

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended: December 31, 2021

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 000-16375



THERMOGENESIS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

94-3018487
(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:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$.001 par value	THMO	Nasdaq Capital Market

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

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

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

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

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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 Non-accelerated filer Smaller reporting company
Emerging growth company

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

As of June 30, 2021, the aggregate market value of the common equity held by non-affiliates of the registrant was approximately \$26,985,000 based on the closing sales price as reported on the Nasdaq Stock Market.

Class	Outstanding at March 24, 2022
Common stock, \$.001 par value	12,829,877

Documents Incorporated By Reference

Information required by Part III is incorporated by reference from registrant’s Proxy Statement for its 2022 annual meeting of stockholders or an amendment to this Annual Report on Form 10-K, which will be filed with the Securities and Exchange Commission within 120 days after the end of its fiscal year ended December 31, 2021.

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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 Capital Market Stock Exchange 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**

Overview

ThermoGenesis Holdings, Inc. ("ThermoGenesis Holdings," the "Company," "we," "our," "us") develops, commercializes, and markets a range of automated technologies for chimeric antigen receptor – T ("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-TXpress™ platform, which streamlines the manufacturing process for the emerging CAR-T immunotherapy market. The Company was founded in 1986 and is incorporated in the State of Delaware and headquartered in Rancho Cordova, CA.

Medical Device Products for Automated Cell Processing

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 for large scale cell manufacturing services. All product lines are reporting as a single reporting segment in the financial statements. The Company and its subsidiaries currently manufacture and market the following products:

Clinical Bio-Banking Applications:

- AXP® II Automated Cell Separation System – an automated, fully closed cell separation system for isolating stem and progenitor cells from umbilical cord blood, registered as a U.S. FDA 510(k) medical device.
- 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, registered as a U.S. FDA 510(k) medical device.

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, registered as a U.S. FDA 510(k) medical device.
- PXP-LAVARE System – an automated, fully closed system that is designed to wash, re-suspend and volume reduce cell suspensions. It allows for volume manipulation, supernatant or media exchange, and cell washing to occur without comprising cell viabilities and maximizing recoveries, registered as a U.S. FDA 510(k) medical device.
- PXP-1000 System – an automated, fully closed system that provides fast, reproducible separation of multiple cellular components from blood with minimal red blood cell contamination, registered as a U.S. FDA 510(k) medical device.

Large Scale Cell Processing and Biomanufacturing:

- X-Series® Products for general laboratory use: 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 Buoyancy-Activated Cell Sorting ("BACS") technology.

- CAR-TXpress™ Platform for Clinical Manufacturing – a modular designed, functionally closed manufacturing platform that addresses the critical unmet need for large scale cellular processing and chemistry, manufacturing and controls (“CMC”) needs for manufacturing cellular therapies, including CAR-T cell therapies.

Planned Expansion of Business— Contract Development and Manufacturing Services for Cell and Cell-Based Gene Therapies

In March 2022, our board of directors approved the planned expansion of the Company’s business to include contract development and manufacturing services for cell and cell-based gene therapies. The Company plans to develop and build-out the capabilities to become a world-class Contract Development and Manufacturing Organization (“CDMO”) for cell and cell-based gene therapies by partnering with Boyalife Genomics Tianjin Ltd., a China-based CDMO organization (“Boyalife Genomics”), to in-license certain know-how and other intellectual property from Boyalife Genomics, and by leasing and building out a cell manufacturing facility in Sacramento, California. We intend to leverage our existing technology and combine it with the in-licensed technologies to develop a proprietary manufacturing platform for cell manufacturing activities.

The Company plans to develop and operate its planned CDMO business through a newly formed division named TG Biosynthesis™. It is anticipated that TG Biosynthesis will provide high-quality development and manufacturing capabilities, cell and tissue processing development, quality systems, regulatory compliance, and other cell manufacturing solutions for clients with therapeutic candidates in various stages of development.

According to recent article published on Science Translational Medicine, cell therapies have become the “next pillar of medicine”. In 2017, US Food and Drug Administration (FDA) approved the first CAR-T cell therapy, Kymriah®, for the treatment of acute lymphoblastic leukemia (ALL). The cellular drug demonstrated close to 90% response rate in the relapsed and refractory cancer patient group. By the end of 2021, FDA has approved five (5) CAR-T therapies for various forms of blood cancers, and globally there were over 1,200 registered CAR-T cell related clinical trials registered on the National Institute of Health (NIH) clinicaltrial.gov website, targeting a variety of blood and solid tumors.

The Company believes that CDMO cell manufacturing services are becoming increasingly important for cell therapies to make their way through clinical trials. One of the major issues with moving cell therapy products from “bench to bedside” has been manufacturing bottlenecks. The heterogeneous nature of cell therapy products has introduced manufacturing complexity and regulatory concerns, as well as scale-up complexities that are not present within traditional pharmaceutical manufacturing. Additionally, establishing a manufacturing facility for cell therapies requires specific expertise and significant capital which can delay clinical trials. These factors often result in a significant number of cell therapy-based companies seeking CDMOs for their cell manufacturing needs. The Company believes that it can leverage its current proprietary automated and semi-automated cell processing technologies to more effectively develop CDMO capabilities.

In furtherance of our planned CDMO business, on March 24, 2022, we entered into a License and Technology Access Agreement with Boyalife Genomics (the “Boyalife License Agreement”). Boyalife Genomics is an affiliate of our Chairman and CEO, Dr. Chris Xu, and is a Tianjin, China-based cell manufacturing organization that has developed substantial manufacturing technology relating to cell manufacturing services. Under the terms of the Boyalife License Agreement, Boyalife Genomics granted the Company and its subsidiaries and affiliates a perpetual exclusive license in the United States to use Boyalife Genomics’ existing and future know-how and U.S. patents rights (if any) relating to cell manufacturing and related processes, including the right to sublicense such know-how and patent rights to affiliates of the Company. Notwithstanding the foregoing exclusivity, Boyalife Genomics retains the right to use (but not license) the licensed intellectual property in the U.S. for its internal use in connection with the provision of products and services to third parties. In consideration of this license, the Company will, among other things, pay to Boyalife Genomics a running royalty of 7.5% of the Company’s annual net sales of products and services that are covered by one of more Boyalife Genomics’ granted U.S. patents and 5.0% of other products and services covered by the licensed intellectual property. The royalty will be payable on each licensed product or service for a period of 10 years from the first commercial sale of the product or service (or if patented, until the expiration of the applicable licensed patents), and the license will be royalty-free thereafter on such licensed product or service. The agreement also grants to the Company a right of first refusal to purchase any cell manufacturing business or operation of Boyalife Genomics upon the same terms as any third-party offer to buy such business or operation.

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Also on March 24, 2022, we entered into a Lease Agreement (the “CDMO Facility Lease”), with Z3 Investment LLC (“Lessor”) for approximately 35,475 square feet of space in the Sacramento, California area in which we plan to partner with the Lessor to build out into a state-of-the-art current good manufacturing practice (cGMP) compliant facility with 12 cGMP clean room suites (with the Lessor paying to the related build-out costs). The CDMO Facility Lease provides for a lease term beginning on April 1, 2022 and ending on September 30, 2027, with a right of the Company to extend the lease for 2 additional periods of 5 years each. Lessor is an affiliate of our Chairman and CEO, Dr. Xu.

We are targeting the launch of our CDMO services to customers by the end of 2022. The successful development and launch of TG Biosynthesis will require us to raise additional capital, acquire various equipment for the planned operations, hire certain personnel needed to launch the operation, and timely complete the build-out of our leased Sacramento facility. There is no assurance that we will be able to successfully obtain such additional capital resources, as such capital may not be available on reasonable terms, or available at all. We will need to hire, train, and retain additional employees who have experiences in the cell manufacturing field in order for our CDMO business to be successful.

Sales and Distribution Channels

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

Research and Development

Research and development expenses related to our medical device products were \$2,209,000 and \$2,477,000 for the years ended December 31, 2021 and 2020, respectively. Research and development activities include expenses associated with the engineering, regulatory, and scientific affairs functions.

We have not to date incurred any material research and development expenses related to our planned CDMO business.

Manufacturing and Raw Materials

We source components for our medical device products from multiple suppliers that manufacture to our engineering specifications. Our high-volume AXP disposable products are manufactured using contract manufacturers. We utilize our manufacturing facility and in-house clean room in Rancho Cordova, California for production of our higher complexity devices and X-Series disposable cartridges. Various raw materials are used to manufacture our products. The raw materials are generally available from multiple sources. We have not had significant difficulty obtaining necessary raw materials.

Quality System

Our quality system for our medical device products business 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.

The Company and its contract manufacturers are subject to inspections by the FDA and other regulatory agencies to ensure compliance with the FDA's 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 medical device products 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.

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.

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 required.

Class II Devices

Several of our products, including the BioArchive and the AXP II 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 35 issued patents globally relating to our medical devices that will expire at various times between April 2022 and May 2040. 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.

Intellectual property for our planned CDMO business, primarily in the form of know-how and proprietary trade information, will generally be licensed to us under the Boyalife License Agreement.

Material Agreements

The following are certain material agreements involving our business in effect as of December 31, 2021:

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 paid a \$2,000,000 upfront fee, in addition to any amounts payable throughout the Term for the Products and any ROFR Products.

CBR Systems, Inc. (“CBR”)

Manufacturing and Supply Agreement

Effective July 13, 2020, the Company entered a Manufacturing and Supply Amending Agreement #2 (the “Amendment”) with CBR Systems, Inc. (“CBR”), an amendment to the Manufacturing Supply Amending Agreement #1 effective March 16, 2020 and the Manufacturing and Supply Agreement effective May 15, 2017 (the “CBR Agreement”), in which we agreed to supply CBR with AXP cord blood processing system and disposables. The term of the CBR 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. The Amendment, among other things, revised the amount of certain products to be purchased, pricing of those products and removal of the safety stock requirement.

Technology License and Escrow Agreement

As part of the Amendment, the Company updated the compliance conditions in the Technology License and Escrow Agreement (the “Escrow Agreement”), which was originally signed by the Company and CBR in June 2010. Under the Escrow Agreement, we granted CBR a perpetual, 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 AXP devices and 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 Escrow Agreement. The Escrow Agreement requires that our cash balance and short-term investments, net of non-convertible debt and borrowed funds that are payable within one year, is greater than \$1,000,000 at the end of each month or we will be in default of the agreement. Upon a default, CBR may take possession of the escrowed intellectual property and initiate manufacturing of AXP device and disposables for their internal use. The Company was in compliance with the License and Escrow Agreement at December 31, 2021.

Employees

As of December 31, 2021, we and our subsidiaries had 40 employees consisting of 36 full-time U.S. employees, 1 part-time U.S. employee and 3 full-time employees 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.

We endeavor to maintain workplaces that are free from discrimination or harassment on the basis of color, race, sex, national origin, ethnicity, religion, age, disability, sexual orientation, gender identification or expression or any other status protected by applicable law. The basis for recruitment, hiring, development, training, compensation and advancement is a person’s qualifications, performance, skills and experience. We believe that our employees are fairly compensated, without regard to gender, race and ethnicity, and routinely recognized for outstanding performance.

