THERMOGENESIS CORP
Form 10-K
September 21, 2012

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: June 30, 2012

Commission File Number: 333-82900

ThermoGenesis Corp.
(Exact name of registrant as specified in its charter)

Delaware	94-3018487
(State of incorporation)	(I.R.S. Employer Identification No.)

2711 Citrus Road
Rancho Cordova, California 95742
(Address of principal executive offices) (Zip Code)

(916) 858-5100
(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act: Common Stock, $0.001 par value Nasdaq Stock Market, LLC Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,

or a smaller reporting company. See the definitions of "large accelerated filer" and "small reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer o Non-accelerated filer* o Smaller reporting company x
*(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock held by non-affiliates as of December 31, 2011 (the last trading day of the second quarter) was $11,539,000 based on the closing sale price on such day.

As of September 13, 2012, 16,518,193 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the registrant's proxy statement for its 2012 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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PART I

ITEM 1.BUSINESS

Business Overview

The mission of ThermoGenesis Corp. (“the Company”, “we”, “our”) is to design, develop and commercialize devices and disposable tools for the processing, storage and administration of cell and tissue therapies used in the practice of regenerative medicine. Regenerative medicine is an emerging field using cell-based therapies to address a number of indications, including the repair or restoration of diseased or damaged tissue and cell function. Our products automate the volume reduction and cryopreservation of adult stem cell concentrates from cord blood and bone marrow for use in laboratory and point of care settings. Our primary business model is based on the sale of medical devices and the recurring revenues generated from their companion single-use, sterile disposable products. We currently sell our products in approximately 30 countries throughout the world to customers that include private and public cord blood banks, surgeons, hospitals and research institutions. Our worldwide commercialization strategy relies primarily on the utilization of distributors. The Company was founded in 1986 and is located in Rancho Cordova, California.

Our growth strategy is to expand our offerings in regenerative medicine while partnering with other pioneers in the stem cell arena to accelerate our worldwide penetration of this potentially explosive market. We plan to have a product line that will facilitate the processing of the increasing number of sources of therapeutic cells and to leverage our technological investments into profitable adjacent markets.

Based upon early clinical results, there is accumulating evidence that many of the stem cell trials underway may result in approved therapies in disease states and tissue regeneration procedures affecting significant patient populations, leading to a revolution in therapeutics involving stem cells. Although understanding the full potential of cell therapies and their ultimate impact on the practice of medicine remains a longer term prospect, we believe there are significant commercial opportunities in the market today for technologies supporting cell-based treatments and research.

Our Solutions

We believe our automated products significantly enhance the safety and viability of regenerative medical procedures and expand the use and success of those products in clinical treatment through their ease of use and high cell recovery rates. Our competitive advantage is achieved through applying our advanced research and engineering capabilities in developing a comprehensive line of products for healthcare providers to utilize in regenerative medicine. Our solutions enable our customers to automate their processes, comply with quality regulations, improve their efficiencies and produce therapeutic doses of high quality stem cell concentrates.

Key Events and Accomplishments

The following are key events and accomplishments that occurred in fiscal 2012:

- Signed Arthrex Inc. (“Arthrex”) Res-Q Distribution Agreement

We signed a five-year agreement with Arthrex to sell, distribute and service our Res-Q60 System technology for use in the preparation of autologous Platelet Rich Plasma (“PRP”) and Bone Marrow Concentrate (“BMC”).

- Received approval for AXP in Thailand and India

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Our AXP® AutoXpress® ("AXP") System received registration approval from India's Ministry of Health and the Food and Drug Administration in Thailand enabling the Company to initiate commercial sales in those countries.

- Received Regulatory Approval for BioArchive in China

China's State Food and Drug Administration approved the registration of our BioArchive System enabling it's direct commercial sale by the Company into the People's Republic of China.

- Sold CryoSeal Product Line to Asahi Kasei Medical Co., Ltd. ("Asahi")

Asahi exercised their option to purchase the intellectual property of the CryoSeal product line for $2,000,000 which was completed in July 2012.

- BioArchive Adopted by Canadian Blood Services

Canada's first national public cord blood bank adopted the BioArchive® System for cryopreservation and archival of stem cells.

- Completed a Tactical Reorganization and Cost Cutting Initiative

As part of a tactical reorganization and cost cutting initiative, we made a number of changes in corporate management and responsibilities. We recorded a one-time expense of approximately $460,000 related to the restructuring.

Recent Significant Event:

- Signed Golden Meditech Holdings Limited ("Golden Meditech") AXP Distribution Agreement

On August 20, 2012, we signed an exclusive agreement to distribute the AXP Disposable Blood Processing Set in China and several southeast Asian countries.

