues with reengineering or the alternative qualified supplier may impact the production schedule, therefore delaying revenues, and this may cause the cost of disposables or key components to increase.

Dependence on contract manufacturers for disposable products. We obtain the majority of our disposable products from contract manufacturers. Production halts or delays by these manufacturers could have a significant impact on our business. Our safety stock levels are generally not sufficient to handle an unexpected shut-down or delay in production by these contract manufacturers. In the event of a significant unplanned delay in production, we may need to find a new contract manufacturer, which could be a lengthy process and require a significant financial commitment, impacting our ability to fulfill customer orders and maintain current sales levels for a period of time until the new contract manufacturer can start production of our disposable products.

Failure to meet the financial covenant in our Technology License and Escrow Agreement could decrease our AXP revenues. Under our License and Escrow Agreement with CBR. if we fail to meet the financial covenant of cash balance and short-term investments net of debt or borrowed funds that are payable within one year of not less than \$2,000,000, they may take possession of the escrowed intellectual property and initiate manufacturing of the applicable device and disposables. If this were to occur, our revenues would be negatively impacted. In order to remain compliant, we may have to complete additional financings or provide consideration to the counter party to modify the obligations.

Failure to retain or hire key personnel may adversely affect our ability to sustain or grow our business. Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, clinical, regulatory, sales, marketing and managerial personnel. Our future success partially depends upon the continued services of key technical and senior management personnel. Our future success also depends on our continuing ability to attract, retain and motivate highly qualified managerial and technical personnel. The inability to retain or attract qualified personnel could have a significant negative effect upon our efforts and thereby materially harm our business and future financial condition.

Most of our operations are conducted at a single location. Any disruption at our facilities could delay revenues or increase our expenses. Our U.S. device operations are conducted at a single location although we contract the manufacturing of certain devices, disposables and components. We take precautions to safeguard our facilities, through insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, and other natural disasters may not be adequate to cover our losses in any particular case.

Failure to maintain and/or upgrade our information technology systems may have an adverse effect on our operations. We rely on various information technology systems to manage our operations, and we evaluate these systems against our current and expected requirements. Although we have no current plans to implement modifications or upgrades to our systems, we will eventually be required to make changes to legacy systems and acquire new systems with new functionality. Any information technology system disruptions, if not anticipated and appropriately mitigated, could have an adverse effect on our business and operations.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us. We are required to establish and maintain adequate internal control

over financial reporting, which are processes designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. We are also required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, which (among other things) requires public companies to conduct an annual review and evaluation of their internal control over financial reporting. However, as a "smaller reporting company," we are not required to obtain an auditor attestation regarding our internal control over financial reporting. If, in the future, we require an attestation report from our independent registered public accounting firm and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer. In the ordinary course of the Company's business, the Company collects and stores sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners and personally identifiable information of the Company's employees on its networks. The secure processing, maintenance and transmission of this information is critical to the Company's operations and business strategy. Despite the Company's security measures, its information, technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise the Company's networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings or regulatory penalties and could disrupt the Company's operations and the services it provides to customers, damage the Company's reputation, and cause a loss of confidence in the Company's products and services, which could adversely affect the Company's business.

Our business and operations may be adversely affected by the recent 2019 Novel Coronavirus (COVID-19) outbreak or other similar outbreaks. Any outbreaks of contagious diseases, including the recent outbreak of the coronavirus and other adverse public health developments in countries where we operate could have a material and adverse effect on our business, financial condition and results of operations. These effects could include disruptions or restrictions on our employees' ability to travel, as well as temporary closures of our facilities or the facilities of our customers, suppliers, or other vendors in our supply chain. In addition, the coronavirus may result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products or our ability to obtain financing. Any of these events, which may result in disruptions to our supply chain or customer demand, could materially and adversely affect our business and our financial results. The extent to which the coronavirus will impact our business and our financial results will depend on future developments, which are highly uncertain and cannot be predicted. Such developments may include the geographic spread of the virus, the severity of the disease, the duration of the outbreak, the actions that may be taken by various governmental authorities in response to the outbreak and the possible impact on the U.S. or global economy. As a result, at the time of this filing, it is impossible to predict the overall impact of the coronavirus on our business, liquidity, capital resources and financial results.

Risks Related to Our Industry

Our business is heavily regulated, resulting in increased costs of operations and delays in product sales. Many of our products require FDA approval or clearance to sell in the U.S. and will require approvals from comparable agencies to sell in foreign countries. These authorizations may limit the U.S. or foreign markets in which our products may be sold. Further, our products must be manufactured under requirements of our quality system for continued CE-Marking so they can continue to be marketed and sold in Europe. These requirements are similar to the QSR of both the FDA and California Department of Public Health. Failure to comply with or incorrectly interpret these quality system requirements and regulations may subject us to delays in production while we correct deficiencies found by the FDA, the State of California, or our

notifying body as a result of any audit of our quality system. If we are found to be out of compliance, we could receive a Warning Letter or an untitled letter from the FDA or even be temporarily shut down in manufacturing and product sales while the non-conformances are rectified. Also, we may have to recall products and temporarily cease their manufacture and distribution, which would increase our costs and reduce our revenues. The FDA may also invalidate our PMA or 510(k) if appropriate regulations relative to the PMA or 510(k) products are not met. The notified bodies may elect to not renew CE-Mark certification. Any of these events would negatively impact our revenues and costs of operations.

Changes in governmental regulations may reduce demand for our products or increase our expenses. We compete in many markets in which we and our customers must comply with federal, state, local and international regulations, such as environmental, health and safety and food and drug regulations. We develop, configure and market our products to meet customer needs created by those regulations. Any significant change in regulations could reduce demand for our products or increase our expenses. For example, many of our instruments are marketed to the industry for enabling new regenerative therapies. Changes in the FDA's regulation of the devices and products directed at regenerative medicine, and development process for new therapeutic applications could have an adverse effect on the demand for these products.

To sell in international markets are subject to regulation in foreign countries. In cooperation with our distribution partners, we market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order for us to market our products in certain non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize current or future products in various foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

Operating in foreign jurisdictions subjects us to regulation by non-U.S. authorities. We have operations in India, and as such are subject to Indian regulatory agencies. A number of risks are inherent in conducting business and clinical operations overseas. In order for us to operate as a majority owned foreign corporation in India, we are subject to financial regulations imposed by the Reserve Bank of India. This includes the rules specific to the capital funding, pledging of assets, repatriation of funds and payment of dividends from and to the foreign subsidiaries and from and to us in the U.S.

In order for us to manufacture and/or market our services and products in India, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, and/or export may differ from the FDA regulatory scheme. Additionally, in order for us to complete clinical trials, clinical trial services and cell banking in India, and other foreign jurisdictions, we need to obtain and maintain approvals and licenses which comply with extensive regulations of the appropriate regulatory body.

International operations also may be limited or disrupted by political, economic or social instability, price controls, trade restrictions and changes in tariffs as ordered by various governmental agencies. Additionally, fluctuations in currency exchange rates may adversely affect the cost of production for our products by increasing the price of materials and other inputs for our products in the currency of the countries in which the products are sold.

If our competitors develop and market products that are more effective than our product candidates or obtain regulatory and market approval for similar products before we do, our commercial opportunity may be reduced or eliminated. The development and commercialization of new pharmaceutical products which target cardiovascular, orthopedic, chronic dermal wounds and other conditions addressed by our current and future products is competitive, and we will face competition from numerous sources, including major biotechnology and pharmaceutical companies worldwide. Many of our competitors have substantially greater financial and technical resources and development, production and marketing capabilities than we do. In addition, many of these companies have more experience than we do in pre-clinical testing, clinical trials and manufacturing of compounds, as well as in obtaining FDA and foreign regulatory approvals. As a result, there is a risk that one of the competitors will develop a more effective product for the same indications for which we are developing a product or, alternatively, bring a similar product to market before we can. With regards to the BioArchive and AXP Systems, numerous larger and better-financed medical device manufacturers may choose to enter this market.

Changes in healthcare policy could subject us to additional regulatory requirements that may delay the commercialization of our products and increase our costs. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of our diagnostic products and tests in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products and services that we believe are fair, which may impact our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and judicial decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue or force us to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging for several reasons, including policies advanced by the current executive administration in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("PPACA"), have substantially changed the way healthcare is financed by both government health plans and private insurers. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our revenues in the future. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, such provisions could materially adversely affect our business, prospects and financial condition.

The Food and Drug Administration Amendments Act of 2007 gives the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical studies of products, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during

product development, clinical studies and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products, all of which could materially adversely affect our business, prospects and financial condition.

Product liability and uninsured risks may adversely affect the continuing operations. We operate in an industry susceptible to significant product liability claims. We may be liable if any of our products or services cause injury, illness, or death. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. We also may be required to recall certain of our products should they become damaged or if they are defective. We are not aware of any material product liability claims against us. However, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. We maintain a product liability policy and a general liability policy that includes product liability coverage. However, a product liability claim against us could have a material adverse effect on our business or future financial condition.

Risks Related to Operating Results and Financial Markets

We have incurred net losses and we anticipate that our losses will continue. We have not been profitable for a significant period. For the years ended December 31, 2019 and 2018, we had a net loss of \$10,099,000 and \$40,940,000 respectively and an accumulated deficit at December 31, 2019, of 236,932,000. The report of our independent auditors on our December 31, 2019 financial statements includes an explanatory paragraph indicating there is substantial doubt about our ability to continue as a going concern. We will continue to incur significant costs as we develop and market our current products and related applications. Although we are executing our business plan to develop, market and launch new products, continuing losses may impair our ability to fully meet our objectives for new product sales or threaten our ability to continue as a going concern in future years.

We will likely need to raise additional capital to fund our operations and in furtherance of our business plan. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we may need to raise additional capital. We have historically relied upon private and public sales of our equity, as well as debt financings to fund our operations. In order to raise additional capital, we may seek to sell additional equity and/or debt securities or obtain a credit facility or other loan, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unfavorable terms.

We may incur significant non-operating, non-cash charges resulting from changes in the fair value of warrants. Our warrants are a derivative instrument; as such they have been recorded at their respective relative fair values at the issuance date and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on the Company's financial results. The fair value of the warrants is tied in large part to our stock price. If the stock price increases between reporting periods, the warrants become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

Risks Related to Our Common Stock

If the price of our common stock does not meet the requirements of the NASDAQ capital market stock Exchange ("NASDAQ"), our shares may be delisted. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted. The listing standards of NASDAQ provide, among other things, that a company may be delisted if the bid price of its stock drops below \$1.00 for a period of 30 consecutive business days. Delisting from NASDAQ could

adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Liquidity of our common stock. Although there is a public market for our common stock, trading volume has been historically low, which could impact the stock price and the ability to sell shares of our common stock. We can give no assurance that an active and liquid public market for the shares of the common stock will continue in the future. In addition, future sales of large amounts of common stock could adversely affect the market price of our common stock and our ability to raise capital. The price of our common stock could also drop as a result of the exercise of options for common stock or the perception that such sales or exercise of options could occur. These factors could also have a negative impact on the liquidity of our common stock and our ability to raise funds through future stock offerings.

We do not pay cash dividends. We have never paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. Instead, we intend to apply earnings, if any, to the expansion and development of our business. Thus, the liquidity of your investment is dependent upon your ability to sell stock at an acceptable price. The price can go down as well as up and may limit your ability to realize any value from your investment, including the initial purchase price.

Our Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive venue for certain litigation that may be initiated by our stockholders, which may limit a stockholder's ability to obtain a favorable judicial forum for such disputes with us or our directors, officers or employees.

Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative venue, the Court of Chancery of the State of Delaware will be the sole and exclusive venue for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein. This choice of venue provision will not apply to actions or proceedings brought to enforce a duty or liability created by the Securities Act or the Exchange Act.

This choice of venue provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage the filing of lawsuits with respect to such claims. If a court were to find this choice of venue provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in another jurisdiction, which could adversely affect our business and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a facility with approximately 28,000 square feet of space located in Rancho Cordova, California. The facility is used by both our Clinical Development and Device Segments and is devoted to warehouse space, manufacturing of products, office space, a biologics lab, a clean room, and a research and development lab. The lease expires May 31, 2024.

In Gurgaon India we lease approximately 1,500 square feet for an office facility for our Clinical Development Segment. The lease expires September 14, 2023 however; either party can terminate the lease with three months' notice.

Additionally, in Gurgaon India, as part of our agreement with Fortis Healthcare, we occupy and manage a 2,800 square foot cord blood banking and cellular therapy processing facility in the Fortis Memorial Research Institute.

We believe our facilities are adequate for our present needs and expect them to remain adequate for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

In the normal course of operations, we may have disagreements or disputes with distributors, vendors or employees. Such potential disputes are seen by management as a normal part of business and while the outcome of such disagreements and disputes cannot be predicted with certainty, except as described below, we do not believe that any pending legal proceedings are material. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

In fiscal 2016, the Company signed an engagement letter with a strategic consulting firm, Mavericks. Included in the engagement letter was a success fee due upon the successful conclusion of certain transactions. On May 4, 2017, a lawsuit was filed in California Superior Court against the Company and its CEO by the consulting firm as the consulting firm argues that it is owed a transaction fee of \$1,000,000 under the terms of the engagement letter due to the conversion of the Boyalife debentures in August 2016. In October 2017, to streamline the case by providing for the dismissal of claims against the Company's CEO based on alter ego theories and without acknowledging any liability, the Company deposited \$1,000,000 with the Court. The trial completed in February 2020 with an adverse jury verdict in favor of Mavericks in the total amount of \$1,000,000. The Action is now in the post-trial phase and no judgment has been entered as the parties are disputing whether the defense of equitable estoppel should bar entry of judgment at all and the proper per-judgment interest start date. At present, the Court is already holding a \$1,000,000 cash bond deposited by the Company early in the litigation. After entry of judgment, the Court will permit release of those funds to the Mavericks. As a result, the Company recorded a \$1,400,000 loss in the quarter ended December 31, 2019. The loss includes the \$1,000,000 transaction fee and an estimated \$400,000 in interest due. The final amount of interest due will be determined by the Court. The \$1,000,000 deposited with the court will be used to settle the transaction fee.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock, \$0.001 par value, is listed on the NASDAQ Capital Market under the symbol THMO.

We have not paid cash dividends on our common stock and do not intend to pay a cash dividend in the foreseeable future. There were approximately 122 stockholders of record on January 31, 2020, not including beneficial owners who own their stock in street name through Cede & Co. and others.

The Company did not repurchase any of its shares during the quarter ended December 31, 2019.

ITEM 6. SELECTED FINANCIAL DATA

We are a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and as such, we are not required to provide the disclosure required under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Certain statements contained in this section and other parts of this Annual Report on Form 10-K which are not historical facts are forward looking statements and are subject to certain risks and uncertainties. Our actual results may differ significantly from the projected results discussed in the forward-looking statements. Factors that might affect actual results include, but are not limited to, those discussed in ITEM 1A "RISK FACTORS" and other factors identified from time to time in our reports filed with the SEC. The following discussion should be read in conjunction with our consolidated financial statements contained in this Annual Report.

Overview

ThermoGenesis Holdings, Inc. ("ThermoGenesis Holdings", the "Company", "our", or "we") develops and commercializes a range of automated technologies for cell-banking, cell-processing, and cell-based therapeutics. Since the 1990's ThermoGenesis Holdings has been a pioneer in, and a leading provider of automated systems that isolate, purify and cryogenically store units of hematopoietic stem and progenitor cells for the cord blood banking industry. The Company was incorporated in 1986 and is registered in the State of Delaware and headquartered in Rancho Cordova, CA. In July 2017, ThermoGenesis Holdings' subsidiary, ThermoGenesis Corp., completed a strategic acquisition of the business and substantially all of the assets of SynGen Inc. ("SynGen"), a research and development company for automated cellular processing.

Following the acquisition of SynGen, we utilized the SynGen assets, together with our own proprietary technology, to develop a novel proprietary CAR-TXpressTM platform that addresses the critical unmet need for better efficiency and cost-effectiveness for the emerging immune-oncology field, in particular, the chimeric antigen receptor ("CAR") T cell market. Since the first quarter of 2018, the Company developed and launched various X-Series® products, including: X-Lab®, X-Wash®, X-Mini® and X-BACSTM.

Recent Corporate Name Change

On November 1, 2019, Cesca Therapeutics Inc. changed its corporate name to ThermoGenesis Holdings, Inc. in order to better reflect its new strategic focus on becoming a key solution provider for cell manufacturing tools and services in the cell and gene therapy markets. In conjunction with the name change, the Company began trading under the new Nasdaq ticker symbol, THMO. In addition, the Company changed its CUSIP number to 88362L100.

Reverse Stock Split

On June 4, 2019, the Company effected a one (1) for ten (10) reverse stock split of its issued and outstanding common stock. The total number of shares of common stock authorized for issuance by the Company of 350,000,000 shares did not change in connection with the reverse stock split.

All historical share amounts disclosed herein have been retroactively restated to reflect the reverse split and subsequent share exchange. No fractional shares were issued as a result of the reverse stock split, as fractional shares of common stock were rounded up to the nearest whole share.