Foreign Sales and Operations

See Note 13 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, 2021, approximately 15% 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, 2021 of \$10,000,000 in principal and \$2,231,000 in accrued interest. The debt facility matures on March 6, 2023, 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, 2021, sales to customers outside the U.S. comprised approximately 45% of revenues. This compares to 39% for the year ended December 31, 2020. 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 customer may adversely affect our financial condition and results of operations. Revenues from our largest customer comprised 23% and 27% of revenues for the years ended December 31, 2021 and 2020, respectively. The loss of a large customer 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 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 re-engineering 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 Sixth Amended and Restated Technology License and Escrow Agreement with CBR if our cash balance and short-term investments net of non-convertible debt and borrowed funds that are payable within one year are not greater than \$1,000,000 at any month end, CBR 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 ham 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 has been adversely affected by the Coronavirus (COVID-19) pandemic and may continue to be adversely affected by the pandemic. We believe that the COVID-19 pandemic has had a material negative impact on our business and results of operations. The pandemic had a significant impact on the cord blood industry, with fewer cord blood units being stored globally after the start of the pandemic. Internationally, customs delays have led some customers to temporarily switch to manual processing due to the long wait to clear products through customs departments with reduced staffing. As a result, the pandemic has resulted in disruption to our supply chain and in customer demand. The continued impact of the pandemic on our business and results of operations will depend on future developments relating to the pandemic in general and the cord blood industry in particular, and such future developments are highly uncertain and cannot be predicted. Such developments may include the continued 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 continued impact on the U.S. or global economy. As a result, at the time of this filing, it is impossible to predict the continued impact of the pandemic 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 we 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 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.

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, 2021 and 2020, we had a net loss of \$11,880,000 and \$16,811,000 respectively and an accumulated deficit at December 31, 2021, of \$264,662,000. The report of our independent auditors on our December 31, 2021 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 we are unable to comply with the continued listed standard of the Nasdaq Capital Market Stock Exchange ("Nasdaq"), our shares may be delisted; which could adversely affect the price of our common stock and its liquidity. Our common stock is currently listed on Nasdaq. We must comply with Nasdaq's continued listing requirements related to, among other things, stockholders' equity, market value, minimum bid price, and corporate governance in order to remain so listed. There can be no assurances that we will be able to comply with the applicable listing requirements.

Nasdaq's listing standards provide 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. On March 7, 2022, we received written notice from the Nasdaq Listing Qualifications Department notifying the Company that it was not in compliance with the minimum bid price requirements set forth in NASDAQ Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market, due to the bid price of the Company's common stock closing below the minimum \$1 per share for the thirty (30) consecutive business days prior to the date of the Notification Letter. In accordance with listing rules, the Company was afforded 180 days, or until September 6, 2022, to regain compliance. If during this 180-day compliance period the closing bid price of the Company's common stock is at least \$1.00 per share for a minimum of ten consecutive business days, then Nasdaq will provide the Company with written confirmation of compliance and the matter will be closed. If compliance cannot be demonstrated by September 6, 2022, the Company may be eligible for additional time. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards on Nasdaq (except the bid price requirement). In addition, the Company would be required to provide written notice of its intention to cure the minimum bid price deficiency during this second 180-day compliance period by effecting a reverse stock split, if necessary. The Notice states that, if the Company meets these standards, then the Company may be eligible to have an additional 180-calendar day compliance period. If the Company is not granted an additional 180-day compliance period, then Nasdaq will provide written notification that the Company's securities will be subject to delisting. At that time, the Company may appeal the determination to delist its securities to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement or otherwise maintain compliance with the other listing requirements.

The Nasdaq listing standards also provide that a company may be delisted if it fails to maintain a minimum amount of stockholders' equity of at least \$2,500,000 if it does not meet the alternative compliance standards relating to the market value of listed securities or net income from continuing operations (the "Minimum Stockholders' Equity Rule"). Our Annual Report on Form 10-K for the year ended December 30, 2021, reflected that our stockholders' equity as of December 31, 2021, was approximately \$3,828,000. There is no assurance that we will be able to maintain stockholders' equity of at least \$2,500,000, may be an independent basis for delisting our common stock.

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 shares of 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.

Risks Related to Our Planned Contract Development and Manufacturing Organization (CDMO) Service

Initiating new business activities or strategies or significantly expanding existing business activities or strategies may expose us to new risks and may increase our costs associated with doing business. Initiating new business activities or strategies or significantly expanding existing business activities or strategies may expose us to new or increased financial, regulatory, reputational and other risks. Such innovations are important and necessary ways to grow our business and respond to changing circumstances in our industry; however, we cannot be certain that we will be able to manage the associated risks and compliance requirements effectively. Such risks include a lack of experienced management-level personnel, increased administrative burden, increased logistical problems common to large, expansive operations, increased credit and liquidity risk and increased regulatory scrutiny.

Will need to raise additional capital in order to execute our planned CDMO business plan, the failure of which could adversely impact our business transformation. Without adequate funding, we may not be able to establish CDMO facilities in the United States. We expect to continue to finance start-up costs related to our CDMO division, primarily by issuing equity or convertible debt securities, which could significantly dilute the ownership of existing stockholders. Furthermore, any newly issued securities could have rights, preferences and privileges senior to those of our existing common stock; and any issuances of equity securities may be at or below the prevailing market price of our common stock, which could cause the market price of our common stock to decline. We may have difficulty obtaining additional funds, and we may have to accept terms that would adversely affect our stockholders. In addition, any adverse conditions in the credit and equity markets may adversely affect our ability to raise funds when needed. The failure to achieve adequate funding may delay our planned CDMO business program and service launches.

Our success may depend on our ability to attract and retain key scientific or professional talents in the CDMO field. The Company currently lacks certain unique personnel for CDMO services. We will need to actively search and recruit the talents that are necessary for our business growth. Our success in transforming into CDMO services depends substantially on the efforts and abilities to recruit and retain key personnel. The competition for qualified CDMO services key personnel, is intense. The inability to hire, train, and retain key personnel, could delay the launching of our CDMO services, disrupt our business, and interfere with our ability to execute our CDMO business plan.

We will need to grow the size and capabilities of our organization to support our CDMO services, and we may experience difficulties in managing this growth. As our development and commercialization plans develop, we will need to add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth may create significant added responsibilities on Company management. Our future financial performance and our ability to successfully run our CDMO services division will depend, in part, on our ability to effectively manage future growth.

Our competitive advantages such as our CAR-TXpress™ technology being able to compete favorably and profitably in the CDMO cell manufacturing business, are critical to the success of our planned CDMO business. While we believe our proprietary CAR-TXpress™ technology platform is superior to other existing cell processing technologies, our data is based on very limited sources. CAR-TXpress™ technology has not been used to manufacture any cell therapy product candidate previously. The ability to accurately calculate total cost for the manufacturing expenses, expected future revenue, and profitability can vary among different product candidates and is difficult to estimate. There is no guarantee that our technology would reduce the manufacturing cost and deliver the competitive advantage that as we anticipated.

We are dependent on our ability to predict the CDMO cell manufacturing market and to identify customers. While there is an increasing number of clinical trials for cell therapies, the number of cell and gene therapy products that have reached commercial production is still limited. Cell therapy is an emerging industry and a significant global market for manufacturing services may never emerge. The number of customers who may use cell-based therapies, and the demand for cell manufacturing services, is difficult to estimate. If cell therapies under development are not proven safe and effective, demonstrate unacceptable risks or side effects or fail to receive regulatory approval if required; our manufacturing business may be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved cell therapy products in the U.S. Ultimately, our success in deriving revenue from manufacturing depends on the development and growth of a broad and profitable global market for cell therapies and services and our ability to capture a share of this market through identifying the proper customers.

We may fail to effectively utilize licensed technologies. We have entered into a licensing agreement, and in the future we may seek additional collaborations or strategic alliances or enter into additional licensing arrangements with organizations that we believe will complement or augment our own technologies and services. Licensing and collaborations arrangements are subject to numerous risks, and we may not realize the benefits of such alliances or licensing arrangements as we anticipated.

External competition from other CDMO cell manufacturing service providers may be harmful to our planned CDMO business. We face competition from other companies that are large, well-established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than ours. We also face competition from academic and research institutions that may choose to self-manufacture rather than utilize a contract manufacturer. To be successful, we will need to convince potential customers that our technology and capabilities are more innovative, of higher-efficiency and more cost-effective than could be achieved through internal manufacturing; and demonstrate that our technology and expertise in automated cell processing is unique to the industry. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in developing innovative cell processing technologies that improve the efficiency and reduce the drug cost associated with cell therapy manufacturing. If we are unable to successfully demonstrate our competitive advantages, we may not be able to compete against other manufacturers.

While there is an increasing number of product candidates in clinical trials with a smaller number that have reached commercial production, cell therapy is a developing industry and a significant global market for manufacturing services may never emerge. Cell therapy is in its early stages and is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace, making it difficult for their own funding to enable them to continue their business. The number of people who may use cell or tissue-based therapies, and the demand for cell processing services, is difficult to forecast. If cell therapies under development by us or by others are not proven safe and effective, demonstrate unacceptable risks or side effects or, where required, fail to receive regulatory approval, our manufacturing business will be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved cell therapy products in the U.S. Ultimately, our success in deriving revenue from manufacturing depends on the development and growth of a broad and profitable global market for cell-, gene- and tissue-based therapies and services and our ability to capture a share of this market.

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 comprised of warehouse space, manufacturing operations, office space, a biologics lab, a clean room, and a research and development lab. The lease expires May 31, 2024.

In Gurugram India, we lease an office facility with approximately 1,500 square feet, which is used for general office space. The lease expires September 14, 2023; however, either party can terminate the lease with three months' notice.

On March 24, 2022, we entered into a lease agreement for 35,475 square feet of space in Rancho Cordova, California for space that will house our planned CDMO cell manufacturing operations. This lease expires in September 30, 2027, with the right of the Company to extend for 2 additional terms of 5 years' each.

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 in Note 9, "Commitments and Contingencies," in "Item 8. Financial Statements – Notes to Consolidated Financial Statements", 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.

The material set forth in Note 11, "Commitments and Contingencies," in "Item 8. Financial Statements – Notes to Consolidated Financial Statements" is incorporated herein by reference.

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 154 stockholders of record on March 1, 2022, 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, 2021.

ITEM 6. Reserved

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.

General Overview

The Company 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 founded in 1986 and is incorporated in the State of Delaware and headquartered in Rancho Cordova, CA.

Medical Device Products for Automated Cell Processing

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 for large scale cell manufacturing services. All product lines are reporting as a single reporting segment in the financial statements.

See the "Business" section in Part I, Item 1 of this Form 10-K for additional information.