Market Overview

The regenerative medicine market continues to experience meaningful advances in clinical efficacy, regulatory approval and product commercialization of cell based therapies. The vast majority of this progress has been achieved through the broader application of adult stem cells, reflecting a greater awareness and appreciation of their therapeutic potential.

Positive results generated from the application of adult stem cells have resulted in greater government and private sector investment in research and development of new cell therapies, including the continued advancement of existing treatments.

The regenerative medicine market is comprised of companies that harvest, process, purify, expand, cryopreserve, store or administer stem cells. Key success factors include:

- Stem cell recovery rates
- Efficiency of cell processing
- Cost of care
- Product quality and efficacy
- Purity, viability and potency of stem cells
- Obtaining regulatory approval / U.S. Food and Drug Administration ("FDA") clearance

Cells are processed in the laboratory as well as in the operating room or point of care setting. Point of care applications involve the processing of patient cells in conjunction with a surgical procedure in an operating room or in an outpatient clinical setting. The laboratory market requirements include, but are not limited to, current Good Manufacturing Practices ("cGMP"), objective quality assurance and the ability to process multiple samples at one time. Requirements for the point of care include sterile field packaging, portability, minimal processing steps and speed of processing. These market requirements must be considered and translated into product features and benefits for successful market adoption.

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The availability of stem cells at the point of care enables physicians to apply cells across an array of applications. Physicians may also choose to study patient outcomes to understand the benefits of stem cells under their own independently-sponsored and regulated studies. Such research efforts are growing and already represent studies in diverse areas such as spinal fusion and orthopedics, wound healing, radiation injury, breast reconstruction and augmentation, cardiovascular applications, peripheral vascular disease and liver disease among many others.

Market Size

Market estimates for the regenerative medicine market include pathologies that affect vast numbers of people of all age groups. A well-known industry analyst, Robin Young, predicts the U.S. regenerative medicine market will grow from $140 million in 2010 to over $6 billion by the year 2020. The following chart highlights the disease states that are expected to be impacted by the advent of stem cell therapies by the year 2020.

Source: Robin Young, Stem Cell Summit, 2011, pg. 18.

Industry Market Drivers

We expect a number of key market drivers to cause the practice of regenerative medicine to proliferate over the next several years. We believe that as regenerative medicine matures, clinical studies and practice of medicine will give way to broad clinical acceptance and substantial commercialization of cell based therapies.

We expect the following key market drivers to be the primary forces in the near future to positively impact the growth of regenerative medicine:

- Legislative/regulatory initiatives
- Government funding
- Evidence based clinical outcomes
- Corporate investment
- Awareness of availability
- Advocacy groups
- Growing endorsement by clinicians
- Increase in prevalence of conditions treated
- New sources of stem cells
- Standardization in surgical procedures and hospital protocols using stem cells for patient treatments

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Product Overview

We provide products and technologies to enable highly-effective cell separation, processing and cryopreservation for storage of biological fluids including umbilical cord blood, peripheral blood and bone marrow in a proprietary format. These proprietary products and technologies are designed for use in the laboratory as well as point of care.

Cord Blood

- The AXP System is a medical device with an accompanying disposable bag set that isolates and retrieves stem cells from umbilical cord blood. The AXP System provides cord blood banks with an automated method to concentrate adult stem cells which reduces the overall processing and labor costs with a reduced risk of contamination under cGMP conditions. The AXP System retains over 97% of the mononuclear cells ("MNCs"). High MNC recovery has significant clinical importance to patient transplant survival rates. Self-powered and microprocessor-controlled, the AXP device contains flow control optical sensors that achieve precise separation.

Our market for the AXP System includes both private and public cord blood banks. In private banks, parents pay to preserve the cord blood cells from their offspring for family use, while a public bank owns cord blood stem cells donated by individuals, which are then available to the public for transplantation. Also there are banks we consider "public/private" that offer both services. Some public sites are evaluating the inclusion of a private bank within their facility. Since the infrastructure to process and store cord blood is already in place, they see it as a way of funding their public side.

The AXP System has been commercially available since 2006, marketed under a Master File with the FDA. In 2007, we received 510(k) clearance from the FDA for use in the processing of cord blood for cryopreservation.

- The BioArchive System is a robotic cryogenic medical device used to cryopreserve and archive stem cells for future transplant and treatment. Launched in fiscal 1998, our BioArchive Systems have been purchased by over 110 umbilical cord blood banks in over 35 countries to archive, cryopreserve and store stem cell preparations extracted from human placentas and umbilical cords for future use.

The BioArchive System is designed to store over 3,600 stem cell samples. It is the only fully-automated, commercially available system on the market that integrates controlled-rate freezing, sample management and long term cryogenic storage in liquid nitrogen. The robotic storage and retrieval of these stem cell units improves cell viability, provides precise inventory management and minimizes the possibility of human error.