ThermoGenesis Holdings now has two separately reported business segments: A "Device Segment" and a "Clinical Development Segment." The Device Segment develops and commercializes automated systems that used for, clinical grade cell-banking, point-of-care applications, and large scale cell processing. The Clinical Development Segment is developing autologous (utilizing the patient's own cells) cell-based therapeutics that address significant unmet medical needs for the vascular, cardiology and orthopedic markets.

ThermoGenesis Holdings' Device Segment

ThermoGenesis Holdings' Device Segment offers automated devices and technologies for cell-banking, point-of-care applications, and large scale cell processing. The automated devices include:

Clinical Bio-Banking Applications:

- **AXP**[®] **System** The innovative AXP System defines a new processing standard for isolating and retrieving over 97% of the stem and progenitor cells from collections of umbilical cord blood in an automated, fully closed, sterile system in 30 minutes. AXP is self-powered, microprocessor-controlled, and contains flow control optical sensors to achieve precise separation.
- **BioArchive** Cryopreservation System The BioArchive Cryopreservation System is the industry's leading, fully automated, robotic, liquid nitrogen controlled-rate-freezing ("CRF") and cryogenic storage system for stem cell samples and clinical products. Using proven, computer-controlled technology, it provides the ultimate performance and protection for today's invaluable cord blood samples and future cell therapeutic products. BioArchive is the preferred system for the highest quality cord blood banks worldwide. A complete technical Master-File has been provided to the FDA to support those highest quality cord blood banks which have been able to qualify for, and obtain, a Biological License from the FDA to allow their cord blood units to be used to treat patients with blood cancers.

Point-of-Care Applications:

• **PXP**[®] **System** – The PXP System is our newly launched point-of-care device. PXP is an automated, closed system that harvests a precise volume of cell concentrate from bone marrow aspirates. PXP can generate a concentration of bone marrow in less than 20 minutes, with consistently high MNC and CD34⁺ stem cell progenitor recovery rates and greater than 98% depletion of contaminating red blood cells (RBCs). Processing data is captured using our proprietary DataTrakTM software to assist with Good Manufacturing Practice ("GMP") process monitoring and reporting information.

Large Scale Cell Processing Applications:

- X-Lab® System for Cell Isolation a semi-automated, functionally-closed, ficoll-free, system for the rapid isolation of mononuclear cells ("MNCs") from collected units of peripheral blood, cord blood, bone marrow aspirate or leukapheresis. The Company had filed a Device Master File ("MAF") with the FDA for the X-Lab. The MAF contains all the relevant information that the FDA will need to allow principal investigators to include ThermoGenesis Holdings' systems in their investigational new drug applications.
- X-Wash® System for Washing and Reformulation a semi-automated, functionally-closed system that separates, washes, and volume-reduces units of fresh or thawed units of blood, bone marrow, leukapheresis or cell cultures and presents these washed cells in a predetermined small volume.
- X-BACSTM System for Cell Purification a semi-automated, functionally-closed system employs a microbubble/antibody reagent to isolate target cells by buoyancy-activated cell sorting ("BACS"). These microbubble/antibody reagents bind to user-selected target cells to increase their buoyancy and provide a complete separation from non-target cells during centrifugation and allowing the harvest of a highly purified population of target cells, with high recovery efficiency and cell viability.

ThermoGenesis Holdings' Clinical Development Segment

Using our proprietary automated point-of-care cellular processing technologies, ThermoGenesis Holdings utilizes autologous (utilizing the patient's own cells) stem cell-based therapeutics for the vascular and orthopedic markets that include:

- <u>Cell Manufacturing Services</u> Through our TotipotentRX subsidiary in Gurgaon, India, we operate an advanced clinical cell manufacturing, processing, testing, and storage facility, compliant with current Good Manufacturing Practices ("GMP"), Good Tissue Practices ("GTP"), and Good Laboratory Practices ("GLP"). We can support the production of a small, personalized medicine cell prescription or a large scale batch process. Patient samples, batch samples, and therapeutic aliquots are all labeled in accordance with ISBT 128 and stored in our own cryogenics' facility. In partnership with Fortis Healthcare we also operate commercial service programs supporting bone marrow transplantation (hematopoietic stem cell transplantation) for hematological and oncological disorders.
- <u>Cell Banking Services</u> Our NovaCord Cord Blood Bank and Repository is a licensed umbilical cord blood and tissue bank. It is a collaborative enterprise between TotipotentRX and Fortis Healthcare. The GMP facility of NovaCord is located inside multi-super specialty Fortis Memorial Research Institute, in Gurgaon, India where expertise is available for both stem cell banking and treating patients using advanced cellular therapies.

Results of Operations

Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018 (unaudited)

Net Revenues

Consolidated net revenues for the year ended December 31, 2019 were \$13,047,000 compared to \$9,672,000 for the year ended December 31, 2018, an increase of \$3,375,000 or 35%. The increase was driven by AXP revenues which increased by \$3,129,000 in 2019 with 688 more cases sold to a distributor in China, 435 more cases sold to domestic end users, 175 more cases sold to new customer in India and 83 more cases sold to our distributors in Europe (resulting in approximately \$2,400,000 more in AXP disposables revenue in the current year). Additionally, AXP device sales increased by approximately \$700,000 in 2019, driven by customers upgrading to AXP II devices in the current year. CAR-TXpress sales increased by approximately \$600,000 due to 2019 containing a full year of sales while 2018 only had a partial year due to relaunching the product line in the second half of 2018. BioArchive sales decreased by approximately \$200,000 due to one fewer device being sold in 2019. Sales in the Clinical Development Segment were approximately \$100,000 less than prior year due to reduced clinical services in India.

Revenues were comprised of the following:

	Year Ended December 31,		
	2019	2018	
Device Segment:			
AXP	\$7,522,000	\$4,393,000	
BioArchive	2,910,000	3,098,000	
Manual Disposables	909,000	976,000	
CAR-TXpress	1,565,000	907,000	
Other	51,000	95,000	
	12,957,000	9,469,000	
Clinical Development Segment:			
Disposables	68,000	135,000	
Other	22,000	68,000	
	90,000	203,000	
	\$13,047,000	\$9,672,000	

Gross Profit

The Company's gross profit was \$5,696,000 or 44% of net revenues for the year ended December 31, 2019 compared to \$2,193,000 or 23% for the year ended December 31, 2018, an increase of \$3,503,000 or 156%. The increase was primarily due to AXP sales, generating approximately \$1,925,000 more in gross profit from disposables and approximately \$275,000 from sales of AXP II devices. The increase in AXP disposable gross profit was due to approximately 1,375 more cases being sold in 2019 as compared to 2018 and lower product costs through price efficiencies from contract manufacturers. The other main driver of the increase is lower overhead costs of approximately \$600,000 in 2019 as compared to 2018 as a result of the June 2018 reorganization. The remainder of the increase is due to increased gross profit from service revenue of approximately \$250,000 and additional sales of CAR-TXpress which resulted in approximately \$300,000 more gross profit.

Sales and Marketing Expenses

Consolidated sales and marketing expenses were \$1,656,000 for the year ended December 31, 2019, as compared to \$1,359,000 for the year ended December 31, 2018, an increase of \$297,000 or 22%. The increase was driven by stock compensation expense of approximately \$125,000 for performance awards granted and achieved by employees during the current year and approximately \$200,000 in increased salaries and benefits.

Research and Development Expenses

Consolidated research and development expenses were \$2,396,000 for the year ended December 31, 2019, compared to \$3,012,000 for the year ended December 31, 2018, a decrease of \$616,000 or 20%. Research and development in the Device Segment decreased by \$406,000 and the Clinical Development Segment decreased by \$210,000. The decrease in both segments is primarily due to a decline in personnel costs related to corporate reorganization in June 2018.

General and Administrative Expenses

Consolidated general and administrative expenses for the year ended December 31, 2019 were \$6,377,000, compared to \$8,286,000 for the year ended December 31, 2018, a decrease of \$1,909,000 or 23%. The decrease was driven by a loss on the disposal of fixed assets in 2018 of approximately \$1,300,000 related to medical devices purchased for clinical trials and implementation costs for a new ERP system as a result of halting the clinical programs in 2018. Additionally, personnel costs decreased by approximately \$630,000 due to the June 2018 reorganization and other headcount reductions in 2018, severance expenses of approximately \$525,000 in 2018, and a one-time legal settlement of \$150,000 in 2018. In 2019, the Company had stock compensation expense, patent legal expense and travel expenses of approximately \$300,000 less combined as compared to 2018. India general and administrative expenses were also approximately \$300,000 less in 2019 due to lower payroll expenses resulting from a reorganization in India in the first quarter of 2019 and a renegotiated settlement of an outstanding debt. These decreases were offset by a \$1,400,000 expense as the result of the verdict against the Company in the Mavericks lawsuit.

Impairment Charges

The Company incurred no impairment charges during the year ended December 31, 2019 as compared to impairment charges of \$33,081,000 during the year ended December 31, 2018. During the twelve months ended December 31, 2018, the Company experienced a significant and sustained decline in its stock price resulting in its market capitalization falling significantly below the recorded value of its consolidated assets. The Company performed a quantitative assessment which determined that the carrying amount for the Company's goodwill and indefinite lived intangible assets relating to the clinical protocols exceeded its estimated fair value. As a result, impairment charges of \$13,195,000 to goodwill and \$19,886,000 to the Company's intangible assets in the Clinical Development Segment were recorded during the twelve months ended December 31, 2018.

Interest Expense

Interest expense increased to \$4,479,000 for the year ended December 31, 2019 as compared to \$2,697,000 for the year ended December 31, 2018, a difference of \$1,782,000. The increase is driven by interest recorded and the amortization of the debt discount, interest expense and the loss on the extinguishment of debt related to the January 2019 Note and Amended Note of approximately \$950,000, as well as approximately \$800,000 more in interest and amortization of the debt discount on the beneficial conversion feature related to the Revolving Credit Agreement with Boyalife, for which amortization started in May 2018 and July 2019 Note interest of \$105,000.

Loss on Extinguishment of Debt

The Company recorded a loss of extinguishment of debt of \$840,000 for the year ended December 31, 2019 as compared to \$0 for the year ended December 31, 2018. The increase is due to the loss on the extinguishment of the January 2019 Note.

Benefit for Income Taxes

For the year ended December 31, 2019, the Company has no income tax benefit compared to \$4,730,000 for the year ended December 31, 2018. The benefit for income tax for the year ended December 31, 2018 was due to the impairment of the indefinite lived intangible assets for the clinical protocols and goodwill. The Company's deferred tax liability is tied to the intangible assets and goodwill.

Non-GAAP Measures

In addition to the results reported in accordance with US GAAP, we also use a non-GAAP measure, adjusted EBITDA, to evaluate operating performance and to facilitate the comparison of our historical results and trends. The Company calculates adjusted EBITDA as income (or loss) from operations less depreciation, amortization, stock compensation and impairment of intangible assets. This financial measure is not a measure of financial performance under US GAAP and should not be considered in isolation or as a substitute for loss as a measure of performance. The calculation of this non-GAAP measure may not be comparable to similarly titled measures used by other companies. Reconciliations to the most directly comparable GAAP measure are provided below.

	Year Ended December 31,		
	2019	2018	
Net Loss	\$(10,099,000)	\$(40,940,000)	
Deduct:			
Interest expense	(4,479,000)	(2,697,000)	
Loss on extinguishment of debt	(840,000)		
Fair value change of derivative instruments and other	(32,000)	572,000	
Loss on equity method investments	(15,000)		
Benefit for income taxes		4,730,000	
Loss from operations	\$(4,733,000)	\$(43,545,000)	
Add:			
Depreciation and amortization	805,000	670,000	
Stock-based compensation expense	614,000	652,000	
Impairment of intangible asset		33,081,000	
Adjusted EBITDA	\$(3,314,000)	\$(9,142,000)	

The adjusted EBITDA loss was \$3,314,000 for the year ended December 31, 2019 compared to a loss of \$9,142,000 for the year ended December 31, 2018, an increase of \$5,828,000 or 64%. The increase was due to \$3,441,000 in additional gross profit as the result of higher sales, decreasing overhead expenses and lowering disposable costs through price efficiencies from contract manufacturers. Additionally, the Company decreased salary related expenses in operating expenses by approximately \$1,000,000 as a result of the June 2018 reorganization and the elimination of other positions during 2018. The year ended December 31, 2018 also included severance expenses of \$525,000, a one-time legal settlement of \$150,000 and a loss on the disposal of fixed assets of approximately \$1,300,000. These decreases were offset by a \$1,400,000 expense as the result of the verdict against the company in the Mavericks lawsuit.

Liquidity and Capital Resources

At December 31, 2019, we had cash and cash equivalents of \$3,157,000 and working capital of \$3,176,000. This compared to cash and cash equivalents of \$2,400,000 and working capital of \$2,261,000 at December 31, 2018. We have primarily financed operations through private and public placement of equity securities and our line of credit facility.

For the year ended December 31, 2019, we used \$3,260,000 of cash for operations primarily the result of the net loss \$10,099,000 in 2019. The loss was offset by approximately \$4,800,000 of non-cash charges, related to the amortization of debt discount, stock-based compensation expense, depreciation and amortization, reserves for slow-moving inventories and loss on the extinguishment of debt. Other drivers of the cash from operations was an increase long term deferred revenue and other noncurrent liabilities of \$1,492,000, primarily due to the exclusivity fee received from Corning; an increase in other current

liabilities of \$1,143,000 primarily due to the short-term portion and an increase in interest payable and an increase prepaid expenses and other assets of \$540,000. These increases were offset by a reduction in accounts payable and accrued payroll of \$1,381,000 and a decrease in inventories of \$610,000.

Cash used in investing activities for the year ended December 31, 2019 was \$182,000 as the result of capital purchases.

Cash generated in financing activities for the year ended December 31, 2019 was \$4,199,000, primarily due to \$1,800,000 received from the issuance of long-term debt from convertible notes issued in January 2019 and July 2019, \$1,513,000 from the draw-down of funds from our related party long-term convertible promissory note, the issuance of 444,445 pre-funded warrants in April of 2019 for \$756,000 and \$154,000 from the exercise of 18,764 warrants and 416,500 pre-funded warrants during the year.

The Company has a Revolving Credit Agreement with Boyalife Asset Holding II, Inc. As of December 31, 2019, the Company had drawn down \$8,713,000 of the \$10,000,000 available under the Revolving Credit Agreement. Future draw-downs may be limited for various reasons including default or foreign government policies that restrict or prohibit transferring funds. At the time of this filing, we are currently unable to draw down on the line of credit. This may change in the near future but there is no assurance that the line of credit will become available at such time when it is needed. Boyalife Investment Fund II, Inc. is a whollyowned subsidiary of Boyalife Group Inc., which is owned and controlled by the Company's Chief Executive Officer and Chairman of our Board of Directors.

The Company has incurred recurring operating losses and as of December 31, 2019 had an accumulated deficit of \$236,932,000. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the filing of this report. The Company anticipates requiring additional capital to grow the business, to fund other operating expenses and to make interest payments on the line of credit with Boyalife. The Company's ability to fund its cash needs is subject to various risks, many of which are beyond its control. The Company may seek additional funding through bank borrowings or public or private sales of debt or equity securities or strategic partnerships. The Company cannot guarantee that such funding will be available on a timely basis, in needed quantities or on terms favorable to us, if at all.

One customer had an accounts receivable balance of \$337,000 or 27% and \$494,000 or 39% at December 31, 2019 and 2018, respectively. One distributor had an accounts receivable balance of \$177,000 or 14% and \$220,000 or 18% at December 31, 2019 and 2018, respectively. A second distributor had an accounts receivable balance of \$170,000 or 14% and \$0 at December 31, 2019 and 2018, respectively.

Revenues from one customer totaled \$3,575,000 or 28% and \$2,120,000 or 22% for the years ended December 31, 2019 and 2018, respectively. Revenues from one distributor totaled \$1,470,000 or 11%, and \$460,000 or 4% for the year ended December 31, 2019 and the year ended December 31, 2018, respectively.

We manage the concentration of credit risk with these customers and distributors through a variety of methods including, letters of credit with financial institutions, pre-shipment deposits, credit reference checks and credit limits. Although management believes that these customers and distributors are sound and creditworthy, a severe adverse impact on their business operations could have a corresponding material effect on their ability to pay timely and therefore on our net revenues, cash flows and financial condition.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to stock-based compensation, depreciation, fair values of intangibles and goodwill, bad debts, inventories, warranties, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. *See Note 2* "Summary of Significant Accounting Policies" to the Notes to the Consolidated Financial Statements contained in Item 8.

We believe the following critical accounting policies affect the more significant judgments and estimates used by the Company in the preparation of its consolidated financial statements.

Off Balance Sheet Arrangements

We have no off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act, and as such, we are not required to provide the disclosure required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of ThermoGenesis Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ThermoGenesis Holdings, Inc. (the "Company"), formerly known as Cesca Therapeutics Inc., as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, equity and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring losses. These recurring losses raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of the guidance in ASC Topic 842, Leases ("Topic 842").

Basis for Opinion

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

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

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

/s/ Marcum LLP Marcum LLP

We have served as the Company's auditor since 2015.