Results of Operations**Year Ended December 31, 2021 Compared to the Year Ended December 31, 2020****Net Revenues**

Net revenues for the year ended December 31, 2021 were \$9,294,000 compared to \$9,744,000 for the year ended December 31, 2020, a decrease of \$450,000 or 5%. The decrease was driven by CAR-TXpress revenues, which declined by \$544,000 in 2021 as compared to 2020. The Company sells this product line primarily through its exclusive worldwide distributor for X-Series products, Coming Incorporated. They have indicated that the COVID-19 pandemic has hindered their ability to expand revenue for the product line, as during 2021 it was challenging to do on site demonstrations and other sales activities due to the pandemic. Additionally, Other revenues decrease by \$245,000 due to COVID-19 testing kits which the Company sold in 2020 but did not sell in 2021. These decreases were offset by an increase of \$313,000 in BioArchive revenues, driven by service revenue and \$204,000 in AXP, driven by increased sales to the Company's distributor in China.

Revenues were comprised of the following:

	Year Ended December 31,	
	2021	2020
AXP	\$ 5,138,000	\$ 4,934,000
BioArchive	2,345,000	2,032,000
CAR-TXpress	1,284,000	1,828,000
Manual Disposables	421,000	599,000
Other	106,000	351,000
	<u>\$ 9,294,000</u>	<u>\$ 9,744,000</u>

Gross Profit

The Company's gross profit was \$3,493,000 or 38% of net revenues for the year ended December 31, 2021 compared to \$1,259,000 or 13% for the year ended December 31, 2020, an increase of \$2,234,000 or 177%. The increase was primarily due to an inventory disposition expense of approximately \$2,800,000 for the remaining inventory of COVID-19 testing kits purchased from ImmuneCytte incurred in 2020. This change was offset by higher inventory reserves in 2021 of approximately \$400,000 driven by BioArchive and X-Series® disposables reserves.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$8,515,000 for the year ended December 31, 2021, as compared to \$7,677,000 for the year ended December 31, 2020, an increase of \$838,000 or 11%. The increase was driven by stock compensation expense, which increased by approximately \$1,500,000 primarily due to the accelerated expense for the stock options that were voluntarily surrendered by Company executives and increased consulting expenses of approximately \$400,000 in the year ended December 31, 2021. The increase is offset by a decrease of approximately \$350,000 in lower legal expenses primarily due to the absence of expenses related to the Mavericks lawsuit incurred in the prior year, approximately \$150,000 less in patent expense, approximately \$125,000 less in information technology expense, approximately \$100,000 less in fixed asset impairment expense, approximately \$75,000 less in severance expense and approximately \$65,000 less in investor relations related expenses in the year ended December 31, 2021 as compared to the same period in 2020.

Research and Development Expenses

Research and development expenses were \$2,209,000 for the year ended December 31, 2021, compared to \$2,477,000 for the year ended December 31, 2020, a decrease of \$268,000 or 11%. The decrease was driven by lower salaries and benefits of approximately \$415,000 offset by increased stock compensation expense of approximately \$150,000 in the year ended December 31, 2021 as compared to the same period in 2020.

Interest Expense

Interest expense decreased to \$6,103,000 for the year ended December 31, 2021 as compared to \$7,908,000 for the year ended December 31, 2020, a difference of \$1,805,000. The decrease is driven an accelerated expense of \$2,486,000 for the unamortized debt discount of the beneficial conversion feature associated with the portions of the Revolving Credit Agreement with Boyalife Asset Holding II, Inc. which were converted in 2020, as compared to no conversions in 2021. This was offset by approximately \$660,000 in additional interest expense and debt discount amortization related to the Revolving Credit Agreement with Boyalife Asset Holding II, Inc. and the \$1,000,000 July 2019 convertible note that were incurred in 2021 as compared to 2020.

Gain on Extinguishment of Debt

The Company recorded a gain of extinguishment of debt of \$652,000 for the year ended December 31, 2021 as compared to \$0 for the year ended December 31, 2020, related to the principal and accrued interest for the Paycheck Protection Program loan the Company received in 2020, which was forgiven in the first quarter of 2021.

Liquidity and Capital Resources

At December 31, 2021, we had cash and cash equivalents of \$7,280,000 and working capital of \$8,616,000. 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, 2021, we used \$6,620,000 of cash for operations primarily the result of the net loss incurred during 2021, offset by non-cash charges for depreciation and amortization. Cash used in investing activities for the year ended December 31, 2021 was \$93,000 as the result of capital purchases. Cash generated in financing activities for the year ended December 31, 2021 was \$6,832,000.

The Company has a Revolving Credit Agreement with Boyalife Asset Holding II, Inc. As of December 31, 2021, the Company had drawn down the full \$10,000,000 that is available under the Revolving Credit Agreement, which matures in March of 2023. Boyalife Asset Holding II, Inc. is a wholly-owned subsidiary of Boyalife Group Inc. (USA), which is owned and controlled by the Company's Chief Executive Officer and Chairman of our Board of Directors.

The Company has incurred historical losses from operations and expects to continue to incur operating losses in the near future. The Company may need to raise additional capital to grow its business, fund operating expenses and make interest payments. The Company's ability to fund its liquidity needs is subject to various risks, many of which are beyond its control. The Company may 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. These factors and other indicators raise substantial doubt about the Company's ability to continue as a going concern within one year from the filing date of this report.

We manage the concentration of credit risk with our customers and distributors through a variety of methods including, pre-shipment deposits, credit reference checks and credit limits. Although management believes that our 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, and contingencies. 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 policies are critical and require significant judgement by the Company:

Revenue Recognition

The Company's revenues consist primarily of device sales and service revenue.

Device Sales

Device sales include devices and consumables for BioArchive, AXP, CAR-TXpress and manual disposables. Revenue is recognized when control of the devices passes to the customer, and the Company's performance obligation has been satisfied.

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.

Revenue is recognized based on the following five-step process as outlined in the Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers": (i) Identify the Contract with the Customer; (ii) Identify Performance Obligations in the Contract; (iii) Determine the Transaction Price; (iv) Allocate the Transaction Price; and (v) Satisfaction of the Performance Obligations (and Recognize Revenue).

Revenues are recorded net of discounts. Shipping and handling fees billed to customers are included in net revenues, while the related costs are included in cost of revenues. Most sales are made with FOB origin shipping terms, with title and control of the goods passing to the customer at the time of shipment. 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.

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).

Except for limited exceptions, there is 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 when revenue is recognized. 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.

Inventories

We value inventory at the lower of cost or net realizable value. Cost is determined on a first in first out basis. This policy requires us to make estimates regarding the net realizable value of our inventory, including an assessment of excess or obsolete inventory. Our determination of excess and obsolete inventory requires judgement, which is based on several factors, including demand forecasts, prior sales history, and industry trends. For disposable items with an expiration date, we consider the remaining shelf life in our analysis. Based on our evaluation, an allowance is recorded for inventory which we believe may ultimately not be sold to customers. We update our evaluation every quarter, increasing or decreasing the allowance based on the most current information available at the time. If our actual demand is less than anticipated, we may be required to take additional obsolete inventory charges, decreasing our gross margin and adversely impacting net operating results.

In addition, we sometimes purchase inventory in large quantities to obtain purchase discounts from our suppliers. This leads to the Company to split inventory between short term and long term. The Company uses judgement and the forecasted demand information available to determine whether inventory should be recorded as long term.

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") as of December 31, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring operating losses. These recurring losses raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory – Excess and Slow-Moving Inventory Reserve

Critical Audit Matter Description

As described in Note 3 to the consolidated financial statements, 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.

We identified the inventory reserve as a critical audit matter as auditing management's estimate of the excess and slow moving inventory reserve was subjective and required significant judgment as the excess and slow-moving inventory reserve is sensitive to changes in the Company's operations and assumptions used to estimate the reserve including management's assumptions with regards to projections of future product demand and market conditions, which includes historical usage, expected future usage, and on-hand quantities of individual materials. This in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's analysis and significant assumptions related to projections of future demand.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the excess and slow-moving inventory reserve included the following, among others:

- We obtained an understanding of the design of controls associated with management's evaluation of excess and slow-moving inventory reserve.
- We tested completeness and accuracy of the underlying data used in developing the estimate for excess and slow-moving inventory reserve.
- We audited management's calculation of the inventory reserve by testing the mathematical accuracy of the Company's reserve calculation.
- We evaluated the appropriateness and consistency of management's methodology and assumptions used in developing their estimate of the excess and slow-moving inventory reserve including consideration of projections of future customer demand, which involved consideration of historical performance of the products.
- We compared actual write-off activity in the current year to the excess and slow-moving reserve estimated by the Company in the prior year to evaluate management's ability to accurately estimate the reserve.
- We looked for indications that the reserve for excess and slow-moving inventory may be understated by evaluating write-off activity of inventory subsequent to December 31, 2021.
- We considered the existence of contradictory evidence based on consideration of internal communication to management and the board of directors, Company press releases, and any changes within the business.

/s/ Marcum llp
Marcum llp

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

New York, NY
March 28, 2022

ThermoGenesis Holdings, Inc.
Consolidated Balance Sheets

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,280,000	\$ 7,161,000
Accounts receivable, net of allowance for doubtful accounts of \$156,000 (\$214,000 at December 31, 2020)	733,000	1,382,000
Inventories	5,373,000	5,877,000
Prepaid expenses and other current assets	1,578,000	878,000
Total current assets	<u>14,964,000</u>	<u>15,298,000</u>
Inventories, non-current	1,709,000	1,221,000
Equipment and leasehold improvements, net	1,261,000	1,424,000
Right-of-use operating lease assets, net	571,000	730,000
Goodwill	781,000	781,000
Intangible assets, net	1,318,000	1,358,000
Other assets	48,000	48,000
Total assets	<u>\$ 20,652,000</u>	<u>\$ 20,860,000</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,280,000	\$ 1,366,000
Accrued payroll and related expenses	348,000	349,000
Deferred revenue – short-term	719,000	608,000
Interest payable – related party	2,231,000	2,082,000
Note payable – short-term	--	447,000
Convertible promissory note, net	813,000	--
Other current liabilities	957,000	1,291,000
Total current liabilities	<u>6,348,000</u>	<u>6,143,000</u>
Convertible promissory note – related party, net	9,245,000	5,935,000
Convertible promissory notes, net	--	493,000
Note payable	--	199,000
Operating lease obligations – long-term	398,000	604,000
Deferred revenue – long-term	1,244,000	1,596,000
Other noncurrent liabilities	20,000	20,000
Total liabilities	<u>17,255,000</u>	<u>14,990,000</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 2,000,000 shares authorized, none outstanding	--	--
Common stock, \$0.001 par value; 350,000,000 shares authorized; 11,911,784 issued and outstanding (8,934,952 at December 31, 2020)	12,000	9,000
Additional paid in capital	268,447,000	259,058,000
Accumulated deficit	(264,662,000)	(253,283,000)
Accumulated other comprehensive loss	31,000	16,000
Total ThermoGenesis Holdings, Inc. stockholders' equity	<u>3,828,000</u>	<u>5,800,000</u>
Noncontrolling interests	(431,000)	70,000
Total equity	<u>3,397,000</u>	<u>5,870,000</u>
Total liabilities and equity	<u>\$ 20,652,000</u>	<u>\$ 20,860,000</u>

See accompanying notes to consolidated financial statements.