Worldwide Cord Blood Banks Growth Rate
(Data Gathered by ThermoGenesis)

	2005	2012	CAGR
Public Banks	116	180	6.5%
Private Banks	89	239	15.2%
Public/Private	4	15	20.8%
Total Banks	209	434	11.0%

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Bone Marrow

- The Res-Q 60 BMC, is a rapid, reliable, and easy to use product for cell processing at the point of care. The product is a centrifuge-based disposable device designed for the isolation and extraction of specific stem cell populations from bone marrow. The product was launched in 2009. The key advantages of the Res-Q 60 BMC include (a) delivering a high number of target cells from a small sample of bone marrow, and (b) providing a disposable that is highly portable and packaged for the sterile field. These features allow the physician to process bone marrow and return the cells to the patient in 15 minutes.

- The MarrowXpress® or MXP System, a derivative product of the AXP and its accompanying disposable bag set, isolates and concentrates stem cells from bone marrow aspirate and its initial application is for the preparation of cells for regeneration of bone in spinal fusion procedures. The product is an automated, closed, sterile system that volume-reduces blood from bone marrow to a user-defined volume in 30 minutes, while retaining over 90% of the MNCs, a clinically important cell fraction. Self-powered and microprocessor-controlled, the MXP System contains flow control optical sensors that achieve precise separation. In June 2008, we received the CE-Mark, enabling commercial sales in Europe. In July 2008, we received authorization from the FDA to begin marketing the MXP in the U.S. for the preparation of cell concentrate from bone marrow.

PRP

- The Res-Q 60 PRP, is designed to be used for the safe and rapid preparation of autologous PRP from a small sample of blood at the point of care. The product allows PRP to be mixed with autograft and/or allograft bone prior to application to a bony defect in the body. The Res-Q 60 PRP received FDA 510(k) clearance in June of 2011. Res-Q 60 PRP is expected to become commercially available in fiscal 2013.

Other

The Company has begun efforts to divest or discontinue the following product lines which are not strategically aligned with our regenerative medicine strategy.

- The ThermoLine® product line includes the ultra-rapid plasma ThermoLine Freezer and ultra-rapid plasma ThermoLine Thawer. The Company is in the process of winding down the ThermoLine product line.

- The CryoSeal® System is an automated system serving the wound market used to prepare an autologous hemostatic surgical sealant from a patient’s own blood or from a single donor in approximately one hour. On June 30, 2012, Asahi exercised the option to purchase certain intangible assets related to this product line, including all associated patents, trademarks and engineering files.

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Sales and Distribution Channels

Worldwide distribution network for our products.

Cord Blood Stem Cell Processing and Storage

AXP System

- CEI
  Certain countries in Latin America

  Concessus
  Western Europe (effective August 2012)
- Danyel Biotech
  Israel
- Delrus
  Russian Federation and CIS countries
- Fenwal, Inc.
  3 countries in Asia

  Golden Profit
  Hong Kong, Malaysia
  and Taiwan (effective August 2012)

  HVD Vertriebs G.m.b.H.
  Middle East and portions of Europe

  GE Healthcare (“GEHC”)
  U.S. and Canada

BioArchive System

- CEI
  Certain countries in Latin America

  Concessus
  Western Europe

  Danyel Biotech
  Israel (effective September 2012)

  Delrus
  Russian Federation and CIS countries

  Fenwal, Inc.
  3 countries in Asia

  Golden Profit
  Hong Kong, Malaysia
  and Taiwan (effective July 2012)

  HVD Vertriebs G.m.b.H.
  Middle East and portions of Europe

Automated Bone Marrow & PRP Processing

MXP System

- Celling Technologies
  Worldwide
- Nanshan Memorial
  Medical Institute
  (“Nanshan”),
  China and Hong Kong,
  excluding
  Taiwan
- TotipotentSC
  3 countries in Asia

Res-Q 60 BMC

- Arthrex
  Private label, Worldwide
- Celling Technologies
  Worldwide

  Nanshan
  China and Hong Kong,
  excluding
  Taiwan

Res-Q 60 PRP

- Arthrex
  Private label, Worldwide
- BioParadox, LLC
  Worldwide

·	ThermoGenesis	TotipotentSC
	All other countries	3 countries in Asia

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Business Development

We continue to have encouraging discussions with multiple potential partners with the goal of identifying and developing growth opportunities beyond our current product offering and in additional geographies. These include leveraging our technology platforms into new markets such as additional cord blood products, other potential bone marrow technologies and adipose tissue processing, while addressing the cell processing work flow continuum from cell sourcing and preparation through to preservation and patient administration.