New York, NY March 23, 2020

THERMOGENESIS HOLDINGS, INC. CONSOLIDATED BALANCE SHEETS

	December 31,		
	2019	2018	
ASSETS			
Current assets:			
Cash and cash equivalents	\$3,157,000	\$2,400,000	
Restricted cash	1,000,000		
Accounts receivable, net of allowance for doubtful accounts of \$226,000 (\$419,000 at December 31, 2018)	1,278,000	1,509,000	
Inventories, net of reserves of \$350,000 (\$258,000 at December 31, 2018)	3,824,000	4,493,000	
Prepaid expenses and other current assets	602,000	224,000	
Total current assets	9,861,000	8,626,000	
Total Carront associa	7,001,000	0,020,000	
Restricted cash – long term		1,000,000	
Equipment and leasehold improvements, net	2,028,000	2,562,000	
Right-of-use operating lease assets, net	859,000	· · · · · ·	
Goodwill	781,000	781,000	
Intangible assets, net	1,467,000	1,591,000	
Other assets	218,000	51,000	
Total assets	\$15,214,000	\$14,611,000	
LIABILITIES AND EQUITY			
Current liabilities:	Φ4. 4. 5 .000	Φα 100 000	
Accounts payable	\$1,447,000	\$2,423,000	
Accrued payroll and related expenses	288,000	703,000	
Deferred revenue – short term	620,000	485,000	
Interest payable – related party	1,869,000	1,513,000	
Other current liabilities	2,461,000	1,241,000	
Total current liabilities	6,685,000	6,365,000	
Convertible promissory note – related party, less debt discount of			
\$5,195,000 (\$6,026,000 at December 31, 2018)	3,518,000	1,174,000	
Convertible promissory note, plus debt premium of \$46,000 (\$0 at December 31,	-,,	-,,	
2018)	413,000		
Note payable	1,000,000		
Operating lease obligations – long term	761,000		
Deferred revenue – long term	1,901,000	303,000	
Other noncurrent liabilities	20,000	38,000	
Total liabilities	14,298,000	7,880,000	
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.001 par value; 2,000,000 shares authorized; none issued			
and outstanding			
Common stock, \$0.001 par value; 350,000,000 shares authorized;			
2,843,601 issued and outstanding (2,168,337 at December 31, 2018)	3,000	2,000	
Additional paid in capital	237,313,000	235,888,000	
Accumulated deficit	(236,932,000)	(227,435,000)	
Accumulated other comprehensive loss	2,000	(13,000)	
Total ThermoGenesis Holdings, Inc. stockholders' equity	386,000	8,442,000	
Noncontrolling interest	530,000	(1,711,000)	
Total equity	916,000	6,731,000	
Total liabilities and equity	\$15,214,000	\$14,611,000	
	. 1		

THERMOGENESIS HOLDINGS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,		
	2019	2018	
Net revenues	\$12,160,000	\$9,003,000	
Net revenues – related party	887,000	669,000	
Total net revenues	13,047,000	9,672,000	
Cost of revenues	7,351,000	7,479,000	
Gross profit	5,696,000	2,193,000	
Expenses:			
Sales and marketing	1,656,000	1,359,000	
Research and development	2,396,000	3,012,000	
General and administrative	6,377,000	8,286,000	
Impairment charges	·	33,081,000	
Total operating expenses	10,429,000	45,738,000	
Loss from operations	(4,733,000)	(43,545,000)	
Other income (expense):			
Fair value change of derivative instruments	1,000	596,000	
Interest expense	(4,479,000)	(2,697,000)	
Loss on extinguishment of debt	(840,000)		
Loss on equity method investments	(15,000)		
Other expenses	(33,000)	(24,000)	
Total other expense	(5,366,000)	(2,125,000)	
Loss before benefit for income taxes	(10,099,000)	(45,670,000)	
Benefit for income taxes		4,730,000	
Net loss	(10,099,000)	(40,940,000)	
Loss attributable to non-controlling interests	(602,000)	(1,224,000)	
Net loss attributable to common stockholders	\$(9,497,000)	\$(39,716,000)	
COMPREHENSIVE LOSS Net loss	\$(10,099,000)	\$(40,940,000)	
Other comprehensive loss:	Ψ(10,072,000)	Ψ(+0,2+0,000)	
Foreign currency translation adjustments	15,000	30,000	
Comprehensive loss	(10,084,000)	(40,910,000)	
Comprehensive loss attributable to non-controlling interests	(602,000)	(1,224,000)	
Comprehensive loss attributable to common stockholders	\$(9,482,000)	\$(39,686,000)	
Per share data:			
Basic and diluted net loss per common share	\$(3.36)	\$(21.57)	
Weighted average common shares outstanding Basic and diluted	2,828,606	1,841,281	

THERMOGENESIS HOLDINGS, INC. CONSOLIDATED STATEMENTS OF EQUITY

	Shares	Common Stock	Paid in Capital in Excess of Par	Accumulated Deficit	AOCL*	Non- Controlling Interests	Total Equity
Balance at December 31, 2017	1,090,664	\$1,000	\$221,381,000	\$(187,640,000)	\$(43,000)	\$(487,000)	\$33,212,000
Stock-based compensation							
expense	41		652,000				652,000
Issuance of common stock and pre-funded warrants in			,				,
financing, net of offering costs	808,465	1,000	6,628,000				6,629,000
Exercise of warrants	269,167		27,000				27,000
Discount due to beneficial							
conversion features			7,200,000				7,200,000
Cumulative-effect adjustment							
from adoption of ASC 606				(79,000)			(79,000)
Foreign currency translation					30,000		30,000
Net loss				(39,716,000)		(1,224,000)	(40,940,000)
Balance at December 31, 2018	2,168,337	\$2,000	\$235,888,000	\$(227,435,000)	\$(13,000)	\$(1,711,000)	\$6,731,000
Stock-based compensation			614,000				614,000
Exercise of pre-funded warrants	416,500	1,000	41,000				42,000
Exercise of warrants	18,764		112,000				112,000
Conversion of note payable to							
stock	240,000		432,000				432,000
Reorganization of subsidiary and							
related change in non-controlling							
interest			(2,843,000)			2,843,000	
Discount due to beneficial							
conversion features			2,313,000				2,313,000
Issuance of common stock pre-							
funded warrants in financing, net							
of offering cost			756,000				756,000
Foreign currency translation					15,000		15,000
Net loss				(9,497,000)		(602,000)	(10,099,000)
Balance at December 31, 2019	2,843,601	\$3,000	\$237,313,000	\$(236,932,000)	\$2,000	\$530,000	\$916,000

^{*} Accumulated other comprehensive loss.

THERMOGENESIS HOLDINGS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
·	2019	2018
Cash flows from operating activities:		
Net loss	\$(10,099,000)	\$(40,940,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	805,000	670,000
Stock-based compensation expense	614,000	652,000
Amortization of debt discount/premium, net	2,349,000	1,174,000
(Recovery of) reserve for excess and slow-moving inventories	92,000	(11,000)
(Recovery of) reserve for bad debt expense	(60,000)	153,000
Change in fair value of derivative	(1,000)	(596,000)
Deferred income tax benefit		(4,730,000)
Loss on disposal of equipment	70,000	1,360,000
Loss on extinguishment of debt	840,000	
Impairment of intangible asset		33,081,000
Net change in operating assets and liabilities:		
Accounts receivable	301,000	1,045,000
Inventories	610,000	61,000
Prepaid expenses and other assets	(525,000)	370,000
Accounts payable	(966,000)	214,000
Interest payable - related party	355,000	(606,000)
Accrued payroll and related expenses	(415,000)	172,000
Deferred revenue	135,000	24,000
Other current liabilities	1,143,000	922,000
Long term deferred revenue and other noncurrent liabilities	1,492,000	2,000
Net cash used in operating activities	(3,260,000)	(6,983,000)
Cash flows from investing activities:	(=) = =) = = /	
Capital expenditures	(182,000)	(1,238,000)
Net cash used in investing activities	(182,000)	(1,238,000)
Cash flows from financing activities:	(102,000)	(1,230,000)
Proceeds from long-term debt	1,800,000	
Proceeds from convertible promissory note-related party	1,513,000	500,000
Payments on finance lease obligations	(24,000)	(45,000)
Proceeds from issuance of common stock and pre-funded warrants	756,000	6,629,000
Proceeds from exercise of warrants and pre-funded warrants	154,000	27,000
Net cash provided by financing activities	4,199,000	7,111,000
Effects of foreign currency rate changes on cash and cash equivalents	, ,	
	757.000	(3,000)
Net decrease in cash, cash equivalents and restricted cash	757,000	(1,113,000)
Cash, cash equivalents and restricted cash at beginning of period	3,400,000	4,513,000
Cash, cash equivalents and restricted cash at end of period	\$4,157,000	\$3,400,000
Supplemental disclosures of cash flow information: Cash paid for interest	\$177,000	\$667,000
Supplemental non-cash financing and investing information:		
Recording of beneficial conversion feature on debt	\$2,313,000	\$7,200,000
Right-to-use asset acquired under operating lease	\$966,000	
Conversion of debt to common stock	\$432,000	
Fair value of amended convertible note issued in connection with the	ψ+32,000	
	¢1 472 000	
extinguishment of original convertible note	\$1,473,000	
Transfer of equipment to inventories	\$44,000	\$172,000
Transfer of inventories to equipment	\$22,000	\$420,000

1. Description of Business, Going Concern and Basis of Presentation

Organization and Basis of Presentation

ThermoGenesis Holdings, Inc. ("ThermoGenesis Holdings," the "Company," "we," "our," "us"), formerly known as Cesca Therapeutics Inc., develops, commercializes and markets a range of automated technologies for CAR-T and other cell-based therapies. The Company currently markets a full suite of solutions for automated clinical biobanking, point-of-care applications, and automation for immuno-oncology, including its semi-automated, functionally closed CAR-TXpressTM platform, which streamlines the manufacturing process for the emerging CAR-T immunotherapy market. The Company was founded in 1986 and is registered in the State of Delaware and headquartered in Rancho Cordova, CA.

The Company provides the AutoXpress® and BioArchive platforms for automated clinical bio-banking, PXP platform for point-of-care cell-based therapies and CAR-TXpress™ platform under development for bio-manufacturing for immuno-oncology applications. The Company and its subsidiaries currently manufactures and markets the following products:

For Clinical Bio-Banking Applications:

- AXP Automated Cell Separation System an automated, fully closed cell separation system for isolating and retrieving stem and progenitor cells from umbilical cord blood.
- BioArchive Automated Cryopreservation System an automated, robotic, liquid nitrogen controlled-rate-freezing and cryogenic storage system for cord blood samples and cell therapeutic products used in clinical applications.

For Point-of-Care Applications:

• PXP Point-of-Care System – an automated, fully closed, sterile system allows for the rapid, automated processing of autologous peripheral blood or bone marrow aspirate derived stem cells at the point-of-care, such as surgical centers or clinics.

For Large Scale Cell Processing and Biomanufacturing:

- X-Series Products: X-Lab® for cell isolation, X-Wash® System for cell washing and reformulation, X-Mini® for high efficiency small scale cell purification, and X-BACS™ System under development for large scale cell purification using our proprietary buoyance-activated cell sorting (BACS) technology.
- CAR-TXpress™ Platform a modular designed, functionally closed platform that addresses the critical unmet need for large scale cellular processing and chemistry, manufacturing and controls ("CMC") needs for manufacturing chimeric antigen receptor ("CAR") T cell therapies. CAR-TXpress is owned and developed through a subsidiary in which we own 80% of the equity interest.

1. Description of Business, Going Concern and Basis of Presentation (Continued)

Organization and Basis of Presentation (Continued)

January 1, 2019, the Company entered into a reorganization of the business and equity ownership of its majority-owned ThermoGenesis Corp. subsidiary. Pursuant to the reorganization, the assets acquired by ThermoGenesis Corp. from SynGen Inc. in July 2017 were contributed to a newly formed Delaware subsidiary of ThermoGenesis Corp. named CARTXpress Bio and the 20% interest in ThermoGenesis Corp. held by a third party was exchanged for a 20% interest in CARTXpress Bio. As a result, the Company holds an 80% equity interest in CARTXpress Bio and the Company has become the owner of 100% of ThermoGenesis Corp. The purpose of the reorganization was to allow CARTXpress Bio to focus on the development and commercialization of the newly launched CARTXpress Bio cellular manufacturing platform.

In the reorganization, the Company reacquired the non-controlling interest shares in ThermoGenesis Corp., which had an accumulated deficit of \$1,711,000, in exchange for a 20% equity interest in the newly formed subsidiary, CARTXpress Bio, which amounted to approximately \$1,100,000. The total amount of \$2,843,000 related to the reorganization of subsidiary and the related increase in non-controlling interest was offset by a charge to additional paid in capital in stockholders' equity.

ThermoGenesis Holdings is an affiliate of the Boyalife Group, a global diversified life science holding company that focuses on stem cell technology and cell-based therapeutics.

Reverse Stock Split

On June 4, 2019, the Company effected a one (1) for ten (10) reverse stock split of its issued and outstanding common stock. The total number of shares of common stock authorized for issuance by the Company of 350,000,000 shares did not change in connection with the reverse stock split.

All historical share amounts disclosed herein have been retroactively restated to reflect the reverse split and subsequent share exchange. No fractional shares were issued as a result of the reverse stock split, as fractional shares of common stock were rounded up to the nearest whole share.

Liquidity and Going Concern

The Company has a Revolving Credit Agreement (the "Credit Agreement") with Boyalife Asset Holding II, Inc. (See Note 5). As of December 31, 2019, the Company had drawn down \$8,713,000 of the \$10,000,000 available under the Credit Agreement. Future draw-downs may be limited for various reasons including default or foreign government policies that restrict or prohibit transferring funds. At the time of this filing, the Company is currently unable to draw down on the line of credit. This may change in the near future; however, there is no assurance that the line of credit will become available at such time when it is needed. Boyalife Asset Holding II, Inc. is a wholly owned subsidiary of Boyalife Group Inc., which is owned and controlled by the Company's Chief Executive Officer and Chairman of our Board of Directors.

1. <u>Description of Business, Going Concern and Basis of Presentation (Continued)</u>

Liquidity and Going Concern (Continued)

At December 31, 2019, the Company had cash and cash equivalents of \$3,157,000 and working capital of \$3,176,000. The Company has incurred recurring operating losses and as of December 31, 2019 has an accumulated deficit of \$236,932,000. These recurring losses raise substantial doubt about the Company's ability to continue as a going concern within one year from the filing of this report. The Company will need to raise additional capital to grow its device business, fund operating expenses and make interest payments that will become due under the line of credit with Boyalife Asset Holding II, Inc. The Company's ability to fund its cash needs is subject to various risks, many of which are beyond its control. The Company plans to seek additional funding through debt borrowings, sales of debt or equity securities or strategic partnerships. The Company cannot guarantee that such funding will be available on a timely basis, in needed quantities or on terms favorable to the Company, if at all.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern; however, the conditions described herein raise substantial doubt about the Company's ability to do so. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may become necessary should the Company be unable to continue as a going concern.

Principles of Consolidation

The consolidated financial statements include the accounts of ThermoGenesis Holdings and its wholly-owned subsidiaries, ThermoGenesis Corp. and TotipotentRX Cell Therapy, Pvt. Ltd and ThermoGenesis Corp's majority-owned subsidiary, CARTXpress Bio. All significant intercompany accounts and transactions have been eliminated upon consolidation.

Non-controlling Interests

The 20% ownership interest of CARTXpress Bio that is not owned by ThermoGenesis Holdings is accounted for as a non-controlling interest as the Company has an 80% ownership interest in the subsidiary. Earnings or losses attributable to other stockholders of a consolidated affiliated company are classified separately as "non-controlling interest" in the Company's consolidated statements of operations. Net loss attributable to non-controlling interest reflects only its share of the after-tax earnings or losses of an affiliated company. The Company's consolidated balance sheets reflect non-controlling interests within the equity section.

2. Summary of Significant Accounting Policies

Use of Estimates

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") and requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used for, but not limited to, the allowance for doubtful accounts, carrying amounts of inventories, depreciation and amortization, warranty obligations, assumptions made in valuing financial instruments issued in various compensation and financing arrangements, deferred income taxes and related valuation allowance and the fair values of intangibles and goodwill. Actual results could materially differ from the estimates and assumptions used in the preparation of the Company's consolidated financial statements.

Revenue Recognition

Revenue is recognized based on the five-step process outlined in Accounting Standards Codification ("ASC") 606:

Step 1 – Identify the Contract with the Customer – A contract exists when (a) the parties to the contract have approved the contract and are committed to perform their respective obligations, (b) the entity can identify each party's rights regarding the goods or services to be transferred, (c) the entity can identify the payment terms for the goods or services to be transferred, (d) the contract has commercial substance and, (e) it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Step 2 – Identify Performance Obligations in the Contract – Upon execution of a contract, the Company identifies as performance obligations each promise to transfer to the customer either (a) goods or services that are distinct or (b) a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer. To the extent a contract includes multiple promised goods or services, the Company must apply judgement to determine whether the goods or services are capable of being distinct within the context of the contract. If these criteria are not met, the goods or services are accounted for as a combined performance obligation.

Step 3 – Determine the Transaction Price – The contract terms and customary business practices are used to determine the transaction price. The transaction price is the amount of consideration expected to be received in exchange for transferring goods or services to the customer. The Company's contracts include fixed consideration.

Step 4 – Allocate the Transaction Price – After the transaction price has been determined, the next step is to allocate the transaction price to each performance obligation in the contract. If the contract only has one performance obligation, the entire transaction price will be applied to that obligation. If the contract has multiple performance obligations, the transaction price is allocated to the performance obligations based on the relative standalone selling price ("SSP") at contract inception.