ThermoGenesis Holdings, Inc.
Consolidated Statements of Operations
and Comprehensive Loss

	Year Ended December 31,	
	2021	2020
Net revenues	9,294,000	9,744,000
Cost of revenues	5,801,000	8,485,000
Gross profit	<u>3,493,000</u>	<u>1,259,000</u>
Expenses:		
Selling, general and administrative	8,515,000	7,677,000
Research and development	2,209,000	2,477,000
Total operating expenses	<u>10,724,000</u>	<u>10,154,000</u>
Loss from operations	<u>(7,231,000)</u>	<u>(8,895,000)</u>
Other income / (expense):		
Interest expense	(6,103,000)	(7,908,000)
Gain on extinguishment of debt	652,000	--
Employee retention tax credit and other income / (expense)	802,000	(8,000)
Total other income / (expense)	<u>(4,649,000)</u>	<u>(7,916,000)</u>
Net loss	<u>\$ (11,880,000)</u>	<u>\$ (16,811,000)</u>
Loss attributable to non-controlling interests	(501,000)	(460,000)
Net loss attributable to common stockholders	<u>\$ (11,379,000)</u>	<u>\$ (16,351,000)</u>
COMPREHENSIVE LOSS		
Net loss	\$ (11,880,000)	\$ (16,811,000)
Other comprehensive loss:		
Foreign currency translation adjustments	15,000	14,000
Comprehensive loss	(11,865,000)	(16,797,000)
Comprehensive loss attributable to non-controlling interests	(501,000)	(460,000)
Comprehensive loss attributable to common stockholders	<u>\$ (11,364,000)</u>	<u>\$ (16,337,000)</u>
Per share data:		
Basic and diluted net loss per common share	<u>\$ (0.96)</u>	<u>\$ (2.60)</u>
Weighted average common shares outstanding Basic and diluted	<u>11,796,065</u>	<u>6,277,986</u>

See accompanying notes to consolidated financial statements.

ThermoGenesis Holdings, Inc.
Consolidated Statements of Equity
For the years ended December 31, 2021 and 2020

	Shares	Common Stock	Additional Paid in Capital	Accumulated Deficit	AOCL*	Non- Controlling Interests	Total Equity
Balance at December 31, 2020	8,934,952	\$ 9,000	\$ 259,058,000	\$ (253,283,000)	\$ 16,000	\$ 70,000	\$ 5,870,000
Stock-based compensation expense	--	--	2,560,000	--	--	--	2,560,000
Issuance of common stock via at-the-market offering, net	2,976,832	3,000	6,829,000	--	--	--	6,832,000
Foreign currency translation gain	--	--	--	--	15,000	--	15,000
Net loss	--	--	--	(11,379,000)	--	(501,000)	(11,880,000)
Balance at December 31, 2021	11,911,784	\$ 12,000	\$ 268,447,000	\$ (264,662,000)	\$ 31,000	\$ (431,000)	\$ 3,397,000
	Shares	Common Stock	Additional Paid in Capital	Accumulated Deficit	AOCL*	Non- Controlling Interests	Total Equity
Balance at December 31, 2019	2,843,601	\$ 3,000	\$ 237,313,000	\$ (236,932,000)	\$ 2,000	\$ 530,000	\$ 916,000
Stock-based compensation expense	--	--	880,000	--	--	--	880,000
Exercise of pre-funded warrants	324,445	--	32,000	--	--	--	32,000
Exercise of warrants	275,137	--	1,651,000	--	--	--	1,651,000
Discount due to beneficial conversion features	--	--	4,981,000	--	--	--	4,981,000
Conversion of related party note payable to common stock	1,666,670	2,000	2,998,000	--	--	--	3,000,000
Conversion of note payable to common stock	204,445	--	368,000	--	--	--	368,000
Sale of common stock, net of fees	3,620,654	4,000	10,835,000	--	--	--	10,839,000
Foreign currency translation gain	--	--	--	--	14,000	--	14,000
Net loss	--	--	--	(16,351,000)	--	(460,000)	(16,811,000)
Balance at December 31, 2020	8,934,952	\$ 9,000	\$ 259,058,000	\$ (253,283,000)	\$ 16,000	\$ 70,000	\$ 5,870,000

*Accumulated other comprehensive loss.

See accompanying notes to consolidated financial statements.

ThermoGenesis Holdings, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (11,880,000)	\$ (16,811,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	633,000	742,000
Stock-based compensation expense	2,560,000	880,000
Amortization of debt discount/premium, net	3,631,000	5,558,000
Reserve for excess and slow-moving inventories	864,000	3,308,000
Reserve for bad debt expense	(56,000)	(12,000)
Loss on disposal of equipment	--	118,000
Gain on extinguishment of debt	(652,000)	--
Net change in operating assets and liabilities:		
Accounts receivable	703,000	(90,000)
Inventories	(1,031,000)	(6,582,000)
Prepaid expenses and other assets	(700,000)	(106,000)
Accounts payable	(74,000)	(76,000)
Interest payable - related party	149,000	213,000
Accrued payroll and related expenses	(1,000)	61,000
Deferred revenue – short term	111,000	(12,000)
Other current liabilities	(323,000)	(1,128,000)
Long-term deferred revenue and other noncurrent liabilities	(554,000)	(456,000)
Net cash used in operating activities	<u>(6,620,000)</u>	<u>(14,393,000)</u>
Cash flows from investing activities:		
Capital expenditures	<u>(93,000)</u>	<u>(23,000)</u>
Net cash used in investing activities	<u>(93,000)</u>	<u>(23,000)</u>
Cash flows from financing activities:		
Proceeds from long-term debt	--	4,287,000
Payments on finance lease obligations	--	(33,000)
Proceeds from sale of common stock, net of expenses	6,832,000	10,839,000
Proceeds from exercise of warrants and pre-funded warrants	--	1,683,000
Proceeds from note payable	--	646,000
Net cash provided by financing activities	<u>6,832,000</u>	<u>17,422,000</u>
Effects of foreign currency rate changes on cash and cash equivalents	--	(2,000)
Net increase in cash, cash equivalents and restricted cash	<u>119,000</u>	<u>3,004,000</u>
Cash, cash equivalents and restricted cash at beginning of period	7,161,000	4,157,000
Cash, cash equivalents and restricted cash at end of period	<u>\$ 7,280,000</u>	<u>\$ 7,161,000</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	<u>\$ 2,322,000</u>	<u>\$ 2,379,000</u>
Supplemental non-cash financing and investing information:		
Recording of beneficial conversion feature on debt	<u>\$ --</u>	<u>\$ 4,981,000</u>
Related party promissory note converted to common stock	<u>\$ --</u>	<u>\$ 3,000,000</u>
Convertible promissory note converted to common stock	<u>\$ --</u>	<u>\$ 368,000</u>
Transfer of inventories to equipment	<u>\$ 181,000</u>	<u>\$ --</u>

See accompanying notes to consolidated financial statements.

ThermoGenesis Holdings, Inc.
Notes to Consolidated Financial Statements

1. Description of Business

The Company develops, commercializes and markets a range of automated technologies for chimeric antigen receptor therapies (“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-TXpress™ platform, which streamlines the manufacturing process for the emerging CAR-T immunotherapy market. The Company was founded in 1986 and is incorporated in the State of Delaware and headquartered in Rancho Cordova, CA.

The Company was founded in 1986 and is a Delaware corporation, with headquarters in Rancho Cordova, CA. Our business involves the manufacturing and related service of cell based medical devices, including the AutoXpress® and BioArchive® platforms for automated clinical bio-banking, PXP® platform for point-of-care cell-based therapies and CAR-TXpress™ platform for large scale cell manufacturing services. All product lines are reporting as a single reporting segment in the financial statements.

Our common stock is traded on the Nasdaq Capital Market exchange under the ticker symbol “THMO”.

2. Going Concern

At December 31, 2021, the Company had cash and cash equivalents of \$7,280,000 and working capital of \$8,616,000. The Company has incurred historical losses from operations and expects to continue to incur operating losses in the near future. The Company may need to raise additional capital to grow its business, fund operating expenses and make interest payments. The Company's ability to fund its liquidity needs is subject to various risks, many of which are beyond its control. The Company may 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. These factors and other indicators raise substantial doubt about the Company's ability to continue as a going concern within one year from the filing date of this report.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. 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 result should the Company be unable to continue as a going concern.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Principles of Consolidation

The consolidated financial statements include the accounts of ThermoGenesis Holdings, Inc. 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 CARTXpress Bio. 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 interests reflects only its share of the after-tax earnings or losses of an affiliated company. The Company's condensed consolidated balance sheets reflect non-controlling interests within the equity section.

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 following five-step process as outlined in the Accounting Standards Codification (“ASC”) Topic 606, “Revenue from Contracts with Customers”: (i) Identify the Contract with the Customer; (ii) Identify Performance Obligations in the Contract; (iii) Determine the Transaction Price; (iv) Allocate the Transaction Price; and (v) Satisfaction of the Performance Obligations (and Recognize Revenue). Revenues are recorded net of discounts. Shipping and handling fees billed to customers are included in net revenues, while the related costs are included in cost of revenues. For more information on revenues, see Note 13.

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 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 \$87,000 and \$83,000 at December 31, 2021 and 2020 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 subsidiary 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.

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.

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.

At times, the Company will purchase inventories in larger quantities to obtain volume purchase discounts. In some cases, purchases may exceed expected sales for certain products in the following year. If the Company purchases inventory which is likely to not be sold in the next year, that inventory is classified as non-current. As of December 31, 2021 and December 31, 2020, the Company had \$1,709,000 and \$1,221,000, respectively of non-current inventory.

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.

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.

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 12*.

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.

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 its 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.

Income Taxes

The tax years 2000-2020 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.

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.

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. For the year ended December 31, 2021, sales and marketing and general and administrative expenses were combined into one line item identified as sales, general and administrative expenses on the Statement of Operations; the loss on equity method investments was combined with other income on the Statement of Operations; and incentive stock options and foreign rate differential were broken out as separate line items in the reconciliation of federal income tax attributable to operations in Note 14.

Recently Adopted 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. The adoption of this standard did not have a material impact on the Company's financial statements.

In January 2020, the FASB issued ASU 2020-01, "*Investments – Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions between Topic 321, Topic 323, and Topic 815*". The new guidance clarifies the interaction of accounting for the transition into and out of the equity method and the accounting for measuring certain purchased options and forward contracts to acquire investments. It is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on the Company's financial statements.

Recently Issued Accounting Standards

In August 2020, the FASB issued ASU 2020-06 “*Debt-Debt with Conversion and Other Options (“Subtopic 470-20”) and Derivatives and Hedging—Contracts in Entity’s Own Equity (“Subtopic 815-40”): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*,” which, among other things, provides guidance on how to account for contracts on an entity’s own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity’s own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher than shareholder’s rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity’s own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective or modified retrospective basis. The ASU is effective for public business entities that meet the definition of a Securities and Exchange Commission (“SEC”) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020. The Company does not anticipate the adoption of this standard to have a material impact on its financial statements.