We maintain a rigorous flow of discussions with numerous organizations having complementary products, services or other relevant assets. We are optimistic that our business development efforts will generate increased sales and shareholder value through advancing existing products into new applications, indications and by new product development and introductions. See Item 1A “Risk Factors”.

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Competition

Following are our major competitors, listed by each of our major products and disclosing the markets in which they currently distribute competing products.

Competitors/Markets	Area of Focus	Geographic Distribution
AXP System		
Biosafe/Sepax	· Processing of cord blood	· Direct sales in the U.S. and major European Union (“EU”) markets; local distribution network in Asia Pacific
BioE/PrepaCyte-CB	· Modified manual processing of cord blood	· Worldwide via local distribution networks
Pall Corporation	· Bag sets for manual processing	· U.S. and Europe
OriGen	· Bag for storage of cord blood	· Worldwide direct and via local distribution networks
BioArchive		
Chart Industries	· Cryopreservation of cells and tissue · BioRepository (Storage of cell lines, primarily in vials) · BioPharma (Storage of drugs or vaccines, primarily in vials) · Cord blood banks	· Worldwide via local distribution networks
Taylor-Wharton	· Cryopreservation of cells and tissue. · BioRepository · BioPharma · Cord blood banks	· Worldwide via local distribution networks
MXP System		
Biosafe/Sepax	· Laboratory processing of bone marrow aspirate	· Direct sales in the U.S. and major EU markets; local distribution network in Asia Pacific
COBE Spectra	· Laboratory processing of bone marrow aspirate	· Worldwide
Ficoll-Paque	· Manual processing of bone marrow aspirate	· Worldwide distribution through GEHC
Res-Q 60 BMC		
Terumo Cardiovascular Systems/SmartPReP2 BMAC	· Point of care and laboratory processing of bone marrow aspirate	· Worldwide direct
Biomet/MarrowStim	· Point of care processing of bone marrow aspirate	· Worldwide direct
Biosafe/Sepax	· Laboratory processing of bone marrow aspirate	· Direct sales in the U.S. and major EU markets; local distribution network in Asia Pacific

Res-Q 60 PRP		
Terumo Cardiovascular Systems/SmartPReP2 BMAC	· Point of care of peripheral blood	· Worldwide direct
Biomet/GPS III and the BioCUE	· Point of care processing of peripheral blood	· Worldwide direct

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Clinical Evaluations

We believe that increasing the amount of available clinical data demonstrating the safety and efficacy of our products is a competitive differentiator and will continue to be a major effort of our growth strategy. As such, indication-specific clinical data will be essential for broad market acceptance and regulatory approval.

Below are examples of third party clinical evaluations we are supporting:

Sponsor/Site	Product	Indication	Purpose	Status
TotipotentSC/ Fortis Hospital, New Delhi, India	Res-Q	Critical Limb Ischemia ("CLI") /Peripheral Artery Disease ("PAD")	Purpose is to establish Res-Q BMC safety/efficacy for CLI (Ph1b study)	Underway – Follow up observations
XianWu Hospital, Beijing, China	Res-Q	CLI/PAD	Purpose is to establish Res-Q BMC safety/efficacy for CLI	Underway – Initial patients enrolled
Celling Technologies/ UC Davis	Res-Q	Non-union bone fractures	Purpose is to establish Res-Q BMC safety/efficacy for non-union bone fractures.	Enrollment complete – Follow up observations and assessment
Second University of Naples, Italy	MXP	CLI /PAD	Purpose is to establish MXP BMC safety/efficacy for CLI	Complete: Data analysis and assessment

Research and Development

Our research and development activities in fiscal 2012 focused principally on product enhancements and cost reductions to existing products. The Company also completed a major effort to support the registration and sale of certain assets of the CryoSeal product line to Asahi-Kasei of Japan. Research and development expenses were $3,729,000, $3,003,000 and $5,013,000 for the years ended June 30, 2012, 2011 and 2010, respectively. These totals include expenses related to engineering, regulatory, scientific and clinical affairs.

In fiscal 2013, development will continue to be balanced between existing product enhancements, cost reductions and new product generation. The Company plans to evaluate product line extensions and enhancements for new disposables for the cord blood market and new point of care disposables to accommodate modified cell compositions for new performance requirements and new cell sources. The Company is also planning continued cost reduction work in most areas of disposables; the effects of which will be felt in fiscal 2013 and beyond.

Manufacturing

Our long-term manufacturing strategy is to utilize high quality, low cost contract manufacturers for the routine production of our products. We have outsourced the manufacturing of virtually all our disposable products. During fiscal 2012, the Company successfully leveraged its relationship with key suppliers to lower costs while improving quality and delivery in both the AXP disposables and Res-Q product family. On the medical device side of the business, some devices and major sub-assemblies have been outsourced. The remaining devices and final assemblies are manufactured in-house due to their low volumes making outsourcing impractical.