Step 5 – Satisfaction of the Performance Obligations (and Recognize Revenue) – When an asset is transferred and the customer obtains control of the asset (or the services are rendered), the Company recognizes revenue. At contract inception, the Company determines if each performance obligation is satisfied at a point in time or over time. For device sales, revenue is recognized at a point in time when the goods are transferred to the customer and they obtain control of the asset. For maintenance contracts, revenue is recognized over time as the performance obligations in the contracts are completed.

2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition (Continued)

Device Sales

Device sales include devices and consumables for BioArchive, AXP, CAR-TXpress and manual disposables. Most devices are sold with contract terms stating that title passes, and the customer takes control at the time of shipment. Revenue is then recognized when the devices are shipped, and the performance obligation has been satisfied. If devices are sold under contract terms that specify that the customer does not take ownership until the goods are received, revenue is recognized when the Company confirms that the customer has received and taken physical possession of the goods.

Service Revenue

Service revenue principally consists of maintenance contracts for BioArchive, AXP and CAR-TXpress products. Devices sold have warranty periods of one to two years. After the warranty expires, the Company offers separately priced annual maintenance contracts. Under these contracts, customers pay in advance. These prepayments are recorded as deferred revenue and recognized over time as the contract performance obligations are satisfied. For AXP and CAR-TXpress products, the Company offers one type of maintenance contract providing preventative maintenance and repair services. Revenue under these contracts is recognized ratably over time, as the customer has the right to use the service at any time during the annual contract period and services are unlimited. For BioArchive, the Company offers three types of maintenance contracts: Gold, Silver and Preventative Maintenance Only. Under the Gold contract, maintenance and repair services are unlimited and revenue is recognized ratably over time. For the Silver and Preventative Maintenance contracts, available services are limited, and revenue is recognized during the contract period when the underlying performance obligations are satisfied. If the services are not used during the contract period, any remaining revenue is recognized when the contract expires. The renewal date for maintenance contracts varies by customer, depending when the customer signed their initial contract.

2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition (Continued)

Clinical Services

Service revenue in our Clinical Development Segment includes point of care procedures and cord blood processing and storage. Point of care procedures are recognized when the procedures are performed. Cord blood processing and storage is recognized as the performance obligations are satisfied. Processing revenue is recognized when that performance obligation is completed immediately after the baby's birth, with storage revenue recorded as deferred revenue and recognized ratably over time for up to 21 years. As of December 31, 2019 and 2018, the total deferred cord blood storage revenue is \$237,000 and \$252,000, respectively. As of December 31, 2019, those amounts were recorded as \$14,000 in current liabilities and \$223,000 in non-current liabilities. As of December 31, 2018, those amounts were recorded as \$14,000 in current liabilities and \$238,000 in non-current liabilities. The customer may pay for both services at the time of processing. The amount of the transaction price allocated to each of the performance obligations is determined by using the standalone selling price of each component, which the Company applies consistently to all such arrangements. The Company did not process and store any new cord blood revenue in 2019. Service revenue recognized in the Clinical Development Segment in 2019 related entirely to revenue deferred from previous years.

The following table summarizes the revenues of the Company's reportable segments for the year ended December 31, 2019:

Year Ended December 31, 2019

	Device	Service	Other	Total
	Revenue	Revenue	Revenue	Revenue
Device Segment:				
AXP	\$7,313,000	\$209,000		\$7,522,000
BioArchive	1,472,000	1,438,000		2,910,000
Manual Disposables	909,000			909,000
CAR-TXpress	1,457,000	13,000	\$95,000	1,565,000
Other			51,000	51,000
Total Device Segment	11,151,000	1,660,000	146,000	12,957,000
Clinical Development Segment:				
Disposables	68,000			68,000
Other		22,000		22,000
Total Clinical Development	68,000	22,000		90,000
Total	\$11,219,000	\$1,682,000	\$146,000	\$13,047,000

2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition (Continued)

The following table summarizes the revenues of the Company's reportable segments for the year ended December 31, 2018:

Year Ended December 31, 2018

evice Ser venue Rev	vice Other enue Revenu	
venue Rev	aniia Pavanii	_
	chuc Kevenu	e Revenue
31,000 \$2	62,000	\$ \$4,393,000
92,000 1,3	06,000	3,098,000
76,000		976,000
07,000		907,000
<u></u>	95,0	95,000
06,000 1,5	68,000 95,0	9,469,000
1	35,000	135,000
38,000	30,000	68,000
38,000	65,000	203,000
44,000 \$1,7	33,000 \$95,0	9,672,000
7))	31,000 \$2 792,000 1,3 976,000 907,000 806,000 1,5 1 38,000 38,000 1	\$262,000 792,000 1,306,000 907,000 135,000 38,000 38,000 165,000

In 2019, there was no right of return provided for distributors or customers. For distributors, the Company has no control over the movement of goods to the end customer. The Company's distributors control the timing, terms and conditions of the transfer of goods to the end customer. Additionally, for sales of products made to distributors, the Company considers a number of factors in determining whether revenue is recognized upon transfer of title to the distributor, or when payment is received. These factors include, but are not limited to, whether the payment terms offered to the distributor are considered to be non-standard, the distributor's history of adhering to the terms of its contractual arrangements with the Company, whether the Company has a pattern of granting concessions for the benefit of the distributor, and whether there are other conditions that may indicate that the sale to the distributor is not substantive.

Payments from domestic customers are normally due in two months or less after the title transfers, the service contract is executed, or the services have been rendered. For international customers, payment terms may extend up to 120 days. All sales have fixed pricing and there are currently no variable components included in the Company's revenue.

2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition (Continued)

Contract Balances

Generally, all sales are contract sales (with either an underlying contract or purchase order). The Company does not have any material contract assets. When invoicing occurs prior to revenue recognition a contract liability is recorded (as deferred revenue on the consolidated balance sheet). Revenues recognized during the year ended December 31, 2019 that were included in the beginning balance of deferred revenue were \$1,049,000. Short term deferred revenues were \$620,000 and \$485,000 at December 31, 2019 and 2018, respectively. Long term deferred revenue, included in other noncurrent liabilities, was \$1,901,000 and \$303,000 at December 31, 2019 and 2018, respectively.

Exclusivity Fee

On August 30, 2019, the Company entered into a Supply Agreement with Corning Incorporated (the "Supply Agreement"). The Supply Agreement has an initial term of five years with automatic two-year renewal terms, unless terminated by either party in accordance with the terms of the Supply Agreement (collectively, the "Term"). Pursuant to the Supply Agreement, the Company has granted to Corning exclusive worldwide distribution rights for substantially all X-Series® products under the CAR-TXpressTM platform (the "Products") manufactured by its subsidiary, ThermoGenesis Corp., for the duration of the Term, subject to certain geographical and other exceptions. As consideration for the exclusive worldwide distribution rights for the Products, Corning has agreed to pay a \$2,000,000 exclusivity fee, in addition to any amounts payable throughout the Term for the Products.

The Company performed an evaluation of the revenue recognition of the \$2,000,000 fee under ASC 606. It determined that the \$2,000,000 will be recognized over time, based on the term of the contract. It was determined that the most likely outcome is the agreement is extended for one additional two-year term after the initial five-year contract is complete. Consequently, the term to recognize the exclusivity fee is over seven years. The Company will allocate the upfront fee evenly to each daily performance obligation of providing exclusivity and recognize the revenue ratably over the seven-year period. As each day passes, the Company will recognize the portion of the exclusivity fee allocated to that day. For the year ended December 31, 2019, the Company recorded revenue of \$96,000 related to the exclusivity fee. The remaining balance of the \$2,000,000 payment of \$1,904,000 was recorded to deferred revenue, with \$286,000 in short-term deferred revenue and \$1,618,000 recorded in long-term deferred revenue.

2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition (Continued)

Backlog of Remaining Customer Performance Obligations

The following table includes revenue expected to be recognized and recorded as sales in the future from the backlog of performance obligations that are unsatisfied (or partially unsatisfied) at the end of the reporting period.

					2024 and	
	2020	2021	2022	2023	beyond	Total
Service revenue	\$848,000	\$632,000	\$228,000	\$90,000	\$30,000	\$1,828,000
Clinical revenue	14,000	14,000	\$14,000	14,000	181,000	237,000
Exclusivity Fee	286,000	286,000	286,000	286,000	760,000	1,904,000
Total	\$1,148,000	\$932,000	\$528,000	\$390,000	\$971,000	\$3,969,000

Revenues are net of normal discounts. Shipping and handling fees billed to customers are included in net revenues, while the related costs are included in cost of revenues.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents is maintained in checking accounts, money market funds and certificates of deposits with reputable financial institutions that may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation. The Company has cash and cash equivalents of \$10,000 and \$11,000 at December 31, 2019 and 2018 in India. The Company has not experienced any realized losses on the Company's deposits of cash and cash equivalents.

Foreign Currency Translation

The Company's reporting currency is the US dollar. The functional currency of the Company's subsidiaries in India is the Indian rupee ("INR"). Assets and liabilities are translated into US dollars at period end exchange rates. Revenue and expenses are translated at average rates of exchange prevailing during the periods presented. Cash flows are also translated at average exchange rates for the period, therefore, amounts reported on the consolidated statement of cash flows do not necessarily agree with changes in the corresponding balances on the consolidated balance sheet. Equity accounts other than retained earnings are translated at the historic exchange rate on the date of investment. A translation gain (loss) of \$15,000 and \$30,000 was recorded at December 31, 2019 and 2018, respectively, as a component of other comprehensive income.

2. Summary of Significant Accounting Policies (Continued)

Goodwill, Intangible Assets and Impairment Assessments

Goodwill represents the excess of the purchase price in a business combination over the fair value of net tangible and intangible assets acquired. Intangible assets that are not considered to have an indefinite useful life are amortized over their useful lives, which generally range from three to ten years. Each period the Company evaluates the estimated remaining useful lives of purchased intangible assets and whether events or changes in circumstances warrant a revision to the remaining periods of amortization.

For goodwill and indefinite-lived intangible assets, the carrying amounts are periodically reviewed for impairment (at least annually) and whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. According to ASC 350, "Intangibles-Goodwill and Other", the Company can opt to perform a qualitative assessment or a quantitative assessment; however, if the qualitative assessment determines that it is more likely than not (i.e., a likelihood of more than 50 percent) the fair value is less than the carrying amount; the Company would recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value.

Fair Value of Financial Instruments

In accordance with ASC 820, *Fair Value Measurements and Disclosures*, fair value is defined as the exit price, or the amount that would be received for the sale of an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date.

The guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors that market participants would use in valuing the asset or liability. The guidance establishes three levels of inputs that may be used to measure fair value:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Unobservable inputs reflecting the reporting entity's own assumptions.

The carrying values of cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to their short duration. The fair value of the Company's derivative obligation liability is classified as Level 3 within the fair value hierarchy since the valuation model of the derivative obligation is based on unobservable inputs. The impairment of goodwill and intangible assets is a non-recurring Level 3 fair value measurement.

2. Summary of Significant Accounting Policies (Continued)

Accounts Receivable and Allowance for Doubtful Accounts

The Company's receivables are recorded when billed and represent claims against third parties that will be settled in cash. The carrying value of the Company's receivables, net of the allowance for doubtful accounts, represents their estimated net realizable value. The Company estimates the allowance for doubtful accounts based on historical collection trends, age of outstanding receivables and existing economic conditions. If events or changes in circumstances indicate that a specific receivable balance may be impaired, further consideration is given to the collectability of those balances and the allowance is adjusted accordingly. A customer's receivable balance is considered past-due based on its contractual terms. Past-due receivable balances are written-off when the Company's internal collection efforts have been unsuccessful in collecting the amount due.

Inventories

Inventories are stated at the lower of cost or net realizable value and include the cost of material, labor and manufacturing overhead. Cost is determined on the first-in, first-out basis. The Company writes-down inventory to its estimated net realizable value when conditions indicate that the selling price could be less than cost due to physical deterioration, obsolescence, changes in price levels, or other causes, which it includes as a component of cost of revenues. Additionally, the Company provides valuation allowances for excess and slow-moving inventory on hand that are not expected to be sold to reduce the carrying amount of slow-moving inventory to its estimated net realizable value. The valuation allowances are based upon estimates about future demand from its customers and distributors and market conditions.

Because some of the Company's products are highly dependent on government and third-party funding, current customer use and validation, and completion of regulatory and field trials, there is a risk that the Company will forecast incorrectly and purchase or produce excess inventories. As a result, actual demand may differ from forecasts and the Company may be required to record additional inventory valuation allowances that could adversely impact its gross margins. Conversely, favorable changes in demand could result in higher gross margins when those products are sold.

Equipment and Leasehold Improvements

Equipment consisting of machinery and equipment, computers and software, office equipment and leasehold improvements is recorded at cost less accumulated depreciation. Repairs and maintenance costs are expensed as incurred. Depreciation for machinery and equipment, computers and software and office furniture is computed under the straight-line method over the estimated useful lives. Leasehold improvements are amortized under the straight-line method over their estimated useful lives or the remaining lease period, whichever is shorter. When equipment and leasehold improvements are sold or otherwise disposed of, the asset account and related accumulated depreciation account are relieved, and the impact of any resulting gain or loss is recognized within general and administrative expenses in the consolidated statement of operations for the period.

Warranty

We provide for the estimated cost of product warranties at the time revenue is recognized. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of our component suppliers, our warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from our estimates, revisions to the estimated warranty liability could have a material impact on our financial position, cash flows or results of operations.

2. Summary of Significant Accounting Policies (Continued)

Debt Discount and Issue Costs

The Company amortizes debt discount and debt issue costs over the life of the associated debt instrument, using the straight-line method which approximates the interest rate method.

Derivative Financial Instruments

In connection with the sale of convertible debt and equity instruments, the Company may also issue freestanding warrants. If freestanding warrants are issued and accounted for as derivative instrument liabilities (rather than as equity), the proceeds are first allocated to the fair value of those instruments. The remaining proceeds, if any, are then allocated to the convertible instrument, usually resulting in that instrument being recorded at a discount from its face amount. Derivative financial instruments are initially measured at their fair value using a Binomial Lattice Valuation Model and then re-valued at each reporting date, with changes in the fair value reported as charges or credits to income.

Stock-Based Compensation

We use the Black-Scholes-Merton option-pricing formula in determining the fair value of our options at the grant date and apply judgment in estimating the key assumptions that are critical to the model such as the expected term, volatility and forfeiture rate of an option. Our estimate of these key assumptions is based on historical information and judgment regarding market factors and trends. If any of the key assumptions change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period. The compensation expense is then amortized over the vesting period.

The Company has three stock-based compensation plans, which are described more fully in *Note 10*.

Valuation and Amortization Method – The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing formula. This fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. The formula does not include a discount for post-vesting restrictions, as we have not issued awards with such restrictions.

Expected Term – For options which the Company has limited available data, the expected term of the option is based on the simplified method. This simplified method averages an award's vesting term and its contractual term. For all other options, the Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and was determined based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior.

Expected Volatility – Expected volatility is based on historical volatility. Historical volatility is computed using daily pricing observations for recent periods that correspond to the expected term of the options.

Expected Dividend – The Company has not declared dividends and does not anticipate declaring any dividends in the foreseeable future. Therefore, the Company uses a zero value for the expected dividend value factor to determine the fair value of options granted.

2. Summary of Significant Accounting Policies (Continued)

Stock-Based Compensation (Continued)

Risk-Free Interest Rate – The Company bases the risk-free interest rate used in the valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with the same expected term.

Estimated Forfeitures – When estimating forfeitures, the Company considers voluntary and involuntary termination behavior as well as analysis of actual option forfeitures.

Research and Development

Research and development costs, consisting of salaries and benefits, costs of disposables, facility costs, contracted services and stock-based compensation from the engineering, regulatory and scientific affairs departments, that are useful in developing and clinically testing new products, services, processes or techniques, as well as expenses for activities that may significantly improve existing products or processes are expensed as incurred. Costs to acquire technologies that are utilized in research and development and that have no future benefit are expensed when incurred.

Acquired In-Process Research and Development

Acquired in-process research and development that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a determination as to the then useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated and begin amortization. The Company tests intangible assets for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than it's carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset with its' carrying value is performed. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Patent Costs

The costs incurred in connection with patent applications, in defending and maintaining intellectual property rights and litigation proceedings are expensed as incurred.

Credit Risk

Currently, the Company primarily manufactures and sells cellular processing systems and thermodynamic devices principally to the blood and cellular component processing industry and performs ongoing evaluations of the credit worthiness of the Company's customers. The Company believes that adequate provisions for uncollectible accounts have been made in the accompanying consolidated financial statements. To date, the Company has not experienced significant credit related losses.

2. Summary of Significant Accounting Policies (Continued)

Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker ("CODM"), or decision-making group, whose function is to allocate resources to and assess the performance of the operating segments. The Company has identified its Chief Executive Officer as the CODM. In determining its reportable segments, the Company considered the markets and the products or services provided to those markets.

The Company has two reportable business segments:

- The Device Segment, engages in the development and commercialization of automated technologies for cell-based therapeutics and bio-processing. The device division is operated through the Company's ThermoGenesis Corp. subsidiary.
- The Clinical Development Segment, is developing autologous (utilizing the patient's own cells) stem cell-based therapeutics that address significant unmet medical needs for applications within the vascular, cardiology and orthopedic markets.