In June 2016, the FASB issued *ASU 2016-13, Financial Instruments - Credit Losses (“Topic 326”)*. The ASU introduced 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 reporting periods beginning after December 15, 2022, including interim reporting periods within those annual reporting periods. The Company is in the processing of assessing the impact of the adoption of the ASU on the Company’s financial statements.

4. Equipment and Leasehold Improvements

Equipment and leasehold improvements consisted of the following:

	Year Ended December 31,		
	2021	2020	Estimated Useful Life (in years)
Machinery and equipment	\$ 6,270,000	\$ 6,004,000	2.5 - 10
Computer and software	631,000	631,000	2 - 5
Office equipment	256,000	256,000	5 - 10
Leasehold improvements	932,000	932,000	5 years or remaining lease term
Total equipment	8,089,000	7,823,000	
Less accumulated depreciation	(6,828,000)	(6,399,000)	
Total equipment and leasehold improvements, net	\$ 1,261,000	\$ 1,424,000	

Depreciation expense for the years ended December 31, 2021 and 2020 was \$429,000 and \$516,000, respectively.

5. Intangible Assets and Goodwill

In 2021, in accordance with ASC 350, the Company performed a qualitative analysis, which determined that it was not more likely than not that the fair value of the reporting units or significant inputs used to determine the fair value of the intangible assets was less than the carrying value of the goodwill and intangible assets recorded on the Company's books as of December 31, 2021. As a result, no impairment was recorded and a quantitative analysis was not performed. 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.

	Intangible Assets	Goodwill
Balance at January 1, 2020, net	\$ 1,467,000	\$ 781,000
Amortization and foreign exchange	(109,000)	--
Balance at December 31, 2020, net	\$ 1,358,000	\$ 781,000
Amortization and foreign exchange	(40,000)	--
Balance at December 31, 2021, net	\$ 1,318,000	\$ 781,000

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

	As of December 31, 2021				
	Weighted Average Amortization Period (in Years)	Gross Carrying Amount	Accumulated Amortization	Impairment	Net
Trade names	3	\$ 52,000	\$ 52,000	\$ --	\$ --
Developed technology	10	318,000	143,000	--	175,000
Licenses	7	418,000	418,000	--	--
Device registration	7	78,000	78,000	--	--
Customer relationships	3	425,000	425,000	--	--
Amortizable intangible assets		\$ 1,291,000	\$ 1,116,000	--	\$ 175,000
In process technology		1,143,000	--	--	1,143,000
Total		\$ 2,434,000	\$ 1,116,000	\$ --	\$ 1,318,000

	As of December 31, 2020				
	Weighted Average Amortization Period (in Years)	Gross Carrying Amount	Accumulated Amortization	Impairment	Net
Trade names	3	\$ 52,000	\$ 52,000	\$ --	\$ --
Developed technology	10	318,000	111,000	--	207,000
Licenses	7	432,000	424,000	--	8,000
Device registration	7	66,000	66,000	--	--
Customer relationships	3	442,000	442,000	--	--
Amortizable intangible assets		1,310,000	1,095,000	--	215,000
In process technology		1,143,000	--	--	1,143,000
Total		\$ 2,453,000	\$ 1,095,000	\$ --	\$ 1,358,000

The change in the gross carrying amount is due to foreign currency exchange fluctuations. In process technology has not yet been introduced to the market place and is therefore not yet subject to amortization. The Company's estimated future amortization expense for amortizable intangible assets in subsequent years, are as follows:

Year Ended December 31,	
2022	32,000
2023	32,000
2024	32,000
2025	32,000
Thereafter	47,000
Total	<u>\$ 175,000</u>

6. Related Party Transactions

HealthBanks Biotech (USA) Inc.

On November 26, 2019 the Company entered into an agreement with HealthBanks Biotech (USA) Inc. ("HealthBanks") to form a new company called ImmuneCyte, Inc. ("ImmuneCyte") to commercialize the Company's proprietary cell processing platform, CAR-TXpress™, for use in immune cell banking as well as for cell-based contract development and manufacturing services (CMO/CDMO). Under the terms of the agreement, ImmuneCyte was initially owned 80% by HealthBanks and 20% by the Company. Healthbanks is a subsidiary of the Boyalife Group (USA), Inc. which is owned by Dr. Xiaochun (Chris) Xu, the Company's Chief Executive Officer and Chairman of our Board of Directors. Due to the significant influence the Company has over ImmuneCyte's operations, the investment was accounted for by the Company using the equity method.

Between November 26, 2019 and September 30, 2020, ImmuneCyte closed on a series of investments with a private institution and qualified investors. After the investments, ImmuneCyte was owned 75.16% by HealthBanks, 18.79% by the Company and 6.05% by the private investors.

In March 2021, ImmuneCyte completed an acquisition to acquire Boyalife's Cellular Therapy Division, for 12,000,000 shares in ImmuneCyte and Shangai KDWinfo Technology Co. Ltd. for 500,000 shares in ImmuneCyte. Following the acquisitions, the Company's ownership percentage in ImmuneCyte decreased from 18.79% to 8.64%. The Company performed an analysis of the transaction and noted that none of the factors supporting significant influence changed as a result of the acquisition. Therefore, it was concluded that significant influence remains and the Company will continue to account for the transaction using the equity method. The Company recognized a dilution gain of \$262,000 representing its share of the net assets acquired by ImmuneCyte. However, at the time of the acquisition, the Company had accumulated losses of \$428,000 in its investment in ImmuneCyte. As the accumulated losses were greater than the dilution gain, no entry was recorded by the Company for its investment in ImmuneCyte following the transaction.

As of December 31, 2021, the value of the Company's investment in ImmuneCyte on its Balance Sheet is \$0. For the year ended December 31, 2021, ImmuneCyte had a net loss of \$666,000; its current assets were \$3,177,000 and current liabilities were \$1,946,000.

Convertible Promissory Note and Revolving Credit Agreement

In March 2017, ThermoGenesis Holdings entered into a Credit Agreement with Boyalife Asset Holding II, Inc. (the “Lender”). The Lender is a wholly owned subsidiary of the Boyalife Group (USA), Inc., which is owned and controlled by the Company’s Chief Executive Officer and Chairman of our Board of Directors. The Credit Agreement, as amended, 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”). As of December 31, 2020, the Company had an outstanding principal balance on the Loan of \$10,000,000. On March 4, 2022, the Company amended the Loan extending the Maturity Date by one year to March 6, 2023.

The Credit Agreement and the Convertible Promissory Note issued thereunder (as amended, 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. The Loan can be prepaid in whole or in part by the Company at any time without penalty.

The Credit Agreement includes a down-round provision that lowers the conversion price of the Note if the Company issues shares of common stock at a lower price per share. At December 31, 2021, the conversion price of the Note was \$1.80 per share.

The following summarizes the Note:

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Carrying Value
At December 31, 2021	3/6/2022	22%	\$ 1.80	\$ 10,000,000	\$ (755,000)	\$ 9,245,000
At December 31, 2020	3/6/2022	22%	\$ 1.80	\$ 10,000,000	\$ (4,065,000)	\$ 5,935,000

The Company amortized \$3,310,000 and \$2,931,000 of debt discount to interest expense for the years ended December 31, 2021 and 2020, respectively. In addition to the amortization, the Company also recorded interest expense of \$2,231,000 and \$2,082,000 for the years ended December 31, 2021 and 2020, respectively. The interest payable balance as of December 31, 2021 and December 31, 2020 was \$2,231,000 and \$2,082,000, respectively.

7. Convertible Promissory Note**July 2019 Note**

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”). The July 2019 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.

The following summarizes the July 2019 Note:

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Carrying Value
At December 31, 2021	7/31/2022	24%	\$ 1.80	\$ 1,000,000	\$ (187,000)	\$ 813,000
At December 31, 2020	7/31/2022	24%	\$ 1.80	\$ 1,000,000	\$ (507,000)	\$ 493,000

The Company recorded amortization expense for the debt discount on the July 2019 Note of \$321,000 and \$187,000 for the years ended December 31, 2021 and 2020, respectively. Interest expense related to the July 2019 Note was \$240,000 for the years ended December 31, 2021 and 2020.

8. Paycheck Protection Program

On April 21, 2020, the Company entered into a promissory note and received a Paycheck Protection Program loan “PPP Loan” from the Small Business Association “SBA”, which was established under the CARES Act. The Company received net proceeds of \$646,000 from the PPP Loan. The term of the PPP Loan is two years with an interest rate of 1.00% per annum, which was deferred for the first six months of the term of the loan or after an application is filed for loan forgiveness, whichever is later. Each monthly payment shall be in the amount which would fully amortize the principal balance outstanding under the PPP Loan. Pursuant to the terms of the CARES Act, the proceeds of the PPP Loan may be used for payroll costs, mortgage interest, rent or utility costs. The promissory note of the PPP Loan contains customary events of default relating to, among other things, payment defaults, breach of representations and warranties, or provisions of the promissory note. The occurrence of an event of default may result in a claim for the immediate repayment of the amount outstanding under the PPP Loan. In late December 2020, the Company applied with the SBA for forgiveness of the PPP Loan and was notified on March 30, 2021 that the SBA had approved our application to forgive the entire amount of the loan and accrued interest. For the year ended December 31, 2021, the Company recorded a gain on extinguishment of debt of \$652,000 representing the principal and accrued interest for the PPP Loan at the time of forgiveness.

9. Leases

The Company leases an approximately 28,000 square foot facility located in Rancho Cordova, California for its corporate offices and in-house manufacturing. The lease was renewed in the first quarter of 2019 and is accounted for as an operating lease. The lease expires in May 2024.

Operating Leases

Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. 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.

The following summarizes the Company’s operating leases:

	December 31, 2021	December 31, 2020
Right-of-use operating lease assets, net	\$ 571,000	\$ 730,000
Current lease liability (included in other current liabilities)	206,000	157,000
Non-current lease liability	398,000	604,000
Weighted average remaining lease term	2.4	3.4
Discount rate	22%	22%

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

2022		319,000
2023		328,000
2024		139,000
Total lease payments	\$	786,000
Less: imputed interest		(182,000)
Present value of operating lease liabilities	\$	604,000

Operating Lease Costs

Lease costs recognized in consolidated statements of operations are summarized below:

	December 31,	
	2021	2020
Operating lease cost	\$ 311,000	\$ 311,000
Variable lease cost	105,000	139,000
Total lease cost	\$ 416,000	\$ 450,000

Statement of Cash Flows

In January 2019, the Company signed an amendment to its Rancho Cordova, California lease. 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 \$310,000 and \$301,000 for the years ended December 31, 2021 and 2020, respectively.

Finance Leases

Finance leases are included in equipment and other current and non-current liabilities on the condensed consolidated balance sheet. The amortization and interest expense are included in general and administrative expense and interest expense, respectively on the statement of operations. These leases were not material for the years ended December 31, 2021 and 2020.