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The majority of raw materials used to produce the Company's products are readily available from a variety of sources and, as such, the Company does not anticipate any shortage of supply. However, the Company does obtain certain disposable products and custom components from a limited number of suppliers. In the event it becomes necessary to obtain materials from a new supplier, we would first be required to qualify the quality systems and product of that alternative supplier.

Quality System

Our quality system has been created to be harmonized with domestic and international standards and is focused to ensure it 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. These requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the FDA Quality System Regulation ("QSR") (21 CFR 820) administered by the FDA and the applicable rules of other governmental agencies.

We, as well as any contract manufacturers of our products, are subject to inspections by the FDA and other regulatory agencies for compliance with applicable regulations, codified in the QSR which include requirements relating to manufacturing processes, extensive testing, control documentation and other quality assurance procedures. Our facilities have undergone International Organization of Standards ("ISO") 13485:2003 and EU Medical Device Directive ("MDD") (93/42/EEC) inspections and we have obtained approval to CE-Mark our products. Failure to obtain or maintain necessary regulatory approvals to market our products would have a material adverse impact on our business.

Regulatory Strategy

Our regulatory strategy is to be involved in selective clinical programs that generate data to help fuel adoption of our product offerings. We have a quality and regulatory compliance management system that complies with the requirements of the ISO 13485: 2003 standard, the FDA's QSR, the European Union MDD, the Canadian Medical Device Regulations ("SOR 98-282"), and other applicable local, state, national and international regulations.

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable state and foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, installation and servicing, clinical testing, post-market surveillance and approval of our products, including investigational, and commercially-distributed medical devices. These international, national, state, and local agencies set the legal requirements for ensuring our products are safe and effective, as well as manufactured, packaged and labeled in conformity with cGMP established by the FDA, as well as comparable regulations under the MDD of the EU. Virtually every activity associated with the manufacture and sale of our products and services are scrutinized on a defined basis and failure to implement and maintain a Quality Management System could subject the Company to civil and criminal penalties.

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Class III Devices

Before certain medical devices may be marketed in the U.S., they must be approved by the FDA. FDA approval depends on the classification of the device. If the product is a Class III device, the FDA approval process includes the following:

- Extensive pre-clinical laboratory and animal testing,
- Submission and approval of an Investigational Device Exemption ("IDE") application,
- Human clinical trials to establish the safety and efficacy of the medical device for the intended indication, and
- Submission and approval of a Premarket Approval ("PMA") application to the FDA.

Pre-clinical trials include laboratory evaluation, through in vitro and in vivo animal studies, to obtain safety and dosage information about the product to justify future clinical trials in human subjects. Safety testing is performed to demonstrate the biocompatibility of the device, particularly if the device is intended to come into contact with blood or other body tissues. Pre-clinical studies must be performed by laboratories which comply with the FDA's Good Laboratory Practices regulations. The results of the pre-clinical studies are submitted to the FDA as part of an IDE application and are reviewed by the FDA before human clinical trials can begin.

Clinical trials involve the application of the medical device or biologic produced by the medical device to patients by a qualified medical investigator, after approval from an Institutional Review Board ("IRB"). Clinical trials are conducted in accordance with FDA Good Clinical Practice regulations, standards developed by the International Conference on Harmonization ("ICH"), and an approved study protocol that details the objectives of the study, the parameters to be used to monitor participant safety and effectiveness of the product, or other criteria to be evaluated. Each protocol is submitted to the FDA as part of the IDE and each clinical study is conducted only after the approval of the IRB. The IRB considers, among other things, ethical factors, the potential risks to subjects participating in the trial, and the possible liability of the institution. The IRB also approves the consent form signed by the study participants.

Medical device clinical trials are typically conducted as a Phase III clinical trial. A Phase II or combined Phase I/II safety pilot trial may be performed prior to initiating the Phase III clinical trial to determine the safety of the product for specific targeted indications or dosage optimization studies. The FDA, the clinical trial sponsor, the investigators or the IRB may suspend clinical trials at any time if any one of them believes that study participants are being exposed to an unacceptable health risk.

The combined results of product development, pre-clinical studies, and Phase III clinical studies are submitted to the FDA as a PMA application for approval of the marketing and commercialization of the medical device in the U.S. The FDA may deny the approval of a PMA application if applicable regulatory criteria are not satisfied or it may require additional clinical testing. Even if the appropriate data is submitted, the FDA may ultimately decide the PMA application does not satisfy the criteria for approval. Product approvals, once obtained, may be withdrawn if compliance with regulatory standards is not maintained or if safety concerns arise after the product reaches the market. The FDA may require post-marketing testing and surveillance programs to monitor the effect of the medical devices that have been commercialized and has the power to prevent or limit future marketing of the product based on the results of such programs.