Income Taxes

The tax years 1999-2018 remain open to examination by the major taxing jurisdictions to which the Company is subject; however, there is no current examination. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged to the Company in relation to the underpayment of income taxes. There were no unrecognized tax benefits during the periods presented.

The Company's estimates of income taxes and the significant items resulting in the recognition of deferred tax assets and liabilities reflect the Company's assessment of future tax consequences of transactions that have been reflected in the financial statements or tax returns for each taxing jurisdiction in which the Company operates. The Company bases the provision for income taxes on the Company's current period results of operations, changes in deferred income tax assets and liabilities, income tax rates, and changes in estimates of uncertain tax positions in the jurisdictions in which the Company operates. The Company recognizes deferred tax assets and liabilities when there are temporary differences between the financial reporting basis and tax basis of assets and liabilities and for the expected benefits of using net operating loss and tax credit loss carryforwards. The Company establishes valuation allowances when necessary to reduce the carrying amount of deferred income tax assets to the amounts that the Company believes are more likely than not to be realized. The Company evaluates the need to retain all or a portion of the valuation allowance on recorded deferred tax assets. When a change in the tax rate or tax law has an impact on deferred taxes, the differences are expected to reverse. As the Company operates in more than one state, changes in the state apportionment factors, based on operational results, may affect future effective tax rates and the value of recorded deferred tax assets and liabilities. The Company records a change in tax rates in the consolidated financial statements in the period of enactment.

2. Summary of Significant Accounting Policies (Continued)

Income Taxes (Continued)

Income tax consequences that arise in connection with a business combination include identifying the tax basis of assets and liabilities acquired and any contingencies associated with uncertain tax positions assumed or resulting from the business combination. Deferred tax assets and liabilities related to temporary differences of an acquired entity are recorded as of the date of the business combination and are based on the Company's estimate of the appropriate tax basis that will be accepted by the various taxing authorities and its determination as to whether any of the acquired deferred tax liabilities could be a source of taxable income to realize the Company's pre-existing deferred tax assets.

Net Loss per Share

Net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding plus the pre-funded warrants. For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the pre-funded warrants have been included since the shares are issuable for a negligible consideration and have no vesting or other contingencies associated with them. There were 324,445 pre-funded warrants included in the year ended December 31, 2019 calculation. The calculation of the basic and diluted earnings per share is the same for all periods presented, as the effect of the potential common stock equivalents noted below is anti-dilutive due to the Company's net loss position for all periods presented. Anti-dilutive securities consisted of the following at December 31:

	Year Ended December 31,		
	2019	2018	
Common stock equivalents of convertible promissory		_	
note and accrued interest	6,683,646	4,840,556	
Vested Series A warrants	40,441	40,441	
Unvested Series A warrants ⁽¹⁾	69,853	69,853	
Warrants – other	1,281,327	1,616,227	
Stock options	291,807	302,364	
Total	8,367,074	6,869,441	

The unvested Series A warrants were subject to vesting based upon the amount of funds actually received by the Company in the second close of the August 2015 financing which never occurred. The warrants will remain outstanding but unvested until they expire in February 2021.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation. The reclassifications did not have an impact on net loss as previously reported.

2. Summary of Significant Accounting Policies (Continued)

Recently Adopted Accounting Standards

On January 1, 2018, the Company adopted ASU No. 2014-09, "Revenue from Contracts with Customers ("Topic 606")" ("ASC606") and related updates. Using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for the reporting period beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under "Revenue Recognition" ("Topic 605"). The Company recorded a net increase to accumulated deficit of \$79,000 as of January 1, 2018 due to the cumulative impact of adopting ASC 606, with the impact related to service obligations requiring deferral. ASC 606 requires the Company to defer costs related to obligations on service contracts with limited performance obligations. Under previous guidance, these service obligations were amortized on a straight-line basis.

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-07, "Compensation-Stock Compensation ("Topic 718"): Improvements to Nonemployee Share-Based Payment Accounting", which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company adopted the standard on January 1, 2019. The adoption of this standard had an immaterial impact on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02 "Leases," which increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The Company adopted the standard on January 1, 2019.

The new standard requires lessees to recognize both the right-of-use assets and lease liabilities in the balance sheet for most leases, whereas under previous GAAP only finance lease liabilities (previously referred to as capital leases) were recognized in the balance sheet. In addition, the definition of a lease has been revised which may result in changes to the classification of an arrangement as a lease. Under the new standard, an arrangement that conveys the right to control the use of an identified asset by obtaining substantially all of its economic benefits and directing how it is used as a lease, whereas the previous definition focuses on the ability to control the use of the asset or to obtain its output. Quantitative and qualitative disclosures related to the amount, timing and judgements of an entity's accounting for leases and the related cash flows are expanded. Disclosure requirements apply to both lessees and lessors, whereas previous disclosures related only to lessees. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. Lessor accounting is also largely unchanged.

2. Summary of Significant Accounting Policies (Continued)

Recently Adopted Accounting Standards (Continued)

The new standard provides a number of transition practical expedients, which the Company has elected, including:

- A "package of three" expedients that must be taken together and allow entities to (1) not reassess whether existing contracts contain leases, (2) carryforward the existing lease classification, and (3) not reassess initial direct costs associated with existing leases, and
- An implementation expedient which allows the requirements of the standard in the period of adoption with no restatement of prior periods.

The impact of adoption did not have a material impact to the Company as of January 1, 2019 as the Company's finance leases are immaterial and its operating leases had remaining terms of less than one year. In January 2019, the Company signed an amendment to its lease for office space at its corporate headquarters in Rancho Cordova, CA. The amendment extended the lease term by five years and was accounted for as a modification. At that time, the Company recorded lease assets and liabilities of \$966,000 and no cumulative effect adjustment to retained earnings.

Recently Issued Accounting Standards

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12 "*Income Taxes* (*Topic 740*): *Simplifying the Accounting of Income Taxes*", which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement ("Topic 820"): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement." This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for all entities for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses ("Topic 326"). The ASU introduces a new accounting model, the Current Expected Credit Losses model ("CECL"), which requires earlier recognition of credit losses and additional disclosures related to credit risk. The CECL model utilizes a lifetime expected credit loss measurement objective for the recognition of credit losses at the time the financial asset is originated or acquired. ASU 2016-13 is effective for annual period beginning after December 15, 2022, including interim reporting periods within those annual reporting periods. We expect that the impact of adoption will not have a material impact.

3. <u>Intangible Assets and Goodwill</u>

U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2019 in the fiscal fourth quarter. In performing the assessment, the Company used current market capitalization, discounted future cash flows, internal forecasts and other factors as the best evidence of fair value. These assumptions represent Level 3 inputs. The assessment determined that the carrying amount for the Company's fair value of its intangible assets and goodwill exceeded its carrying value and no impairment loss existed for the year ended December 31, 2019. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if conditions exist that may represent an impairment.

During the year ended December 31, 2018, the Company experienced a significant and sustained decline in its stock price. The decline resulted in the Company's market capitalization falling significantly below the recorded value of its consolidated net assets. As a result, the Company performed a quantitative assessment as of June 30, 2018 and computed a fair value for its intangible assets and goodwill. The assessment determined that the carrying amount for the Company's goodwill exceeded the estimated fair value in 2018. Additionally, the Company's indefinite-lived intangible assets, relating to the clinical protocols was also determined to be impaired. Also, the Company has significantly reduced its operating activities in India and impaired the remaining goodwill and substantially all of the intangible assets including the remainder of the clinical protocols, associated with the acquisition of our Totipotent subsidiaries. As a result, the Company recorded an impairment loss in the year ended December 31, 2018.

	Intangible Assets	Goodwill
Balance at December 31, 2017, net	\$21,629,000	\$13,976,000
Amortization and foreign exchange	(152,000)	
Impairment loss	(19,886,000)	(13,195,000)
Balance at December 31, 2018, net	\$1,591,000	\$781,000
Amortization and foreign exchange	(124,000)	
Balance at December 31, 2019, net	\$1,467,000	\$781,000

3. Intangible Assets and Goodwill (Continued)

Intangible assets consist of the following based on the Company's determination of the fair value of identifiable assets acquired:

		As of	December 31, 2019		
	Weighted				
	Average				
	Amortization	Gross			
	Period	Carrying	Accumulated		
	(in Years)	Amount	Amortization	Impairment	Net
Trade names	3	\$53,000	\$45,000	\$	\$8,000
Developed technology	10	318,000	79,000		239,000
Licenses	7	437,000	367,000		70,000
Device registration	7	66,000	66,000		
Customer relationships	3	443,000	436,000		7,000
Amortizable intangible assets		1,317,000	993,000		324,000
In process technology		1,143,000			1,143,000
Clinical protocols					
Total		\$2,460,000	\$993,000	\$	\$1,467,000

	As of December 31, 2018				
	Weighted Average				
	Amortization	Gross			
	Period	Carrying	Accumulated		
	(in Years)	Amount	Amortization	Impairment	Net
Trade names	3	\$54,000	\$38,000		\$16,000
Developed technology	10	318,000	48,000		270,000
Licenses	7	448,000	307,000		141,000
Device registration	7	84,000	68,000	\$16,000	
Customer relationships	3	451,000	430,000		21,000
Amortizable intangible assets		1,355,000	891,000	16,000	448,000
In process technology		1,143,000			1,143,000
Clinical protocols		19,870,000		19,870,000	
Total		\$22,368,000	\$891,000	\$19,886,000	\$1,591,000

The change in the gross carrying amount is due to foreign currency exchange fluctuations and the write-off of assets for impairment. Amortization of intangible assets was \$124,000 for the year ended December 31, 2019 and \$131,000 for the year ended December 31, 2018. In process technology has not yet been introduced to the market place and is therefore not yet subject to amortization. Clinical protocols were not introduced to the market place and is therefore were not subject to amortization prior to being written off during the year ended December 31, 2018. The Company's estimated future amortization expense for amortizable intangible assets in subsequent years, are as follows:

Year Ended December 31,				
2020	109,000			
2021	40,000			
2022	32,000			
2023	32,000			
2024	32,000			
Thereafter	79,000_			
Total	\$324,000			

4. Equipment and Leasehold Improvements, Net

Equipment and leasehold improvements consisted of the following:

	Year Ended December 31,		
	2019	2018	Estimated Useful Life
Machinery and equipment	\$6,107,000	\$6,136,000	2.5-10 years
Computer and software	631,000	664,000	2-5 years
Office equipment	256,000	264,000	5-10 years
			Shorter of 5 years or
Leasehold improvements	932,000	931,000	remaining lease term
Total equipment	7,926,000	7,995,000	
Less accumulated depreciation	(5,898,000)	(5,433,000)	
Total equipment and leasehold			
improvements, net	\$2,028,000	\$2,562,000	

Depreciation expense for the years ended December 31, 2019 and 2018 were \$574,000 and \$539,000, respectively.

5. Related Party Transactions

Healthbanks Biotech (USA) Inc.

On November 26, 2019 the Company entered into a joint venture agreement with HealthBanks Biotech (USA) Inc. (the "JV Agreement") to form a new company called ImmuneCyte Life Sciences, Inc. ("ImmuneCyte") to commercialize the Company's proprietary cell processing platform, CAR-TXpressTM, for use in immune cell banking as well as for cell-based contract development and manufacturing services (CMO/CDMO). Under the terms of the JV Agreement, ImmuneCyte will initially be owned 80% by HealthBanks Biotech and 20% by ThermoGenesis. ImmuneCyte will be among the first immune cell banks in the U.S. and offer customers the ability to preserve younger, healthier and uncontaminated immune cells for future potential use in dendritic and chimeric antigen receptor ("CAR-T") cell therapies, in a GMP compliant processing environment. The Company's principal contribution to ImmuneCyte was a supply agreement under which ImmuneCyte will have the exclusive right to purchase the Company's proprietary cell processing equipment in the immune cell banking business and a non-exclusive right to purchase it for other cell-based contract development and manufacturing ("CMO/CDMO") services at a price equal to 115% of the Company's cost. The Company also contributed to ImmuneCyte intellectual property and trademarks relating to the Company's clinical development assets which were fully impaired by the Company in 2018 and had no book value. Healthbanks contributed to ImmuneCyte a paid-up, royalty free license to use its proprietary business management system, customer relationship management software, and laboratory information statement, and it will also make available a \$1,000,000 unsecured, nonconvertible line of credit to ImmuneCyte to provide initial operating capital. Healthbanks is a subsidiary of Boyalife Group, Inc. (USA), the owner of Boyalife Asset Holding II, Inc., which is the largest stockholder of the Company, and is owned by Dr. Xiaochun (Chris) Xu, the Company's Chief Executive Officer and Chairman of our Board of Directors.

5. Related Party Transactions (Continued)

Healthbanks Biotech (USA) Inc. (Continued)

In December 2019, ImmuneCyte closed a \$3,000,000 equity investment with a private institution. The investor received 600,000 shares of Class A common stock at \$5.00 per share, representing a 5.66% ownership in the joint venture. As a result of this equity investment in ImmuneCyte, the Company's equity in the joint venture is no longer subject to the anti-dilution provision. After this investment, ImmuneCyte is owned 75.47% by HealthBanks, 18.87% by ThermoGenesis Holdings and 5.66% by the private institution.

The Company initially determined that ImmuneCyte would be considered a variable interest entity, as a result of the significant influence the Company has over operations and its' lack of sufficient equity at inception. After the additional investment of \$3,000,000, ImmuneCyte's equity at risk was considered sufficient and the Company determined it would no longer be classified as a variable interest entity. The Company's investment in ImmuneCyte will be accounted for under the equity method based on management's conclusion that the Company can exercise significant influence over ImmuneCyte via its equity interest and the related Supply Agreement. The Company recorded the investment initially at the value of the nonfinancial assets contributed of \$28,000, which consisted of the book value of certain assets contributed at the time of formation.

For 2019, ImmuneCyte had no revenue or gross profit and net income was a loss of \$78,000. The Company's portion of that was 18.87% or \$15,000. On the Balance Sheet, ImmuneCyte had \$3,000,000 in current assets and \$8,000 in non-current assets, as well as \$14,000 in current liabilities and \$0 in non-current liabilities.

Convertible Promissory Note and Revolving Credit Agreement

In March 2017, ThermoGenesis Holdings entered into a Credit Agreement with Boyalife Investment Fund II, Inc., which later merged into Boyalife Asset Holding II, Inc. (the "Lender"). The Lender is a wholly owned subsidiary of Boyalife Group Inc., which is owned and controlled by the Company's Chief Executive Officer and Chairman of our Board of Directors. The Credit Agreement and its subsequent amendments, grants to the Company the right to borrow up to \$10,000,000 (the "Loan") at any time prior to March 6, 2022 (the "Maturity Date"). The Company has drawn down a total of \$8,713,000 and \$7,200,000 as of December 31, 2019 and 2018, respectively. The Company's ability to draw-down the remaining \$1,287,000 may be impacted by reasons such as default or foreign government policies that restrict or prohibit transferring funds. At the time of this filing, we are currently unable to draw down on the line of credit. This may change in the near future but there is no assurance that the line of credit will become available at such time when it is needed.

The Credit Agreement and the Convertible Promissory Note issued thereunder (the "Note") provide that the principal and all accrued and unpaid interest under the Loan will be due and payable on the Maturity Date, with payments of interest-only due on the last day of each calendar year. The Loan bears interest at 22% per annum, simple interest. The Company has five business days after the Lender demands payment to pay the interest due before the Loan is considered in default. Subsequent to December 31, 2019, the Lender has not demanded and the Company has not paid the interest due as of December 31, 2019. The Note can be prepaid in whole or in part by the Company at any time without penalty.

5. Related Party Transactions (Continued)

Convertible Promissory Note and Revolving Credit Agreement (Continued)

The Maturity Date of the Note is subject to acceleration at the option of the Lender upon customary events of default, which include; a breach of the Loan documents, termination of operations, or bankruptcy. The Lender's obligation to make advances under the Loan is subject to the Company's representations and warranties in the Credit Agreement continuing to be true at all times and there being no continuing event of default under the Note.

The Credit Agreement and Note were amended in April 2018. The amendment granted the Lender the right to convert, at any time, outstanding principal and accrued but unpaid interest into shares of Common Stock at a conversion price of \$16.10 per share and if the Company issues shares of Common Stock at a lower price per share, the conversion price of the Note is lowered to the reduced amount. The Company completed two transactions in 2018, lowering the conversion price to \$1.80.

It was concluded that the conversion option contained a beneficial conversion feature and as a result of the modifications to the conversion price, the Company recorded a debt discount in the amount of \$7,200,000 in 2018 and added \$1,513,000 to the debt discount as a result of the draw-down during the quarter ended March 31, 2019. Such discount represented the fair value of the incremental shares up to the proceeds received from the convertible notes. The Company amortized \$2,344,000 and \$1,174,000 of such debt discount to interest expense for the years ended December 31, 2019 and 2018, respectively. In addition to the amortization, the Company also recorded interest expense of \$1,869,000 and \$1,513,000 for the years ended December 31, 2019 and 2018, respectively.