10. Warranty

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

The warranty liability is included in other current liabilities in the consolidated balance sheets. 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,	
	2021	2020
Beginning balance	\$ 154,000	\$ 277,000
Warranties originated during the year	65,000	71,000
Claims settled made during the year	(149,000)	(212,000)
Changes in reserve estimate	(3,000)	18,000
Ending balance	\$ 67,000	\$ 154,000

11. Commitments and Contingencies

Financial Covenants

On July 13, 2020, the Company, entered into a Manufacturing and Supply Amending Agreement #2 with CBR Systems, Inc. (“CBR”) with an effective date of July 13, 2020 (the “Amendment”). The Amendment amends the Manufacturing and Supply Agreement entered into on May 15, 2017 and Amendment #1 dated March 16, 2020 by the Company and CBR. The Amendment, among other things, revised the amount of certain products to be purchased, pricing of those products and removal of the safety stock requirement. In addition, the Amendment updated the financial requirement to exclude convertible debt from the definition of short-term debt under events or conditions that constitute a default. The Amendment states that the Company’s cash balance and short-term investments net of non-convertible debt and borrowed funds that are payable within one year must be greater than \$1,000,000 at any month end. The Company was in compliance with this agreement as of December 31, 2021.

Potential Severance Payments

We have entered into an employment agreement with the Company Chief Executive Officer under which payment and benefits would become payable in the event of termination by us for any reason other than cause, or upon a change in control of our Company, or by the employee for good reason.

Contingencies

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, 2021, 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.

12. Stockholders’ Equity

Common Stock

On March 25, 2020, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with three institutional and accredited investors (the “Investors”), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the “RDO”), an aggregate of 1,000,002 shares of the Company’s common stock at an offering price of \$3.50 per share, for gross proceeds of approximately \$3,500,000 before the deduction of \$393,000 in placement agent fees and offering expenses. The Purchase Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

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 the Company’s common stock, having an aggregate offering price of up to \$4,400,000 and on May 19, 2020 the ATM Agreement was amended to increase the aggregate value of up to \$ 15,280,313 (the “HCW Shares”). As of December 31, 2020, the Company sold a total of 2,620,652 shares of the Company’s common stock for aggregate gross proceeds of \$8,224,000 at an average selling price of \$3.14 per share, resulting in net proceeds of approximately \$7,731,000 after deducting legal expenses, accounting fees, commissions and other transaction costs of approximately \$493,000.

Warrants

A summary of warrant activity is as follows:

	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted-Average Remaining Contract Term
Balance at January 1, 2020	1,716,066	\$ 25.23	1.57
Warrants granted	–	\$ –	
Warrants exercised	(599,582)	\$ 2.81	
Warrants expired/canceled	–	\$ –	
Outstanding at December 31, 2020	<u>1,116,484</u>	<u>\$ 37.27</u>	<u>0.49</u>
Exercisable at December 31, 2020	<u>1,046,631</u>	<u>\$ 34.42</u>	<u>0.54</u>
Balance at January 1, 2021	1,116,484	\$ 37.27	0.49
Warrants granted	–	\$ –	
Warrants exercised	–	\$ –	
Warrants expired/canceled	(463,236)	\$ 80	
Outstanding and Exercisable at December 31, 2021	<u>653,248</u>	<u>\$ 6.97</u>	<u>1.4</u>

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 60,000 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 132,500 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 132,500 shares to 392,500 shares. As of December 31, 2021, 41,386 awards were available for issuance under the Amended 2016 Plan.

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 30,000 shares available for issuance as of December 31, 2021.

Stock Based Compensation

The Company recorded stock-based compensation of \$2,560,000 for the year ended December 31, 2021 and \$880,000 for the year ended December 31, 2020, as comprised of the following:

	Year Ended December 31,	
	2021	2020
Cost of revenues	\$ 17,000	\$ 9,000
Selling, general and administrative	2,275,000	757,000
Research and development	268,000	114,000
	<u>\$ 2,560,000</u>	<u>\$ 880,000</u>

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On June 4, 2020, the Chief Executive Officer, Chief Financial Officer and other employees were granted 565,500 options to purchase shares of the Company's common stock at an exercise price of \$5.94 per share. In May 2021, five Company executives voluntarily surrendered the options they were awarded. At the time they were surrendered, the exercise price of the options was underwater. No payment or other consideration was paid to the Company executives for surrendering the options. In total 490,000 options were cancelled. As a result of the cancellation, the remaining unamortized expense of \$2,008,000 was accelerated and expensed in the year ended December 31, 2021.

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:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2021	889,636	\$ 8.57	8.7	\$ --
Granted	--			
Expired	(766)	\$ 272.21		\$ --
Forfeited/cancelled	(535,450)	\$ 5.89		\$ --
Outstanding at December 31, 2021	353,420	\$ 12.04	6.8	\$ --
Vested and Expected to Vest at December 31, 2021	326,596	\$ 12.46	6.7	\$ --
Exercisable at December 31, 2021	279,520	\$ 13.29	6.6	\$ --

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.

Non-vested stock option activity for the year ended December 31, 2021, is as follows:

	Non-vested Stock Options	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2021	658,800	\$ 5.25
Granted	--	
Vested	(61,400)	\$ 6.18
Cancelled/forfeited	(523,500)	\$ 5.05
Outstanding at December 31, 2021	73,900	\$ 5.94

The fair value of the Company's stock options granted for the year ended December 31, 2020 was estimated using the following weighted-average assumptions:

	Year Ended December 31, 2020
Expected life (years)	6
Expected volatility	116%
Risk-free interest rate	0.54%
Dividend yield	0%

The weighted average grant date fair value of options granted during the year ended December 31, 2020 was \$5.05.

At December 31, 2021, the total compensation cost related to options granted under the Company's stock option plans but not yet recognized was \$262,000. This cost will be amortized on a straight-line basis over a weighted-average period of approximately one year and will be adjusted for subsequent forfeitures.

Net Loss Per Share

Net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding. 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:

	2021	2020
Common stock equivalents of convertible promissory notes and accrued interest	7,960,811	7,300,897
Vested Series A warrants	--	40,441
Unvested Series A warrants(1)	--	69,853
Warrants – other	653,248	1,006,190
Stock options	326,596	889,636
Total	<u>8,940,655</u>	<u>9,307,017</u>

(1) 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.

13. Revenues

The Company's revenues consist primarily of device sales and service revenue.

Device Sales

Device sales include devices and consumables for BioArchive, AXP, CAR-TXpress and manual disposables. Revenue is recognized when control of the devices passes to the customer, and the Company's performance obligation has been satisfied.

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.

Revenue is recognized based on the following five-step process as outlined in the Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers": (i) Identify the Contract with the Customer; (ii) Identify Performance Obligations in the Contract; (iii) Determine the Transaction Price; (iv) Allocate the Transaction Price; and (v) Satisfaction of the Performance Obligations (and Recognize Revenue).

Revenues are recorded net of discounts. Shipping and handling fees billed to customers are included in net revenues, while the related costs are included in cost of revenues. Most sales are made with FOB origin shipping terms, with title and control of the goods passing to the customer at the time of shipment. 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.

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).

Except for limited exceptions, there is 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 when revenue is recognized. 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.

The following table summarizes the revenues by product line and type:

	Year Ended December 31, 2021			
	Device Revenue	Service Revenue	Other Revenue	Total Revenue
AXP	\$ 4,940,000	\$ 198,000	\$ --	\$ 5,138,000
BioArchive	827,000	1,518,000	--	2,345,000
CAR-TXpress	875,000	123,000	286,000	1,284,000
Manual Disposables	421,000	--	--	421,000
Other	65,000	--	41,000	106,000
Total	<u>\$ 7,128,000</u>	<u>\$ 1,839,000</u>	<u>\$ 327,000</u>	<u>\$ 9,294,000</u>

	Year Ended December 31, 2020			
	Device Revenue	Service Revenue	Other Revenue	Total Revenue
AXP	\$ 4,774,000	\$ 160,000	\$ --	\$ 4,934,000
BioArchive	855,000	1,177,000	--	2,032,000
CAR-TXpress	1,471,000	71,000	286,000	1,828,000
Manual Disposables	599,000	--	--	599,000
Other	289,000	--	62,000	351,000
Total	<u>\$ 7,988,000</u>	<u>\$ 1,408,000</u>	<u>\$ 348,000</u>	<u>\$ 9,744,000</u>

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, 2021 and 2020 that were included in the beginning balance of deferred revenue were \$608,000 and \$620,000, respectively. Short term deferred revenues were \$719,000 and \$608,000 at December 31, 2021 and 2020, respectively. Long-term deferred revenue was \$1,244,000 and \$1,596,000 at December 31, 2021 and 2020, respectively.

Exclusivity Fee

In 2019, the Company entered into a Supply Agreement with Coming Incorporated (the "Supply Agreement"). The Supply Agreement has an initial term of five years with Coming having two options to renew for an additional two-years (up to four years total), 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 Coming exclusive worldwide distribution rights for substantially all X-Series® products under the CAR-TXpress™ platform (the "Products") for the duration of the Term, subject to certain geographical and other exceptions. In addition to any amounts payable throughout the Term for the Products, as consideration for the exclusive worldwide distribution rights Coming paid a \$2,000,000 exclusivity fee. The Company recorded \$286,000 in revenue for the years ended December 31, 2021 and 2020.

Distribution Agreement

The Company signed a new agreement with its AXP distributor in China through 2023. The new agreement contains annual purchase minimums. In return for the minimum purchase commitment, the Company provided the distributor with AXP processing devices to use during the term of the agreement. The Company maintains ownership of these devices and they must be returned to the Company at the end of the agreement. The Company analyzed the relevant accounting guidance and determined that the equipment and AXP bagsets represented distinct performance obligations. The equipment was concluded to be an embedded lease, accounted for as a sales-type operating lease. At December 31, 2021, the book value of those assets was approximately \$170,000 and they will be amortized over their estimated useful life of five years. For the year ended December 31, 2021, the Company recorded \$41,000 in revenue relating to the lease.

Backlog of Remaining Customer Performance Obligations

The following table represents revenue expected to be recognized in the future from the backlog of performance obligations that are unsatisfied (or partially unsatisfied) at the end of the reporting period:

	2022	2023	2024	2025	2026 and beyond	Total
Service revenue	\$ 927,000	\$ 462,000	\$ 189,000	\$ 86,000	\$ --	\$ 1,664,000
Device revenue (1)	732,000	732,000	41,000	--	--	1,505,000
Exclusivity fee	286,000	286,000	286,000	286,000	190,000	1,334,000
Clinical revenue	13,000	13,000	13,000	13,000	147,000	199,000
Total	\$ 1,958,000	\$ 1,493,000	\$ 529,000	\$ 385,000	\$ 337,000	\$ 4,702,000

(1) Represents the minimum purchase requirements under the distribution agreement the Company signed with its AXP distributor in China.