Class II Devices

Several of our medical devices, such as the BioArchive, Res-Q 60 PRP and AXP are categorized as Class II. These devices have a lower potential safety risk to the patient, user, or caregiver. A PMA submission is not a requirement for these devices. A similar (but simpler and shorter) process of premarket notification, known as a 510(k) submission, is required to demonstrate that the device is as safe and effective as a substantially-equivalent medical device that has been legally marketed in the U.S. prior to May 29, 1976. Once the FDA has notified the Company that

the product file has been cleared, the medical device may be marketed and distributed in the U.S.

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Class I Devices

Some of our products, such as MXP and Res-Q 60 BMC that have minimal risk to the intended user have been deemed by the FDA as being exempt from FDA approval or clearance processes. While submissions to the FDA are not a requirement for these Class I (low risk) devices, compliance with the QSR is still mandated.

Other U.S. Regulatory Information

Failure to comply with applicable FDA requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production or loss of distribution rights. It may also include the refusal of the FDA to grant approval of a PMA or clearance of a 510(k). Actions by the FDA may also include withdrawal of marketing clearances and possibly criminal prosecution. Such actions, if taken by the FDA, could have a material adverse effect on the Company's business, financial condition, and results of operation.

Each manufacturing establishment must be registered with the FDA and is subject to a biennial inspection for compliance with the Federal Food, Drug, and Cosmetic Act and the QSRs. In addition, each manufacturing establishment in California must be registered with the California State Food and Drug Branch of the California Department of Public Health and be subject to an annual inspection by the State of California for compliance with the applicable state regulations. Companies are also subject to various environmental laws and regulations, both within and outside the U.S. Our operations involve the use of substances regulated under environmental laws, primarily manufacturing and sterilization processes. Workplace safety, hazardous material, and controlled substances regulations also govern our activities. The Company has a California Environmental Protection Agency Identification number for the disposal of biohazardous waste from its research and development biological lab. Our cost associated with environmental law compliance is immaterial. The California State Food and Drug Branch of the California Department of Public Health completed a quality system compliance audit resulting with zero observations in fiscal 2011. The FDA audited ThermoGenesis in fiscal 2012 resulting in two minor non-conformances that were resolved before the end of the audit.

International Regulatory Requirements

Internationally, we are required to comply with a multitude of other regulatory requirements. These regulations may differ from the FDA regulatory scheme. In the EU, a single regulatory approval process has been created and approval is represented by the CE-Mark. 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 to the MDD. Marketing authorization for our products is subject to revocation by the applicable governmental agency or notified body under the EU which are subject to annual audit confirmations with respect to our quality system.

Patents and Proprietary Rights

The Company believes that patent protection is important for its products and potential segments of its current and proposed business. In the U.S., the Company currently holds 11 patents, and has 4 patents pending to protect the designs of products that the Company intends to market.

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Patent positions of medical device companies, including our company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or whether any existing or future patent will be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. 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 the subject matter covered by each of our pending U.S. patent applications or that we were the first to file non-U.S. patent applications for such subject matter.

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 proceeding declared 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.

Third parties may claim that our products infringe on their patents and other intellectual property rights. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product designs, license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third-party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management’s time and effort. Such claims could also cause our customers or potential customers to defer or limit their purchase or use of the affected products until resolution of the claim.

Licenses and Distribution Rights

Golden Meditech
In August 2012, the Company entered into a Product Purchase and International Distributor Agreement with Golden Meditech Holdings Limited (“Golden Meditech”). Under the terms of the agreement, Golden Meditech obtained the exclusive, subject to existing distributors and customers, rights to develop an installed base for the Company’s AXP System in specified countries. This right includes the right to distribute AXP Disposable Blood Processing Sets and use rights to the AXP System, and other accessories used for the processing of stem cells from cord blood. Golden Meditech has rights in the People’s Republic of China (excluding Hong Kong and Taiwan), India, Singapore, Indonesia, and the Philippines and may begin selling once relevant approval has been obtained in each respective country. Additionally, Golden Meditech is subject to certain annual minimum purchase commitments. The term of the agreement is for 5 years with one year renewal options by mutual agreement.

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Asahi

Effective June 30, 2012 Asahi exercised its option to purchase certain intellectual property rights (Assets) of the Company for the CryoSeal System, including, but not limited to, patents and patent applications, trademarks and any and all commercial and technical know-how. The Assets were sold for $2,000,000 which was received in August 2012.