Distributor Agreement

On August 21, 2017, ThermoGenesis Corp. entered into an International Distributor Agreement with Boyalife W.S.N. Under the terms of the agreement, Boyalife W.S.N. was granted the exclusive right, subject to existing distributors and customers (if any), to develop, sell to, and service a customer base for the ThermoGenesis Corp's AXP AutoXpress System and BioArchive System in the People's Republic of China (excluding Hong Kong and Taiwan), Singapore, Indonesia, and the Philippines (the "Territories"). Boyalife W.S.N. is related to our Chief Executive Officer and Chairman of our Board of Directors, and an affiliate of Boyalife (Hong Kong) Limited. Boyalife W.S.N,'s rights under the agreement include the exclusive right to distribute AXP Disposable Blood Processing Sets and use rights to the AXP AutoXpress System, BioArchive System and other accessories used for the processing of stem cells from cord blood in the Territories. Boyalife W.S.N. is also appointed as the exclusive service provider to provide repairs and preventative maintenance to ThermoGenesis Corp. products in the Territories.

The term of the agreement is for three years with ThermoGenesis Corp. having the right to renew the agreement for successive two-year periods at its option. However, ThermoGenesis Corp. has the right to terminate the agreement early if Boyalife W.S.N. fails to meet specified minimum purchase requirements.

Revenues

During the year ended December 31, 2019, the Company recorded \$794,000 of revenues from Boyalife W.S.N. and it's affiliates and had an accounts receivable balance of \$20,000 at December 31, 2019. For the year ended December 31, 2018, the Company recorded \$665,000 of revenues from Boyalife and had an accounts receivable balance of \$0 at December 31, 2018.

5. Related Party Transactions (Continued)

License Agreement

On March 12, 2018, ThermoGenesis Corp. entered into a License Agreement (the "Agreement") with IncoCell Tianjin Ltd., a Chinese company and wholly-owned subsidiary of China-based Boyalife Group ("IncoCell"). Boyalife Group is an affiliate of the Company's Chief Executive Officer and Chairman of our Board of Directors, and Boyalife (Hong Kong) Limited. Under the terms of the Agreement, IncoCell was granted the exclusive license to use the ThermoGenesis Corp. X-Series products in the conduct of IncoCell's contract manufacturing and development operations in the People's Republic of China, Japan, South Korea, Taiwan, Hong Kong, Macau, Singapore, Malaysia, Indonesia and India (the "Territories").

Pursuant to the terms of the Agreement, ThermoGenesis Corp. has granted IncoCell an exclusive license to purchase and use, at a discounted purchase price, X-Series cellular processing research devices, consumables, and kits for use in the conduct of contract manufacturing and development services in the Territories. In exchange, ThermoGenesis Corp. is entitled to a percentage of IncoCell's gross contract development revenues, including any potential upfront payments, future milestones or royalty payments, during the term of the Agreement. The term of the Agreement is ten years, provided that either party may terminate the Agreement earlier upon ninety (90) days' prior notice to the other party. For the years ended December 31, 2019 and 2018, the Company recorded \$83,000 and \$14,000 of revenues from IncoCell and had an accounts receivable balance of \$83,000 and \$14,000 at December 31, 2019 and 2018, respectively.

6. Convertible Promissory Note

On January 29, 2019, the Company agreed to issue and sell an unsecured note payable to an accredited investor (the "Accredited Investor") for an aggregate of \$800,000 face value (the "January 2019 Note") that, after six months, is convertible into shares of the Company's common stock at a conversion price equal to the lower of (a) \$1.80 per share or (2) 90% of the closing sale price of the Company's common stock on the date of conversion (subject to a floor conversion price of \$0.50).

The January 2019 Note bears interest at the rate of twenty-four percent (24%) per annum and is payable quarterly in arrears. Unless sooner converted in the manner described below, all principal under the January 2019 Note, together with all accrued and unpaid interest thereupon, will be due and payable eighteen (18) months from the date of the issuance of the January 2019 Note. The January 2019 Note may be prepaid without penalty at any time after it becomes convertible (at which time the holder will have the right to convert it before prepayment thereof).

On the date that is six months after the issuance of the January 2019 Note, and for so long thereafter as any principal and accrued but unpaid interest under the January 2019 Note remains outstanding, the holder of the January 2019 Note may convert such holder's January 2019 Note, in whole or in part, into a number of shares of the Company's common stock equal to (i) the principal amount being converted, together with any accrued or unpaid interest thereon, divided by (ii) the conversion price in effect at the time of conversion. The January 2019 Note has customary conversion blockers at 4.99% and 9.99% unless otherwise agreed to by the Company and the holder. It was concluded that the conversion option was beneficial. Accordingly, the Company recorded a debt discount in the amount of \$800,000, upon stockholder approval of the conversion feature, which occurred on May 30, 2019. The discount represented the fair value of the incremental shares up to the proceeds received from the convertible note.

6. Convertible Promissory Note (Continued)

The January 2019 Note contains customary events of default, including the suspension or failure of the Company's common stock to be traded on a trading platform, the Company's failure to pay interest or principal when due, or if the Company files for bankruptcy or takes some other similar action for the benefit of creditors. In the event of any default under the January 2019 Note, the holder may accelerate all outstanding interest and principal due on the January 2019 Note.

On July 23, 2019, the Company entered into Amendment No. 1 to the January 2019 Note ("Amended Note"). Under the terms of the amendment, the maturity date of the January 2019 Note was extended from July 29, 2020 to July 31, 2022. All other terms of the January 2019 Note remain the same. The Amended Note was accounted for as an extinguishment of the January 2019 Note as the change in the fair value of the embedded conversion option featured in the January 2019 Note immediately before and after the amendment exceeded 10% of the carrying amount of the January 2019 Note. Accordingly, the Company recorded a loss on the constructive extinguishment of this debt in the amount of \$840,000 for the year ended December 31, 2019. The fair value of the Amended Note, which amounted to \$1,473,000 was recorded as liability. The Company also evaluated the conversion option embedded in the Amended Note and determined it was beneficial. Accordingly, the Company recorded a debt discount in the amount of \$556,000 on the Amended Note for the year ended December 31, 2019. The Company amortized \$77,000 of the debt discount for the January 2019 Note to interest expense for the year ended December 31, 2019. The Company utilized a Monte Carlo simulation model to determine the fair value of the Amended Note. The key assumptions used in the simulation model were:

Stock price at date of issuance	\$3.05
Exercise price ⁽¹⁾	\$1.80
Risk-free interest rate	1.8%
Expected dividend yield	
Expected term (in years)	3.02
Expected volatility	93%

⁽¹⁾ For the exercise price, the model inputs also accounted for the fair value protection under the Amended Note, which allows for the holder to convert at the lower of \$1.80 share or 90% of the listed price of the stock on the day of conversion, whichever is lower (subject to a floor of \$0.50).

During the year ended December 31, 2019, the holder converted a portion of the face value of the note into shares of common stock. In total, \$432,000 was converted into 240,000 shares of common stock. Additionally, the unamortized premium for the portion of the note that was converted of \$60,000 was recorded to interest income during the year ended December 31, 2019.

On July 23, 2019, the Company entered into a private placement with the Accredited Investor, pursuant to which the Company issued and sold to such investor an unsecured convertible promissory note in the original principal amount of \$1,000,000 (the "July 2019 Note"). After six months and subject to the receipt of stockholder approval of the conversion feature of the July 2019 Note, such note is convertible into shares of the Company's common stock at a conversion price equal to the lower of (a) \$1.80 per share or (b) 90% of the closing sale price of the Company's common stock on the date of conversion (subject to a floor conversion price of \$0.50). The July 2019 Note bears interest at the rate of twenty-four percent (24%) per annum and is payable quarterly in arrears. Unless sooner converted in the manner described below, all principal under the July 2019 Note, together with all accrued and unpaid interest thereupon, will be due and payable three years from the date of the issuance on July 31, 2022.

6. Convertible Promissory Note (Continued)

However, if stockholder approval of the conversion feature of the July 2019 Note is not obtained at the Company's next annual meeting of stockholders (expected to be in the second quarter of 2020), the maturity date will accelerate to the date that is fourteen days after the next annual meeting.

The July 2019 Note may be prepaid without penalty at any time after it becomes convertible (at which time the holder will have the right to convert it before prepayment thereof). On the date that is six months after the issuance of the July 2019 Note and after receiving stockholder approval of the conversion feature described above, the holder may convert the July 2019 Note, in whole or in part, into a number of shares of the Company's common stock equal to (i) the principal amount being converted, together with any accrued or unpaid interest thereon, divided by (ii) the conversion price in effect at the time of conversion. The Company has accounted for the July 2019 Note as a debt instrument until such time the conversion feature is approved by the Company's stockholders. The Company will account for the conversion feature at the time of its effectiveness if approved.

On August 28, 2018, the Company completed a private placement transaction with an accredited investor, in which the Company sold 100,000 shares of Common Stock for a purchase price of \$1.80 per share and 296,500 pre-funded warrants for a purchase price of \$1.70 per pre-funded warrant. Each pre-funded warrant is immediately exercisable for one share of Common Stock at an exercise price of \$0.10 per share and will remain exercisable until exercised in full. The Company received \$684,000 in gross proceeds, net proceeds of \$623,000 after deducting offering expenses of \$61,000. As of December 31, 2019, all of the pre-funded warrants issued in the August 2018 private placement have been exercised. In addition, subject to certain exceptions, in the event the Company sold or issued any shares of Common Stock or common stock equivalents at a lower price through February 26, 2019, the Company was required to issue the investor a number of shares of Common Stock (or additional pre-funded warrants to purchase shares of common stock) equal to the number of shares the investor would have received had the purchase price for such shares been at such lower purchase price. The Company did not sell or issue any shares at a lower price prior to February 26, 2019. The Company evaluated the pre-funded warrants issued and determined that the warrants should be classified as equity instruments.

7. Derivative Obligations

Series A Warrants

Series A warrants to purchase 40,441 common shares were issued and vested during the year ended June 30, 2016. At the time of issuance, the Company determined that because such warrants can be settled for cash at the holders' option in a future fundamental transaction, they constituted a derivative liability. The Company has estimated the fair value of the derivative liability, using a Binomial Lattice Valuation Model and the following assumptions:

	Year Ended December 31,	
	2019	2018
Market price of common stock	\$4.40	\$2.70
Expected volatility	96%	94%
Contractual term (years)	1.2	2.2
Discount rate	1.59%	2.48%
Dividend rate	0%	0%
Exercise price	\$80.00	\$80.00

Expected volatilities are based on the historical volatility of the Company's common stock. Contractual term is based on remaining term of the respective warrants. The discount rate represents the yield on U.S. Treasury bonds with a maturity equal to the contractual term.

The Company recorded a gain (loss) of \$1,000 during the year ended December 31, 2019 and \$596,000 during the year ended December 31, 2018, representing the net change in the fair value of the derivative liability, which is presented as fair value change of derivative instruments, in the accompanying consolidated statements of operations and comprehensive loss.

The following table represents the Company's fair value hierarchy for its financial liabilities measured at fair value on a recurring basis as of December 31, 2019 and 2018:

	Year Ended December 31,		
Derivative Obligation	2019	2018	
Balance		\$1,000	
Level 1	\$-	\$-	
Level 2	\$-	\$-	
Level 3	\$	\$1,000	

The following table reflects the change in fair value of the Company's derivative liability:

	Amount
Balance – December 31, 2017	\$597,000
Change in fair value of derivative obligation	(596,000)
Balance – December 31, 2018	1,000
Change in fair value of derivative obligation	(1,000)
Balance – December 31, 2019	\$

8. <u>Commitments and Contingencies</u>

Financial Covenants

Effective May 15, 2017, the Company entered into a Sixth Amended and Restated Technology License and Escrow Agreement with CBR Systems, Inc. which modified the financial covenant that the Company must meet in order to avoid an event of default. The Company must maintain a cash balance and short-term investments net of debt or borrowed funds that are payable within one year of not less than \$2,000,000 (amended to \$1,000,000 in March 2020). The Company was in compliance with this financial covenant as of December 31, 2019.

Potential Severance Payments

The Company's Chief Executive Officer has rights upon termination under his employment agreement. With respect to his agreement at December 31, 2019, potential severance amounted to \$2.3 million.

Contingencies and Restricted Cash

In fiscal 2016, the Company signed an engagement letter with a strategic consulting firm ("Mavericks"). Included in the engagement letter was a success fee due upon the successful conclusion of certain transactions. On May 4, 2017, a lawsuit was filed in California Superior Court against the Company and its Chief Executive Officer by the consulting firm, which argued that it was owed a transaction fee of \$1,000,000 under the terms of the engagement letter due to the conversion of the Boyalife debentures in August 2016. In October 2017, to streamline the case by providing for the dismissal of claims against the Company's Chief Executive Officer based on alter ego theories and without acknowledging any liability, the Company deposited \$1,000,000 with the Court, which was recorded as restricted cash. The Company filed a Motion for Summary Judgment, which was denied by the Court on June 26, 2018. On September 24, 2018, Mavericks filed an amended complaint, adding back the Company's Chief Executive Officer as a named defendant, as well as Boyalife Investment, Inc. (a dissolved company) and Boyalife (Hong Kong) Limited under new theories of liability, namely intentional interference with contract and inducement of breach of contract. On July 22, 2019, Mavericks filed a Request for Dismissal requesting the Court to dismiss the served Boyalife entities and the Company's Chief Executive Officer as well as the intentional interference with performance of contract and inducing breach of contract causes of action from the lawsuit. As such, the only remaining claim at present is the original breach of contract claim against the Company. The trial completed in February 2020 with an adverse jury verdict in favor of Mavericks in the total amount of \$1,000,000. The Action is now in the post-trial phase and no judgment has been entered as the parties are disputing whether the defense of equitable estoppel should bar entry of judgment at all and the proper per-judgment interest start date. At present, the Court is already holding a \$1,000,000 cash bond deposited by the Company early in the litigation. After entry of judgment, the Court will permit release of those funds to the Mavericks. As a result, the Company recorded in other current liabilities a \$1,400,000 loss in general and administrative for the year ended December 31, 2019. The loss includes the \$1,000,000 transaction fee and an estimated \$400,000 in interest due. The \$1,000,000 deposited with the court will be used to settle the transaction fee.

In the normal course of operations, the Company may have disagreements or disputes with customers, employees or vendors. Such potential disputes are seen by management as a normal part of business. As of December 31, 2019, except as disclosed, management believes any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on the Company's consolidated financial position, operating results or cash flows.

8. <u>Commitments and Contingencies (Continued)</u>

Warranty

The Company offers a warranty on all its non-disposable products of one to two years. The Company warrants disposable products through their expiration date. The Company periodically assesses the adequacy of the warranty reserves and adjusts as necessary.

Changes in the Company's warranty reserve, which is included in other current liabilities in the accompanying consolidated balance sheet is as follows:

	Year Ended December 31,	
	2019	2018
Beginning balance	\$186,000	\$291,000
Warranties originated during the year	254,000	199,000
Claims settled made during the year	(154,000)	(252,000)
Changes in reserve estimate	(9,000)	(52,000)
Ending balance	\$277,000	\$186,000

Coronavirus (COVID-19)

In December 2019, a novel strain of coronavirus was reported in Wuhan, China. The World Health Organization has declared the outbreak to constitute a "Public Health Emergency of International Concern." The COVID-19 outbreak is disrupting supply chains and affecting production and sales across a range of industries. The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on our customers, employees and vendors all of which are uncertain and cannot be predicted. At this point, the extent to which COVID-19 may impact our financial condition or results of operations is uncertain.

9. Leases

Operating Leases

The Company leases the Rancho Cordova, California and Gurgaon, India facilities pursuant to operating leases. The Rancho Cordova lease expires in May 2024. The Gurgaon lease expires in September 2023; however, either party can terminate after September 2019 with three months' notice. As such it was accounted for as a short-term lease.

Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of remaining minimum lease payments. Operating lease assets represent our right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, we use the Company's cost of capital based on existing debt instruments. Our material leases typically contain rent escalations over the lease term. We recognize expense for these leases on a straight-line basis over the lease term.

9. <u>Leases (Continued)</u>

Operating Leases (Continued)

The following summarizes the Company's operating leases:

	December 31,
	2019
Right-of-use operating lease assets, net	\$859,000
Current lease liability	118,000
Non-current lease liability	761,000
Weighted average remaining lease term	4.4
Discount rate	22%

Maturities of lease liabilities by calendar year for our operating leases are as follows:

2020	301,000
2021	310,000
2022	319,000
2023	328,000
2024	139,000
Thereafter	
Total lease payment	\$1,397,000
Less: imputed interest	(538,000)
Present value of operating lease liabilities	\$859,000

Statement of Cash Flows

In January 2019, the Company signed an amendment to its lease for office space at its corporate headquarters in Rancho Cordova, CA. The amendment was accounted for as a modification and resulted in a right-of-use asset of \$966,000 being recognized as a non-cash addition on the date of the amendment. Cash paid for amounts included in the measurement of operating lease liabilities in cash flows from operating activities were \$291,000 for the years ended December 31, 2019.

Operating Lease Costs

Operating lease costs were \$410,000 during the year ended December 31, 2019, which included \$204,000 for interest expense, \$108,000 in amortization expense, \$72,000 in variable lease costs and \$26,000 for short term lease costs. These costs are primarily related to long-term operating leases, but also include immaterial amounts for variable lease costs and short-term leases with terms greater than 30 days.