14. Concentrations

The Company had accounts receivable balances or revenues in excess of 10% for the years ended December 31, 2021 and 2020 as shown in the table below:

Accounts Receivable	2021		2020	
Customer 1	\$ 206,000	13%	\$ 531,000	38%
Customer 2	\$ 200,000	13%	\$ 337,000	24%
Customer 3	--	--	\$ 139,000	10%

Revenues	2021		2020	
Customer 1	\$ 2,180,000	23%	\$ 2,646,000	27%
Customer 2	1,373,000	15%	938,000	10%
Customer 3	\$ 809,000	9%	\$ 1,293,000	13%

One supplier accounted for 71% and 40% of total inventory purchases during the years ended December 31, 2021 and 2020, respectively.

For the year ended December 31, 2021, sales to customers outside the U.S. comprised approximately 45% of revenues. This compares to 39% for the year ended December 31, 2020.

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,	
	2021	2020
United States	\$ 647,000	\$ 810,000
Costa Rica	292,000	390,000
India	139,000	169,000
All other countries	183,000	55,000
Total equipment, net	\$ 1,261,000	\$ 1,424,000

15. Employee retention Tax Credit

Employee Retention Tax Credits (“ERTC”), created in the March 2020 CARES Act and then subsequently amended by the Consolidated Appropriation Act (“CAA”) of 2021 and the American Rescue Plan Act (“ARPA”) of 2021, is a refundable payroll credit for qualifying businesses keeping employees on their payroll during the COVID-19 pandemic. Under CAA and ARPA amendments, employers can claim a refundable tax credit against the employer share of social security tax equal to 70% of the qualified wages (including certain health care expenses) paid to employees from January 1, 2021 to September 30, 2021. Qualified wages are limited to \$10,000 per employee per quarter in 2021 so the maximum ERTC available is \$7,000 per employee per quarter.

The Company is eligible to receive the ERTC credits under the gross receipts decline test when comparing the first, second and third quarters of 2021 to the same quarters in 2019, which qualified the Company to claim ERTC the first three quarters of 2021 under the amended ERTC program. The Company qualified for a refundable payroll tax credit totaling \$842,000 for the first three quarters of 2021, which is recorded in other income on the Company’s consolidated statement of operations for the year ended December 31, 2021, and prepaid and other current assets on the Company’s consolidated balance sheet as of December 31, 2021.

16. Income Taxes

Loss before income tax benefits was comprised of \$11,850,000 from US and \$30,000 from foreign jurisdictions for the year ended December 31, 2021 and \$16,728,000 from US and \$83,000 from foreign jurisdictions for the year ended December 31, 2020.

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,	
	2021	2020
Statutory federal income tax benefit	\$ (2,495,000)	\$ (3,530,000)
Intangible assets	-	69,000
PPP loan forgiveness	(137,000)	-
Incentive stock options	257,000	56,000
Change in valuation allowance	(72,000)	197,000
Expiration of net operating losses	1,242,000	1,558,000
Disallowed financing costs	1,282,000	1,619,000
State and local taxes	(195,000)	(31,000)
Foreign rate differential	26,000	13,000
Other	92,000	49,000
Total income tax expense	<u>\$ -</u>	<u>\$ -</u>

At December 31, 2021, we had federal net operating loss carryforwards of approximately \$125,077,000 to offset future federal taxable income, with \$101,805,000 available through 2037 and \$23,272,000 available indefinitely. We also had state net operating loss carryforwards of approximately \$60,984,000 that may offset future state taxable income through 2041. We also had foreign net operating loss carryforwards of approximately \$629,000 that may offset future foreign taxable income through 2029.

At December 31, 2021, the Company has research and experimentation credit carryforwards of \$1,521,000 for federal tax purposes that expire in various years between 2022 and 2041, and \$1,616,000 for state income tax purposes that do not have an expiration date, and some of which expire in 2031 and 2032.

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

	Year Ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 27,088,000	\$ 27,312,000
Income tax credit carryforwards	2,797,000	2,852,000
Stock compensation	437,000	369,000
Lease obligation	127,000	160,000
Deferred revenue	313,000	366,000
Inventory reserve	449,000	234,000
Other	213,000	268,000
Total deferred tax assets	31,424,000	31,561,000
Deferred tax liabilities		
Depreciation and amortization	(320,000)	(352,000)
Lease asset	(120,000)	(153,000)
Total deferred tax liabilities	(440,000)	(505,000)
Valuation allowance	(30,984,000)	(31,056,000)
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 \$72,000 and increased by \$197,000 during the years ended December 31, 2021 and 2020, respectively.

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 – 2021.

On March 27, 2020, the Coronavirus, Aid, Relief and Economic Stimulus Act (CARES Act) was enacted. The CARES Act made various tax law changes including among other things (i) increasing the limitation under Section 163(j) of the Internal Revenue Code of 1986, as amended (the "IRC") for 2019 and 2020 to permit additional expensing of interest (ii) enacting a technical correction so that qualified improvement property can be immediately expensed under IRC Section 168(k), (iii) making modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes and (iv) enhancing the recoverability of alternative minimum tax credits. As of December 31, 2020, the Company has taken advantage of the PPP loan provided by the CARES Act. The PPP loan was forgiven in 2021 and forgiveness income was fully reversed as per federal guidance. The provisions of the CARES Act have not changed the amount of income tax paid, nor will they impact the GAAP tax expense benefit expected to be recorded in 2021.

On June 29, 2020, California's Governor Newsom signed AB85 suspending California net operating loss ("NOL") utilization and imposing a cap on the amount of business incentives tax credits (R&D credit) for tax years 2020-2022. Given an expected tax loss for 2021, the suspension will not have an impact on the company's NOL or credits in California.

17. Employee Retirement Plan

401(k) Plan

The Company provides a retirement plan, in accordance with Section 401(k) of the Internal Revenue Code, to all eligible employees. Employees may elect to contribute up to the Internal Revenue Service maximum annual contribution limit. The Company matches employee contributions up to a maximum of 4% per year. The Company recognized an expense of \$135,000 and \$147,000 for the years ended December 31, 2021 and 2020, respectively, related to matching contributions.

18. Subsequent Events

On February 3, 2022, the Company and the Sales Agent entered into Amendment No. 2 to the Offering Agreement At the Market Offering Agreement (the "Offering Agreement") with H.C. Wainwright & Co., LLC to further increase the maximum aggregate offering price of shares of Common Stock that may be offered and sold from time to time under the Amended Offering Agreement from \$15,280,313 to \$19,555,261, which enables the Company to sell an additional \$4,275,000 of shares after taking into account prior sales under the Offering Agreement (the "Additional Shares"). Amendment No. 2 also amended the Offering Agreement to change the expiration date of the Amended Offering Agreement from August 9, 2022 to the date on which all of the Additional Shares are sold by the Company or until the Amended Offering Agreement is otherwise mutually terminated, subject to the early termination provisions set forth in the agreement. The terms and conditions of the Offering Agreement otherwise remain unchanged. Subsequent to December 31, 2021, the Company sold a total of 918,093 shares of common stock under the H.C. Wainwright ATM Agreement for aggregate gross proceeds of \$681,000 at an average selling price of \$0.74 per share, resulting in net proceeds of approximately \$594,000 after deducting commissions and other transaction costs of approximately \$87,000. These sales lowered the conversion price on the Second Amended and Restated Convertible Promissory Note with Boyalife Asset Holding II, Inc. to \$0.65 per share as of February 28, 2022.

On March 4, 2022, the Company entered into an Amendment No. 1 (the "Amendment to Note") to its Second Amended and Restated Convertible Promissory Note with Boyalife Asset Holding II, Inc. (the "Note"), and an Amendment No. 2 (the "Amendment to Credit Agreement") to its First Amended and Restated Revolving Credit Agreement with Boyalife Asset Holding II, Inc. (the "Credit Agreement"). The Amendment to Note amends the maturity date of the Note to be March 6, 2023, and provides that interest accrued and unpaid as of March 6, 2022 is due and payable as of March 6, 2022. After March 6, 2022, accrued and unpaid interest shall become due and payable annually on December 31st of each year. The Amendment to Credit Agreement amends the Credit Agreement to change the defined term "Termination Date" to be March 6, 2023.

On March 24, 2022, the Company entered into a License and Technology Access Agreement with Boyalife Genomics (the "Boyalife License Agreement"), for the purpose of creating a contract manufacturing and development organization ("CDMO") division of the Company. The newly formed division will be called TG Biosynthesis. Boyalife Genomics is an affiliate of our Chairman and CEO, Dr. Chris Xu, and is a Tianjin, China-based cell manufacturing organization that has developed substantial manufacturing technology relating to cell manufacturing services. Under the terms of the Boyalife License Agreement, Boyalife Genomics granted the Company and its subsidiaries and affiliates an exclusive license in the United States to use Boyalife Genomics' existing and future know-how and U.S. patents rights (if any) relating to cell manufacturing and related processes. Notwithstanding the foregoing exclusivity, Boyalife Genomics retains the right to use the licensed intellectual property in the U.S. solely for its internal use in connection with the provision of products and services to third parties. In consideration of this license, the Company will pay to Boyalife Genomics a running royalty of 7.5% of the Company's annual net sales of products and services that are covered by one of more Boyalife Genomics' patents and 5.0% of other products and services covered by the licensed intellectual property; and transfer to Boyalife Genomics' all of the Company's 8.63% minority equity interest in ImmuneCyte Inc.

Also on March 4, 2022, we entered into a Lease Agreement with Z3 Investment LLC ("Lessor") for approximately 35,475 square feet of space in the Sacramento, California. Under the terms of the agreement, the Lessor will build out the facility into a state-of-the-art current good manufacturing practice (cGMP) compliant facility with 12 cGMP clean room suites (the "CDMO Facility Lease"). The Lessor anticipates the build out to be completed in late 2022 at which time the Company can then begin to offer CDMO services to customers. The CDMO Facility Lease provides for a lease term beginning on April 1, 2022 and ending on September 30, 2027, with a right of the Company to extend the lease for 2 additional periods of 5 years each.

ITEM 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

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, 2021.

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, 2021 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, 2021.

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, 2021, 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.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent inspections

Not applicable.

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 2022 annual meeting of stockholders (or an amendment to this Form 10-K), which we intend to file within 120 days after the end of our fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders (or an amendment to this Form 10-K), which we intend to file within 120 days after the end of our fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders (or an amendment to this Form 10-K), which we intend to file within 120 days after the end of our fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders (or an amendment to this Form 10-K), which we intend to file within 120 days after the end of our fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders (or an amendment to this Form 10-K), which we intend to file within 120 days after the end of our fiscal year ended December 31, 2021.

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.

	<u>Page Number</u>
(a) (1) Financial Statements	
Report of Independent Registered Public Accounting Firm (PCAOB ID #688)	28
Consolidated Balance Sheets at December 31, 2021 and 2020	30
Consolidated Statements of Operations and Comprehensive Loss for the Year Ended December 31, 2021 and 2020	31
Consolidated Statements of Equity for the Year Ended December 31, 2021 and 2020	32
Consolidated Statements of Cash Flows for the Year Ended December 31, 2021 and 2020	33
Notes to Consolidated Financial Statements	34

Management’s Report on Internal Control over Financial Reporting is contained as part of this Annual Report under Item 9A “Controls and Procedures.”