In June 2010, the Company and Asahi entered into an amendment (the "Amendment") of their Distribution and License Agreement, originally effective March 28, 2005. Under the terms of the Amendment, Asahi obtained exclusive rights to distribute the CryoSeal System in South Korea, North Korea, Taiwan, the People's Republic of China, the Philippines, Thailand, Singapore, India and Malaysia. These rights included the exclusive right to market, distribute and sell the processing disposables and thrombin reagent for production of thrombin in a stand alone product. The Company will provide support to Asahi in the form of maintaining manufacturing capabilities of the CryoSeal System until the earlier of when Asahi receives regulatory approval from the Ministry of Health, Labour and Welfare ("MHLW") or December 31, 2012, upon which the Company shall have no further obligation to manufacture. Asahi received regulatory approval on August 31, 2011. Asahi shall continue to have the right to manufacture such products in Japan and shall additionally have a non-exclusive right to manufacture such products outside of Japan and would make royalty payments to the Company for products it manufactures and sells. The Amendment extends the agreement eight years with automatic one year renewals. Asahi paid us a $1,000,000 license fee, which was fully earned and non-refundable as of June 30, 2012. Concurrent with exercising the purchase option, the terms and conditions of the Amendment terminated.

Arthrex

In January 2012, the Company entered into an agreement with Arthrex. Under the terms of the agreement, Arthrex obtained exclusive rights in certain territories to sell, distribute and service the Company's Res-Q60 System technology for use in the preparation of autologous PRP and BMC for sports medicine applications and orthopedic procedures. The Company granted Arthrex a limited license to use the Company's intellectual property as part of enabling Arthrex to sell the products. Arthrex will purchase products from the Company to distribute and service at certain purchase prices, which may be changed after an initial period. The agreement contains purchase minimums that must be met on a yearly basis for Arthrex to maintain its exclusivity. Arthrex also pays a certain royalty rate based upon volume of products sold. The term of the agreement is for 5 years, subject to an extension right of an additional 3 years.

Nanshan

In November 2010, the Company and Nanshan entered into an International Distributor Agreement. Under the terms of the agreement, Nanshan obtained rights to sell, distribute, and service the Company's MXP and Res-Q product lines in the People's Republic of China and Hong Kong (not including Taiwan). The term of the agreement is for four years, subject to extension rights. Nanshan was granted restricted common stock upon execution of the agreement in the amount of 0.5% of the total outstanding common stock of the Company which equaled 70,117 shares. Nanshan has the right to additional grants of restricted common stock of the Company over the term of the agreement in an amount up to 806,000 shares upon the achievement of certain milestones up to $43 million in cumulative sales.

BioParadox LLC ("BioParadox")

In October 2010, the Company and BioParadox entered into a License and Distribution Agreement. Under the terms of the agreement BioParadox obtained exclusive world-wide rights for the use, research and commercialization of the Res-Q technology in the production of PRP in the diagnosis, treatment and prevention of cardiovascular disease. The term of the agreement will depend on the satisfaction by BioParadox of certain milestones, or the payment of extension fees. If certain delivery or financial metrics are not maintained, the agreement requires the Company to place in escrow the detailed instructions for manufacturing the products. BioParadox will have the right to manufacture the product for the cardiac field for the term of the agreement in the event of a default by the Company or

if certain on-time delivery metrics or supply requirements are not met.

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Cord Blood Registry Systems, Inc. (“CBR”)
In June 2010, the Company and CBR entered into a License and Escrow Agreement as a method to provide assurances to CBR of continuity of product delivery and manufacturing for CBR’s business, and to alleviate concerns about long term supply risk. We are the sole provider for CBR of devices and disposables used in the processing of cord blood samples in CBR’s operations. Under the agreement, the Company granted CBR a non-exclusive, royalty-free license to certain intellectual property necessary for the potential manufacture and supply of AXP devices and certain AXP disposables. The license is for the sole and limited purpose of manufacturing and supplying the AXP and related disposables for use by CBR. The licensed intellectual property will be maintained in escrow and will be released to and used by CBR if and only if the Company defaults under the Agreement. Default occurs if the Company (1) fails to meet certain positive cash flow metrics for each rolling quarterly measurement period beginning December 31, 2010, except where the following two measures are met, (2) failure to meet cash balance and short-term investments of at least $6 million at the end of any given month, or (3) failure to meet a quick ratio of 2 to 1 at the end of any given month. The Company is in compliance at June 30, 2012.

On August 22, 2006, the Company announced that GEHC and CBR, the world’s largest family cord blood bank, signed a multi-year contract to supply CBR with the Company’s AXP System. In conjunction with this agreement, the Company signed a Product Development and Supply Assurance Agreement with CBR which assures the supply of AXP products for a 15-year period.