Finance Leases

Finance leases are included in equipment and other current and non-current liabilities in the accompanying condensed consolidated balance sheet. The amortization and interest expense are included in general and administrative expense and interest expense, respectively in the accompanying statements of operations. These leases are not material as of December 31, 2019.

10. Stockholders' Equity

Common Stock

On December 13, 2019, the Company entered into an At The Market Offering Agreement, by and between the Company and H.C. Wainwright & Co., LLC, as agent ("H.C. Wainwright") (the "ATM Agreement"), pursuant to which the Company may offer and sell, from time to time through H.C. Wainwright, shares of Common Stock, having an aggregate offering price of up to \$4.4 million (the "HCW Shares"). The offer and sale of the HCW Shares is made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-235509). Pursuant to the ATM Agreement, H.C. Wainwright may sell the HCW Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers' transactions, including on The NASDAQ Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. H.C. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the HCW Shares from time to time, based upon instructions from the Company, including any price or size limits or other customary parameters or conditions the Company may impose. The Company is not obligated to make any sales of the HCW Shares under the ATM Agreement. The offering of HCW Shares pursuant to the ATM Agreement will terminate upon the earliest of (a) the sale of all of the HCW Shares subject to the ATM Agreement, (b) the termination of the ATM Agreement by H.C. Wainwright or the Company, as permitted therein, or (c) August 9, 2022. The Company will pay H.C. Wainwright a commission rate equal to 3% of the aggregate gross proceeds from each sale of HCW Shares and have agreed to provide H.C. Wainwright with customary indemnification and contribution rights. The Company will also reimburse H.C. Wainwright for certain specified expenses in connection with entering into the ATM Agreement. Subsequent to December 31, 2019, the Company has sold a total of 50,746 shares of Common Stock for aggregate gross proceeds of \$280,000 at an average selling price of \$5.44 per share, resulting in net proceeds of approximately \$113,000 after deducting legal expenses, audit fees, commissions and other transaction costs of approximately \$167,000.

On April 18, 2019, the Company entered into a Securities Purchase Agreement with an accredited investor pursuant to which the Company agreed to issue and sell to such investor (the "April Offering") 444,445 pre-funded warrants to purchase shares of Common Stock for a purchase price of \$1.70 per pre-funded warrant. Each pre-funded warrant is immediately exercisable for one share of Common Stock at an exercise price of \$0.10 per share and will remain exercisable until exercised in full. The gross proceeds to the Company, excluding the proceeds, if any, from the exercise of the pre-funded warrants, was approximately \$756,000. The April Offering closed on April 26, 2019 and the pre-funded warrants were accounted for as equity by the Company. Subject to certain exceptions, in the event the Company sells or issues any shares of common stock or common stock equivalents at a lower price during the period beginning on the closing date of the April Offering and ending on the date that is three-hundred and sixty-five (365) days following such date, the Company is required to issue the investor a number of shares of common stock (or additional pre-funded warrants to purchase shares of common stock) equal to the number of shares the investor would have received had the purchase price for such shares been at such lower purchase price. As December 31, 2019, 120,000 of the pre-funded warrants issued in the April Offering had been exercised, leaving 324,445 pre-funded warrants outstanding.

10. Stockholders' Equity (Continued)

Common Stock (Continued)

On August 28, 2018, the Company completed a private placement transaction with an accredited investor, in which the Company sold 100,000 shares of Common Stock for a purchase price of \$1.80 per share and 296,500 pre-funded warrants for a purchase price of \$1.70 per pre-funded warrant. Each pre-funded warrant is immediately exercisable for one share of Common Stock at an exercise price of \$0.10 per share and will remain exercisable until exercised in full. The Company received \$623,000 in net proceeds after deducting offering expenses of \$61,000. In addition, subject to certain exceptions, in the event the Company sells or issues any shares of Common Stock or common stock equivalents at a lower price through February 26, 2019, the Company is required to issue the investor a number of shares of Common Stock (or additional pre-funded warrants to purchase shares of common stock) equal to the number of shares the investor would have received had the purchase price for such shares been at such lower purchase price. The Company did not issue any shares at a lower price prior to February 26, 2019. The Company determined that the pre-warrants should be classified as equity instruments. As of December 31, 2019, all 296,500 of the pre-funded warrants issued in the August 2018 private placement have been exercised.

On May 18, 2018, the Company completed a public offering for 647,501 Units and 269,167 Pre-Funded Units for a purchase price of \$6.00 per Unit, resulting in aggregate gross proceeds of approximately \$5,473,000, net proceeds of \$4,792,000 after deducting the offering expenses of \$679,000. Each Unit consists of one share of Common Stock, and one common warrant to purchase one share of Common Stock, and each Pre-Funded Unit consists of one pre-funded warrant to purchase one share of Common Stock and one common warrant to purchase one share of Common Stock. The common warrants included in the Units and Pre-Funded Units were immediately exercisable at a price of \$6.00 per share of Common Stock, subject to adjustment in certain circumstances, and will expire five years from the date of issuance. The Company evaluated the warrants issued and determined that they should be classified as equity instruments. All 269,167 Pre-Funded units issued in the May 2018 public offering were exercised in the second quarter of fiscal 2018.

On March 28, 2018, the Company sold 60,964 shares of Common Stock at a price of \$22.70 per share. The net proceeds to the Company from the sale and issuance of the shares, after deducting the offering expenses borne by the Company of approximately \$171,000, were \$1,213,000. Additionally, the investors received unregistered warrants in a simultaneous private placement to purchase up to 30,482 shares of common stock. The warrants have an exercise price of \$26.80 per share and were exercisable six months following the issuance date, or September 28, 2018, and have a term of 5.5 years and were accounted for as equity by the Company.

10. Stockholders' Equity (Continued)

Warrants

A summary of warrant activity is as follows:

	Year Ended December 31,			
	2019		2018	
	Number of	Weighted- Average Exercise	Number of	Weighted- Average Exercise
	Shares	Price Per Share	Shares	Price Per Share
Beginning balance	1,726,522	\$29.88	482,873	\$93.70
Warrants granted	444,445	\$0.10	1,512,816	\$4.20
Warrants exercised	(435,264)	\$0.35	(269,167)	\$0.10
Warrants expired/canceled	(19,637)			
Outstanding	1,716,066	\$25.23	1,726,522	\$29.88
Exercisable	1,646,214	\$22.91	1,656,668	\$27.80

Equity Plans and Agreements

The Amended 2016 Equity Incentive Plan (the "Amended 2016 Plan") was approved by the stockholders in May 2017, under which up to 600,000 shares may be issued pursuant to grants of shares, options, or other forms of incentive compensation. On June 22, 2018, the stockholders approved an amendment to the Amended 2016 Plan to increase the number of shares that may be issued to 1,325,000 shares. On May 30, 2019, the shareholders approved an amendment to the Amended 2016 Plan to increase the number of shares that may be issued from 1,325,000 shares to 3,925,000 shares. As of December 31, 2019, 103,803 awards were available for issuance under the Amended 2016 Plan.

The 2012 Independent Director Plan (the "2012 Plan") permits the grant of stock or options to independent directors. A total of 2,500 shares were approved by the stockholders for issuance under the 2012 Plan. Options are granted at prices that are equal to 100% of the fair market value on the date of grant and expire over a term not to exceed ten years. Options generally vest in monthly increments over one year, unless otherwise determined by our Board of Directors. As of December 31, 2019, there were 234 shares available for issuance.

The 2006 Equity Incentive Plan (the "2006 Plan") permitted the grant of options, restricted stock units, stock bonuses and stock appreciation rights to employees, directors and consultants. The 2006 Plan, but not the awards granted thereunder, expired in 2016. As of December 31, 2019, 3,865 option awards remained outstanding.

On December 29, 2017, the Board of Directors of ThermoGenesis Corp. adopted the ThermoGenesis Corp. 2017 Equity Incentive Plan (the "ThermoGenesis Plan") and on the same day granted options to purchase an aggregate of 280,000 shares of ThermoGenesis Corp. common stock to employees, directors, consultants, and advisors of ThermoGenesis Corp. The ThermoGenesis Plan was unanimously approved by the ThermoGenesis stockholders (including the Company) on December 29, 2017. The ThermoGenesis Plan authorizes the issuance of up to 1,000,000 shares of ThermoGenesis common stock. There are 20,000 shares available for issuance as of December 31, 2019.

10. Stockholders' Equity (Continued)

Equity Plans and Agreements (Continued)

On April 7, 2019, two employees were granted performance-based options to purchase an aggregate of 800,000 shares of Thermo Genesis Corp. common stock at an exercise price of \$0.65 if certain milestones were met. One milestone was met resulting in 300,000 options vesting in the year ended December 31, 2019.

On December 14, 2018, the CEO, the CFO and other employees were granted 214,000 options to purchase shares of the Company's common stock at an exercise price of \$2.979 per share. The options vest in five equal installments on the date of grant and the first four anniversaries of the grant date. A portion of the grant, 169,934 shares were subject to approval of the 2016 Plan Amendment by the Company's stockholders, which was approved on May 30, 2019.

Stock Based Compensation

The Company recorded stock-based compensation of \$614,000 for the year ended December 31, 2019 and \$652,000 for the year ended December 31, 2018, as comprised of the following:

Year Ended December	31,
---------------------	-----

	2019	2018
Cost of revenues	\$3,000	\$15,000
Sales and marketing	185,000	63,000
Research and development	98,000	136,000
General and administrative	328,000	438,000
_	\$614,000	\$652,000

Stock Options

The Company issues new shares of common stock upon exercise of stock options. The following is a summary of option activity for the Company's stock option plans:

Outstanding at January 1, 2019	Number of Shares 302,368	Weighted-Average Exercise Price \$13.99	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Granted Forfeited/cancelled Outstanding at December 31, 2019	11,450 (22,011) 291,807	\$4.38 \$9.42 \$13.96	8.3	\$280,000
Vested and Expected to Vest at December 31, 2019 Exercisable at December 31, 2019	224,102 147,124	\$15.72 \$19.79	8.2 7.9	\$203,000 \$115,000

10. Stockholders' Equity (Continued)

Stock Options (Continued)

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock. There were no options that were exercised during the years ended December 31, 2019 and 2018.

Non-vested stock option activity for the year ended December 31, 2019, is as follows:

	Non-vested Stock	Weighted-Average
	Options	Grant Date Fair Value
Outstanding at January 1, 2019	212,172	\$6.39
Granted	11,450	\$3.30
Vested	(63,675)	\$6.73
Cancelled/forfeited	(15,264)	\$2.74
Outstanding at December 31, 2019	144,683	\$6.38

The fair value of the Company's stock options granted for the year ended December 31, 2019 and year ended December 31, 2018 was estimated using the following weighted-average assumptions:

	Year Ended December 31,	
	2019 2018	
Expected life (years)	5	6
Risk-free interest rate	1.68%	2.7%
Expected volatility	103%	103%
Dividend yield	0%	0%

The weighted average grant date fair value of options granted during the years ended December 31, 2019 and 2018 was \$3.30 and \$3.20 respectively.

At December 31, 2019, the total compensation cost related to options granted under the Company's stock option plans but not yet recognized was \$1,051,000. This cost will be amortized on a straight-line basis over a weighted-average period of approximately three years and will be adjusted for subsequent changes in estimated forfeitures. The total fair value of options vested during the year ended December 31, 2019 and year ended December 31, 2018 was \$428,000 and \$633,000 respectively.

11. Concentrations

One customer had an accounts receivable balance of \$337,000 or 26% and \$494,000 or 33% at December 31, 2019 and 2018, respectively. Revenues from that customer totaled \$3,575,000 or 28% and \$2,120,000 or 22% for the years ended December 31, 2019 and 2018, respectively. One distributor had an accounts receivable balance of \$177,000 or 14% and \$229,000 or 15% at December 31, 2019 and 2018, respectively. Revenues from that distributor totaled \$1,470,000 or 11% and \$861,000 or 9% for the years ended December 31, 2019 and 2018, respectively. A second distributor had an accounts receivable balance of \$170,000 or 13% and \$220,000 or 15% at December 31, 2019 and 2018, respectively.

Two suppliers accounted for 57% and 18% of total inventory purchases during the year ended December 31, 2019. Two suppliers accounted for 43% and 14% of total inventory purchases during the year ended December 31, 2018.

The Company has a contract manufacturer in Costa Rica that produces certain disposables. The Company's equipment and leasehold improvements, net of accumulated depreciation, is summarized below by geographic area:

	Year Ended December 31,	
	2019	2018
United States	\$1,108,000	\$1,614,000
Costa Rica	582,000	601,000
India	225,000	211,000
All other countries	113,000	136,000
Total equipment, net	\$2,028,000	\$2,562,000

12. Segment Reporting

Depreciation and amortization

Goodwill

Total assets

Stock-based compensation expense

The Company has two reportable segments, which are the same as its operating segments:

The Device Segment, engages in the development and commercialization of automated technologies for cell-based therapeutics and bio-processing. The device division is operated through the Company's ThermoGenesis Corp. subsidiary.

The Clinical Development Segment, utilizes autologous (utilizing the patient's own cells) stem cell-based therapeutics through the Company's TotipotentRX subsidiary in Gurgaon, India.

The following table summarizes the operating results of the Company's reportable segments:

	Year Ended December 31, 2019		
		Clinical	_
	Device	Development	Total
Net revenues	\$12,957,000	\$90,000	\$13,047,000
Cost of revenues	7,175,000	176,000	7,351,000
Gross profit	5,782,000	(86,000)	5,696,000
Operating expenses	7,081,000	3,348,000	10,429,000
Operating loss	\$(1,299,000)	\$(3,434,000)	\$(4,733,000)
Depreciation and amortization	\$530,000	\$275,000	\$805,000
Stock-based compensation expense	\$393,000	\$221,000	\$614,000
Goodwill	\$781,000	\$	\$781,000
Total assets	\$13,420,000	\$1,794,000	\$15,214,000
	Year Er	nded December 31, 2018	}
-		Clinical	
	Device	Development	Total
Net revenues	\$9,469,000	\$203,000	\$9,672,000
Cost of revenues	7,205,000	274,000	7,479,000
Gross profit	2,264,000	(71,000)	2,193,000
Operating expenses	8,398,000	37,340,000	45,738,000
Operating loss	\$(6,134,000)	\$(37,411,000)	\$(43,545,000)

\$398,000

\$179,000

\$781,000

\$10,815,000

\$670,000

\$652,000

\$781,000

\$14,611,000

\$272,000

\$473,000

\$3,796,000

12. Segment Reporting (Continued)

The Company had sales in the following geographical areas for the:

	Year Ended Dece	Year Ended December 31,	
	2019	2018	
United States	\$6,787,000	\$4,854,000	
Asia – other	2,108,000	1,717,000	
Europe	1,233,000	1,165,000	
China	2,346,000	1,143,000	
Other	573,000	793,000	
	\$13,047,000	\$9,672,000	

The Company attributes revenue to different geographic areas based on where items are shipped, or services are performed.

13. <u>Income Taxes</u>

Loss before income tax benefits was comprised of \$9,934,000 from US and \$150,000 from foreign jurisdictions for the year ended December 31, 2019 and \$45,458,000 from US and \$212,000 from foreign jurisdictions for the year ended December 31, 2018.

The reconciliation of federal income tax attributable to operations computed at the federal statutory tax rate to income tax benefit is as follows for the:

Year Ended December 31,	
2019	2018
\$(2,118,000)	\$(9,591,000)
673,000	3,119,000
(681,000)	(2,084,000)
1,187,000	1,271,000
1,119,000	240,000
(205,000)	2,344,000
25,000	(29,000)
\$	\$(4,730,000)
	2019 \$(2,118,000) 673,000 (681,000) 1,187,000 1,119,000 (205,000) 25,000

For the year ended December 31, 2019, the Company had no tax expense compared to \$4,730,000 of tax benefit for the year ended December 31, 2018. The income tax expense in 2019 is due to state minimum taxes. The income tax benefit for the year ended December 31, 2018 was due to the impairment of the indefinite lived intangible assets for the clinical protocols and goodwill. The Company's deferred tax liability is tied to the intangible assets and goodwill.

13. <u>Income Taxes (Continued)</u>

At December 31, 2019, we had federal net operating loss carryforwards of approximately \$121,195,000 to offset future federal taxable income, with \$109,293,000 available through 2037 and \$11,902,000 available indefinitely. We also had state net operating loss carryforwards of approximately \$43,870,000 that may offset future state taxable income through 2039. We also had foreign net operating loss carryforwards of approximately \$2,495,000 that may offset future foreign taxable income through 2027.

At December 31, 2019, the Company has research and experimentation credit carryforwards of \$1,591,000 for federal tax purposes that expire in various years between 2020 and 2039, and \$1,476,000 for state income tax purposes that do not have an expiration date.

Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes are as follows:

	Year Ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	\$26,758,000	\$27,312,000
Income tax credit carryforwards	2,757,000	2,769,000
Stock compensation	384,000	850,000
Lease Obligation	185,000	
Deferred Revenue	419,000	
Other	943,000	1,027,000
Total deferred tax assets	31,446,000	31,958,000
Deferred tax liabilities		
Indefinite lived intangible assets		
Depreciation and amortization	(408,000)	(419,000)
Lease asset	(180,000)	
Total deferred tax liabilities	(588,000)	(419,000)
Valuation allowance	(30,858,000)	(31,539,000)
Net deferred taxes	\$	\$

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

The valuation allowance decreased by \$681,000 and \$2,266,000 during the years ended December 31, 2019 and 2018, respectively.