(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 on the next page, which are incorporated herein by this reference.

ITEM 16. Form 10-K Summary

None.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
1.1	At the Market Offering Agreement, dated December 13, 2019, by and between ThermoGenesis Holdings, Inc. and H.C. Wainwright & Co., LLC, incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 (Registration No. 333-235509) filed on December 13, 2019.
1.2	Amendment No.1 to At the Market Offering Agreement dated May 19, 2020, by and between ThermoGenesis Holdings, Inc. and H.C. Wainwright & Co., LLC, incorporated by reference to Exhibit 1.1 to Form 8-K filed May 20, 2020.
1.3	Amendment No. 2 to At the Market Offering Agreement dated May 19, 2020, by and between ThermoGenesis Holdings, Inc. and H.C. Wainwright & Co., LLC, incorporated by reference to Exhibit 1.3 to Form 8-K filed February 3, 2022.
3.1	Amended and Restated Certificate of Incorporation of ThermoGenesis Holdings, Inc. dated as of July 5, 2020, incorporated by reference to Exhibit 3.1 to Form 8-K filed June 6, 2020.
3.2	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.
3.3	First Amendment to the Amended and Restated Bylaws of ThermoGenesis Holdings, Inc., incorporated by reference to Exhibit 3.1 to Form 8-K filed December 17, 2021.
4.1	Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on March 28, 2018.
4.2	Form of Common Warrant, incorporated by reference to Exhibit 10.37 of amended Registration Statement on Form S-1 filed with the SEC on May 14, 2018.
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, 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.
4.5	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934, as amended, incorporated by reference to Exhibit 4.8 to Form 10-K filed with the SEC on March 24, 2020.
10.1	Form of Stock Option Award Agreement, incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on January 3, 2020.
10.2	Manufacturing and Supply Amending Agreement #1, effective as of March 16, 2020, between ThermoGenesis Corp. and CBR Systems, Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on March 20, 2020.
10.3	Payment Protection Program Loan and Promissory note between ThermoGenesis Holdings, Inc. and Comerica Bank dated April 21, 2020, incorporated by reference to Exhibit 10.5 to Form 10-Q filed with the SEC on August 14, 2020.
10.4†	Supply Agreement dated as of April 22, 2020, between ThermoGenesis Corp. and ImmuneCyte Life Sciences Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed April 28, 2020.
10.5	Fourth Amendment to the ThermoGenesis Holdings, Inc. 2016 Equity Incentive Plan, Effective June 4, 2020, incorporated by reference to Exhibit 10.1 to Form 8-K filed June 9, 2020.
10.6	Form of Stock Option Agreement dated as of June 4, 2020, incorporated by reference to Exhibit 10.2 to Form 8-K filed June 9, 2020.

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10.7†	Manufacturing and Supply Amending Agreement #2, between ThermoGenesis Holdings, Inc. and CBR Systems dated as of July 13, 2020, incorporated by reference to Exhibit 10.1 to Form 8-K filed July 17, 2020.
10.8	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.
10.9	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.
10.10	Right of First Refusal and Co-Sale 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 10.4 to Form 8-K filed with the SEC on January 4, 2019.
10.11	Investors' Rights Agreement, dated January 1, 2019, between CARTXpress Bio, Inc., Bay City Capital Fund V, L.P. and Bay City Capital Fund V Co-Investment Fund, L.P., incorporated by reference to Exhibit 10.3 to Form 8-K filed with the SEC on January 4, 2019.
10.12	Amended and Restated Certificate of Incorporation of CARTXpress Bio, Inc., incorporated by reference to Exhibit 10.5 to Form 8-K filed with the SEC on January 4, 2019.
10.13	Supply Agreement, dated as of August 30, 2019, between Coming Incorporated and ThermoGenesis Holdings, Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on September 6, 2019.
10.14	Supply Agreement, dated November 22, 2019 between ThermoGenesis Holdings, Inc and ImmuneCyte Life Sciences Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on November 22, 2019.
10.15	Contribution Agreement, dated November 22, 2019 between ThermoGenesis Holdings, Inc and ImmuneCyte Life Sciences Inc., incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on November 22, 2019.
10.16	Stockholder's Agreement, dated November 22, 2019 between ThermoGenesis Holdings, Inc and ImmuneCyte Life Sciences Inc., incorporated by reference to Exhibit 10.3 to Form 8-K filed with the SEC on November 22, 2019.
10.17	Joint Venture Agreement, dated October 21, 2019, between ThermoGenesis Holdings, Inc. and Healthbanks Biotech (USA) Inc., and ImmuneCyte Life Sciences, Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on October 22, 2019.
10.18	Amendment No.1, dated August 12, 2019 but effective as of July 23, 2019, to the Convertible Promissory Note, dated July 23, 2019 between ThermoGenesis Holdings, Inc. and Orbrex (USA) Co. Limited, incorporated by reference to Exhibit 10.4 to Form 10-Q filed with the SEC on August 13, 2019.
10.19#	ThermoGenesis Holdings, Inc. Amended 2016 Equity Incentive Plan, incorporated by reference to Exhibit 10.5 to Form 10-Q filed with the SEC on August 13, 2019.

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10.20*	Sixth Amended and Restated Technology License and Escrow Agreement between the Company, ThermoGenesis Corp. and CBR Systems, effective May 15, 2017, incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on May 31, 2017.
10.21	Purchase Agreement between the Company and Boyalife Investment Inc. and Boyalife (Hong Kong) Limited, incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on February 3, 2016.
10.22	Form of Nomination and Voting Agreement, incorporated by reference to Exhibit 10.4 to Form 8-K filed with the SEC on February 3, 2016.
10.23#	Amended and Restated 2006 Equity Incentive Plan, incorporated by reference to Exhibit 10.6.1 to Form 8-K filed with the SEC on May 1, 2014.
10.24	Form of Security Agreement, incorporated by reference to Exhibit 10.5 to Form 8-K filed on February 3, 2016.
10.25	Form of Indemnification Agreement, incorporated by reference to Exhibit 10.1 to Form 8-K/A filed with the SEC on November 17, 2016.
10.26#	Form of Notice of Grant of Stock Options and Option Agreement, incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on May 11, 2017.
10.27#	Executive Employment Agreement, dated November 13, 2017, between the Company and Xiaochun Xu, incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on November 15, 2017.
10.28#	Form of Stock Option Agreement, incorporated by reference to Exhibit 10.4 to Form 8-K filed with the SEC on November 15, 2017.
10.29*	Exclusive License Agreement, dated March 12, 2018, between ThermoGenesis Corp. and IncoCell Tianjin Ltd., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on March 16, 2018.
10.30	First Amended and Restated Revolving Credit Agreement, dated April 16, 2018, between Cesca Therapeutics Inc. and Boyalife Asset Holding II, Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on April 18, 2018.
10.31	Second Amended and Restated Convertible Promissory Note, dated April 16, 2018, issued by Cesca Therapeutics Inc. to Boyalife Asset Holding II, Inc., incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on April 18, 2018.
10.32	Amendment No. 1 to Second Amended and Restated Convertible Promissory Note, dated March 4, 2022, Second Amended and Restated Convertible Promissory Note, dated April 16, 2018, issued by ThermoGenesis Holdings, Inc. to Boyalife Asset Holding II, Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on March 8, 2022.
10.33	First Amended and Restated Nomination and Voting Agreement, dated April 16, 2018, between Cesca Therapeutics Inc. and Boyalife (Hong Kong) Limited, incorporated by reference to Exhibit 10.3 to Form 8-K filed with the SEC on April 18, 2018.
10.34	Amendment No. 1 to First Amended and Restated Revolving Credit Agreement, dated May 7, 2018, between Cesca Therapeutics Inc. and Boyalife Asset Holding II, Inc., incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on May 7, 2018.
10.35	Amendment No. 2 to First Amended and Restated Revolving Credit Agreement, dated March 4, 2022, ThermoGenesis Holdings, Inc. and Boyalife Asset Holding II, Inc., incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on March 8, 2022.
10.36#	Form of Stock Option Agreement, incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on December 19, 2018.

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10.37	License and Technology Access Agreement, dated March 24, 2022, between ThermoGenesis Holdings, Inc. and Boyaife Genomics Tianjin Ltd., incorporated by reference to Exhibit 10.1 to Form 8-K filed on March 28, 2022.
10.38	Lease Agreement, dated March 24, 2022, between ThermoGenesis Holdings, Inc. and Z3 Investment LLC, incorporated by reference to Exhibit 10.2 to Form 8-K filed on March 28, 2022.
21.1	Subsidiaries of ThermoGenesis Holdings, Inc.
23.1	Consent of Marcum LLP, Independent Registered Public Accounting Firm
31.1	Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Footnotes to Exhibit Index

- # 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.
- † Portions of this exhibit has been redacted because the Company has determined that such information (i) is not material and (ii) would likely cause competitive harm to the Company if it were to be publicly disclosed.

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 28, 2022

By: /s/

ThermoGenesis Holdings, Inc.
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 28, 2022
Chris Xu, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

By: /s/ Jeffery Cauble Dated: March 28, 2022
Jeffery Cauble, Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

By: /s/ Debra Donaghy Dated: March 28, 2022
Debra Donaghy, Director

By: /s/ Russell Medford Dated: March 28, 2022
Russell Medford, Director

By: /s/ Joseph Thomis Dated: March 28, 2022
Joseph Thomis, Director

By: /s/ Haihong Zhu, Director Dated: March 28, 2022
Haihong Zhu

ThermoGenesis Holdings, Inc. List of Subsidiaries

1. ThermoGenesis Corp.
Wholly-owned by ThermoGenesis Holdings, Inc.
Incorporated in the state of Delaware

2. TotipotentRX
Wholly-owned by ThermoGenesis Holdings, Inc.
Incorporated in India

3. CARTXpress Bio Inc.
Subsidiary of ThermoGenesis Corp. 80% equity interest held by ThermoGenesis Holdings, Inc.
Incorporated in the state of Delaware

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of ThermoGenesis Holdings, Inc. on Forms S-8 [Files No. 333-233731, 333-227425, 333-218082, 333-206996, 333-187197, 333-171564 and 333-140668] and on Forms S-3 [Files No. 333-227426, 333-231526, 333-235509, 333-215638 and 333-212314] of our report dated March 28, 2022, 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, 2021 and 2020 and for each of the two years ended in the period ended December 31, 2021, which report is included in this Annual Report on Form 10-K of ThermoGenesis Holdings, Inc. for the year ended December 31, 2021.

/s/ Marcum llp

Marcum llp
New York, NY
March 28, 2022

**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 28, 2022

/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 28, 2022

/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, 2021, 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 28, 2022

/s/Chris Xu

Chris Xu
Chief Executive Officer

Dated: March 28, 2022

/s/ Jeffery Cauble

Jeffery Cauble
Chief Financial Officer