13. Income Taxes (Continued)

The transition tax is based on total post-1986 earnings and profits which were previously deferred from U.S. income taxes. At December 31, 2019, the Company did not have any undistributed earnings of our foreign subsidiaries. As a result, no additional income or withholding taxes have been provided for. The Company does not anticipate any impacts of the global intangible low taxed income ("GILTI") and base erosion anti-abuse tax ("BEAT") and as such, the Company has not recorded any impact associated with either GILTI or BEAT.

In August 2016, the conversion of the Boyalife debentures effected an "ownership change" as defined under the provisions of the Tax Reform Act of 1986. As a result, any net operating loss and credit carryovers existing at that date will be subject to an annual limitation regarding their utilization against taxable income in future periods. Additionally, before the conversion of the debentures, it is possible that "ownership changes" occurred, which could create additional limitations on the use of our net operating losses and credit carryovers. Additionally, ownership changes may have occurred in the periods after 2016 which could limit our utilization of losses and credits generated in the years 2016 – 2019.

14. Employee Retirement Plan

The Company sponsors an Employee Retirement Plan, generally available to all employees, in accordance with Section 401(k) of the Internal Revenue Code. Employees may elect to contribute up to the Internal Revenue Service annual contribution limit. Under this Plan, at the discretion of the Company's Board of Directors, the Company may match a portion of the employees' contributions. The Company made no discretionary or matching contributions to the Plan for the year ended December 31, 2019 and year ended December 31, 2018.

15. Subsequent Events

The Company has evaluated events subsequent to the balance sheet date for inclusion in the accompanying consolidated financial statements through the date of issuance and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosures in the notes thereto other than as disclosed below.

On February 13, 2020, the Company received a conversion notice from Boyalife to convert a total of \$3,000,000 of the outstanding balance of the Second Amended and Restated Convertible Promissory Note (the "Note") issued by the Company to Boyalife on April 16, 2018. The amount converted represents the unpaid accrued interest as of December 31, 2019 of \$1,869,000 and \$1,131,000 of the outstanding principal balance. The conversion resulted in the issuance of 1,666,670 shares of the Company's common stock at a conversion price of \$1.80 per share. Immediately after the conversion, the new outstanding principal balance of the Note was \$7,582,000.

On March 17, 2020, the Company's wholly owned subsidiary ThermoGenesis Corp. entered into a Manufacturing and Supply Amending Agreement #1 with CBR with an effective date of March 16, 2020 (the "Amendment"). The Amendment amends the Manufacturing and Supply Agreement entered into on May 15, 2017 by the Company and CBR (the "Original Agreement"). The Amendment, among other things, amends the Original Agreement by lowering the default threshold under which CBR may, upon a default by the Company, purchase licensed products directly from the Company's manufacturers and suppliers from \$2,000,000 to \$1,000,000 for a cash balance coupled with short-term investments net of debt or borrowed funds that are payable within one year at any month end unless the Company cures such default within thirty (30) days of the end of such month.

ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.</u>

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined by Exchange Act Rule 13a-15(e) and 15d-15(e)) as of the end of our last fiscal quarter pursuant to Exchange Act Rule 13a-15. The term "disclosure controls and procedures" means controls and other procedures designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of its internal control over financial reporting as of December 31, 2019 based on criteria established in the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Attestation Report of Independent Registered Public Accounting Firm

We are a "non-accelerated filer" as defined by Rule 12b-2 of the Exchange Act, and as such, we are not required to provide an attestation report on the Company's internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2019.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2019.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2019.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2019.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2019.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as a part of this Annual Report on Form 10-K.

		Page Number
(a)	(1) Financial Statements	
	Report of Independent Registered Public Accounting Firm	34
	Consolidated Balance Sheets at December 31, 2019 and 2018	35
	Consolidated Statements of Operations and Comprehensive Loss for the Year Ended December 31, 2019 and Year Ended December 31, 2018	
	Consolidated Statements of Equity for the Year Ended December 31, 2019 and Year Ended December 31, 2018	37
	Consolidated Statements of Cash Flows for the Year Ended December 31, 2019 and Ended December 31, 2018	
	Notes to Consolidated Financial Statements	39
	nagement's Report on Internal Control over Financial Reporting is contained as part port under Item 9A "Controls and Procedures."	of this Annual
(a)	(2) Financial Statement Schedules	
	Financial statement schedules have been omitted because they are not required.	
(b)	Exhibits	
	Exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index which are incorporated herein by this reference.	on the next page,
ITI	EM 16. FORM 10-K SUMMARY	
Noi	ne.	

EXHIBIT INDEX

Exhibit		
No.	Document Description	Incorporation by Reference
3.1	Sixth Amended and Restated Certificate of Incorporation of ThermoGenesis Holdings, Inc., as amended.	Incorporated by reference to Exhibit 3.1 to Form S-8 filed with the SEC on September 12, 2019
3.2	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation of ThermoGenesis Holdings, Inc.	Incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on June 4, 2019.
3.3	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation of ThermoGenesis Holdings, Inc.	Incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on October 31, 2019.
3.4	Amended and Restated Bylaws of ThermoGenesis Holdings, Inc.	Incorporated by reference to Exhibit 3.2 to Form 8-K filed with the SEC on October 30, 2019.
4.1	Form of Pre-Funded Common Stock Purchase Warrant.	Incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on April 25, 2019.
4.2	Form of Convertible Promissory Note	Incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on January 31, 2019.
4.3	Investors' Rights Agreement, dated January 1, 2019, among CARTXpress Bio, Inc., Bay City Capital Fund V, L.P., and Bay City Capital Fund V Co-Investment Fund, L.P.	Incorporated by referenced to Exhibit 10.3 to Form 8-K filed with the SEC on January 4, 2019
4.4	Form of Convertible Promissory Note.	Incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on July 29, 2019.
4.5	Form of Convertible Promissory Note, dated as of July 23, 2019, between ThermoGenesis Holdings, Inc. and Orbrex USA Co.	Incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on July 29, 2019.
4.6	Form of Indenture, dated December 13, 2019, between ThermoGenesis Holdings, Inc. and the Purchaser identified on the signature page thereto.	Incorporated by reference to Exhibit 4.5 to the Form S-3 filed with the SEC on December 13, 2019.
4.7	Form of Pre-Funded Warrant, dated as of April 26, 2019, between ThermoGenesis Holdings, Inc. and Yuan Lan Fang.	Incorporated by reference to Exhibit 4.1 to Form 8-K/A filed with the SEC on September 24, 2019.
4.8	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934, as amended.	Filed herewith.
10.1	Reorganization and Share Exchange Agreement, dated January 1, 2019, among ThermoGenesis Corp., ThermoGenesis Holdings, Inc., CARTXpress Bio, Inc., Bay City Capital Fund V. L.P. and Bay City Capital Fund V. Co-Investment Fund, L.P.	Incorporated by referenced to Exhibit 10.1 to Form 8-K filed with the SEC on January 4, 2019
10.2	Voting Agreement, dated January 1, 2019, among CARTXpress Bio, Inc., ThermoGenesis Corp., Bay City Capital Fund V, L.P., and Bay City Capital Fund V Co-Investment Fund, L.P.	Incorporated by referenced to Exhibit 10.2 to Form 8-K filed with the SEC on January 4, 2019
10.3	Right of First Refusal and Co-Sale Agreement, dated January 1, 2019, among CARTXpress	Incorporated by referenced to Exhibit 10.4 to Form 8-K filed with the SEC on January 4, 2019

	Bio, Inc., ThermoGenesis Corp., Bay City		
	Capital Fund V, L.P., and Bay City Capital		
	Fund V Co-Investment Fund, L.P.		
10.4	Investors' Rights Agreement, dated January 1,	Incorporated by reference to Exhibit 10.3 to Form 8-	
	2019, between CARTXpress Bio, Inc., Bay	K filed with the SEC on January 4, 2019.	
	City Capital Fund V, L.P. and Bay City Capital	•	
	Fund V Co-Investment Fund, L.P.		
10.5	Amended and Restated Certificate of	Incorporated by reference to Exhibit 10.5 to Form 8-	
	Incorporation of CARTXpress Bio, Inc.	K filed with the SEC on January 4, 2019	
10.6	Securities Purchase Agreement, dated January	Incorporated by reference to Exhibit 10.1 to Form 8-	
	29, 2019, between ThermoGenesis Holdings,	K filed with the SEC on January 31, 2019.	
	Inc. and the Purchaser identified on the		
	signature pages thereto.		
10.7	Securities Purchase Agreement, dated April 18,	Incorporated by reference to Exhibit 10.1 to Form 8-	
	2019, between ThermoGenesis Holdings, Inc.	K filed with the SEC on April 25, 2019.	
	and the Purchaser identified on the signature		
	pages thereto.		
10.8	Third Amendment to ThermoGenesis Holdings,	Incorporated by reference to Exhibit 10.1 to Form 8-	
	Inc. Amended 2016 Equity Incentive Plan	K filed with the SEC on June 4, 2019	
	Dated December 14, 2018.		
10.0		Leading and a disconnected by mafaging as to Euclided 10.1 to Earns 0	
10.9	Amendment No. 1 dated July 23, 2019, to the	Incorporated by reference to Exhibit 10.1 to Form 8-	
	Convertible Note, dated July 29, 2019, between	K filed with the SEC on July 29, 2019	
	ThermoGenesis Holdings, Inc. and Orbrex USA Co. Limited		
10.10	Securities Purchase Agreement, dated July 23,	Incorporated by reference to Exhibit 10.1 to Form 8-	
10.10	2019, between ThermoGenesis Holdings, Inc.	K filed with the SEC on July 29, 2019	
	and the Purchaser identified on the signature	it filed with the BEE on July 25, 2015	
	page thereto.		
10.11	Securities Purchase Agreement dated as of July	Incorporated by reference to Exhibit 10.1 to Form 8-	
10.11	23, 2019, between ThermoGenesis Holdings,	K filed with the SEC on July 29, 2019.	
	Inc, and the Purchaser identified on the	it filed with the BEE on July 25, 2015.	
	signature pages thereto.		
10.12	Supply Agreement, dated as of August 30,	Incorporated by reference to Exhibit 10.1 to Form 8-	
10.12	2019, between Corning Incorporated and	K filed with the SEC on September 6, 2019.	
	ThermoGenesis Holdings, Inc.	K med with the SEC on September 0, 2019.	
10.13	Supply Agreement, dated November 22, 2019	Incorporated by reference to Exhibit 10.1 to Form 8-	
10.13	between ThermoGenesis Holdings, Inc and	K filed with the SEC on November 22, 2019.	
	ImmuneCyte Life Sciences Inc.	K med with the SEC on November 22, 2019.	
10.14	Contribution Agreement, dated November 22,	Incorporated by reference to Exhibit 10.2 to Form 8-	
10.14	2019 between ThermoGenesis Holdings, Inc	K filed with the SEC on November 22, 2019.	
	and ImmuneCyte Life Sciences Inc.	K med with the BEE on November 22, 2017.	
10.15	Stockholder's Agreement, dated November 22,	Incorporated by reference to Exhibit 10.3 to Form 8-	
10.13	2019 between ThermoGenesis Holdings, Inc	K filed with the SEC on November 22, 2019.	
	and ImmuneCyte Life Sciences Inc.	11 1100 with the SDC on 110 venion 22, 2017.	
10.16	Joint Venture Agreement, dated October 21,	Incorporated by reference to Exhibit 10.1 to Form 8-	
10.10	2019, between ThermoGenesis Holdings, Inc.	K filed with the SEC on October 22, 2019.	
	and Healthbanks Biotech (USA) Inc., and	is filed with the BDC on October 22, 2017.	
	ImmuneCyte Life Sciences, Inc.		
	minunce you this belefices, file.		

10.17	Amendment No.1, dated August 12, 2019 but effective as of July 23, 2019, to the Convertible	Incorporated by reference to Exhibit 10.4 to Form 10-Q filed with the SEC on August 13, 2019.	
	Promissory Note, dated July 23, 2019 between		
	ThermoGenesis Holdings, Inc. and Orbrex		
	(USA) Co. Limited		
10.18	ThermoGenesis Holdings, Inc. Amended 2016	Incorporated by reference to Exhibit 10.5 to Form 10-	
	Equity Incentive Plan	Q filed with the SEC on August 13, 2019.	
10.19	Manufacturing and Supply Amending	Incorporated by reference to Exhibit 10.1 to Form 8-	
	Agreement #1, effective as of March 16, 2020,	K filed with the SEC on March 20, 2020	
	between ThermoGenesis Corp. And CBR		
	Systems, Inc.		
21.1	Subsidiaries of ThermoGenesis Holdings, Inc.	Filed herewith.	
	Consent of Marcum LLP, Independent		
23.1	Registered Public Accounting Firm	Filed herewith.	
	Certification by the Principal Executive Officer		
	pursuant to Section 302 of the Sarbanes-Oxley		
31.1	Act of 2002	Filed herewith.	
	Certification by the Principal Financial Officer		
	pursuant to Section 302 of the Sarbanes-Oxley		
31.2	Act of 2002	Filed herewith.	
	Certification of Principal Executive Officer and		
	Principal Financial Officer pursuant to Section		
32	906 of the Sarbanes Oxley Act of 2002	Filed herewith.	
101.INS	XBRL Instance Document;		
101.SCH	XBRL Taxonomy Extension Schema Document‡		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document;		
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document‡		
101.LAB	XBRL Taxonomy Extension Label Linkbase Document:		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document;		

Footnotes to Exhibit Index

- ^ Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request.
- # Represents a management contract or compensatory plan, contract or arrangement.
- * Confidential treatment has been requested for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act. In accordance with Rule 24b-2, these confidential portions have been omitted from this exhibit and filed separately with the SEC.
- ‡ XBRL information is furnished and not filed for purpose of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: March 23, 2020

By:/s/

Xiaochun "Chris" Xu

Xiaochun "Chris" Xu, Chief

Executive Officer

(Principal Executive Officer)

KNOW ALL THESE PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Xiaochun "Chris" Xu and Jeffery Cauble and each of them, jointly and severally, his attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each said attorneys-in-fact or his substitute or substitutes, may do or cause to be done by virtue hereof.

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

By:/s/	Chris Xu	Dated: March 23, 2020
	Chris Xu, Chief Executive Officer and	
	Chairman of the Board	
	(Principal Executive Officer)	
By:/s/	Jeffery Cauble	Dated: March 23, 2020
	Jeffery Cauble, Chief Financial Officer	
	(Principal Financial Officer and	
	Principal Accounting Officer)	
By: /s/	Debra Donaghy	Dated: March 23, 2020
	Debra Donaghy, Director	
By: /s/	Russell Medford	Dated: March 23, 2020
	Russell Medford, Director	
By: /s/	Joseph Thomis	Dated: March 23, 2020
	Joseph Thomis, Director	
- , ,		D 11/ 100
By: /s/	Mark Westgate	Dated: March 23, 2020
	Mark Westgate, Director	

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of ThermoGenesis Holdings, Inc., formerly known as Cesca Therapeutics Inc. on Form S-3 (File No. 333-235509), Form S-8 (File No. 333-23731) pertaining to Amended 2016 Equity Incentive Plan, Form S-3 (File No. 333-231526), Form S-8 (File No. 333-227425) pertaining to 2016 Equity Incentive Plan, as amended and restated, Form S-8 (File No. 333-218082) pertaining to 2016 Equity Incentive Plan, Form S-8 (File No. 333-218092) pertaining to 2006 Equity Incentive Plan and 2012 Independent Director Equity Plan, Form S-8 (File No. 333-171564) pertaining to 2006 Equity Incentive Plan, Form S-8 (File No. 333-140668) pertaining to 2006 Equity Incentive Plan, Form S-8 (File No. 333-140668) pertaining to 2006 Equity Incentive Plan, Form S-8 (File No. 333-212002) Independent Directors Equity Incentive Plan, and Non- Qualified Independent Director Stock Option Agreement, Form S-3 (File No. 333-227426), Form S-3, as amended (File No. 333-215638), and Form S-3, as amended (File No. 333-212314) of our report dated March 23, 2020, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of ThermoGenesis Holdings, Inc. as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019, which report is included in this Annual Report on Form 10-K of ThermoGenesis Holdings, Inc. for the year ended December 31, 2019.

Our report on the consolidated financial statements refers to a change in the method of accounting for leases due to the adoption of the guidance in ASC Topic 842 effective January 1, 2019.

/s/ Marcum LLP

Marcum LLP New York, NY March 23, 2020

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Chris Xu, certify that:

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

Dated: March 23, 2020

/s/ Chris Xu

Chris Xu

Chief Executive Officer

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffery Cauble, certify that:

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

Dated: March 23, 2020

/s/ Jeffery Cauble

Jeffery Cauble Chief Financial Officer

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

In connection with the Annual Report of ThermoGenesis Holdings, Inc. (the "Company") on Form 10-K for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Annual Report.

Dated: March 23, 2020 /s/Chris Xu

Chris Xu

Chief Executive Officer

Dated: March 23, 2020 /s/ Jeffery Cauble

Jeffery Cauble

Chief Financial Officer