GEHC
In May 2010, the Company and GEHC signed a non-exclusive distribution agreement for the Res-Q 60 BMC System. Under the agreement, GEHC has the right to distribute the Res-Q 60 BMC in the U.S., excluding orthopedic indications, Canada and 19 European countries. The agreement has a two and a half year term, with automatic one year renewals, unless terminated by either party with six months advance notice. The Agreement provides for a price reduction mechanism should the Company fail to meet certain product quality and delivery metrics. The parties mutually agreed to terminate effective December 31, 2011.

In January 2010, the Company and GEHC also signed an amendment (the "Amendment") to extend their Amended and Restated International Distribution Agreement, effective February 1, 2010. Under the terms of the Amendment, the contract runs through July 31, 2012, GEHC will continue to distribute the AXP product line in the United States, Canada and approximately 25 countries throughout the world, excluding certain countries in Latin America, Asia, CIS, Eastern Europe and the Middle East. The parties will implement a Joint Operating Committee to oversee, review and coordinate marketing and sales activities and performance of the parties. GEHC will provide incremental funding for marketing support and market research beyond its previous commitments. The Amendment provides incentives for both parties related to sales success, product quality and delivery. The Amendment will automatically renew for one year terms unless terminated at least six months prior to the end of the then current term. Under the original agreement, signed October 13, 2005, the Company received fees for the rights granted under the agreement. The amounts received are being recognized as revenue on the straight-line method over the initial five year term of the contract.

In January 2012, the Company and GEHC signed an amendment (the “2012 Amendment”), effective August 1, 2012. Under the terms of the 2012 Amendment, GEHC will continue to distribute the AXP product line in the United States and Canada. The purchase prices for the products are fixed. The 2012 Amendment will automatically renew for one year terms unless terminated by either party with 90 days notice.

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Fenwal, Inc. (“Fenwal”)
In March 2010, the Company and Fenwal signed a five-year distribution agreement. Under the agreement, Fenwal will have exclusive rights to market and distribute the AXP System and BioArchive System for use in cord blood processing and storage in China, India and Japan.

Celling Technology, LLC. (“Celling”)
In September 2008, the Company and Celling signed a distribution agreement for the Company’s MXP and Res-Q 60 BMC product lines. The distribution rights are for the field of use in orthopedic intraoperative or point of care applications. The five-year agreement provides Celling with an initial two-year period of exclusive distribution rights in the U.S. and non-exclusive distribution rights throughout the rest of the world, excluding Central and South America, Russia and certain Eastern European countries. The exclusivity period and field of use may be extended under certain circumstances. The parties amended the agreement in July 2009 to provide shared funding for clinical studies to demonstrate the clinical effectiveness of the products in orthopedic applications. The parties amended the agreement in January 2012. The revised distribution rights are world-wide, non-exclusive within field of use for the MXP and exclusive within field of use in the United States and non-exclusive in Mexico for the Res-Q.

New York Blood Center (“NYBC”)/Pall Medical
In March 1997, the Company and NYBC, as licensors, entered into a license agreement with Pall Medical, a subsidiary of Pall Corporation, as a Licensee through which Pall Medical became the exclusive worldwide manufacturer (excluding Japan) for a system of sterile, disposable containers developed by the Company and NYBC for the processing of hematopoietic stem cells sourced from placental cord blood (“PCB”). The system is designed to simplify and streamline the harvesting of stem cells from umbilical cord blood and the manual concentration, cryopreservation (freezing) and transfusion of the PCB stem cells while maintaining the highest stem cell population and viability from each PCB donation. In May 1999, the Company and Pall Medical amended the original agreement, and the Company regained the rights to distribute the bag sets outside North America and Europe under the Company’s name. In fiscal 2012, the Company and NYBC signed an agreement which provides for the equal sharing of royalties between the two parties effective July 1, 2011, except for calendar 2012, in which NYBC shall receive 75% and the Company 25%.

Backlog

Our backlog was $1,528,000 and $1,118,000 as of June 30, 2012 and 2011, respectively. Our backlog consists of product orders for which a customer purchase order has been received and is scheduled for shipment within the next twelve months. Orders are subject to cancellation or rescheduling by the customer, sometimes with a cancellation charge. Due to timing of order placement, product lead times, changes in product delivery schedules and cancellations, and because sales will often reflect orders shipped in the same quarter received, our backlog at any particular date is not necessarily indicative of sales for any succeeding period.

Employees

As of June 30, 2012, the Company had 68 employees, 30 of whom were engaged in manufacturing operations and quality control, 13 in research and new product development, regulatory affairs, clinical and scientific affairs, 13 in sales, marketing and customer service, and 12 in administration. The Company also utilizes temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are represented by a collective bargaining agreement, nor have we experienced any work stoppage.

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Foreign Sales and Operations

For fiscal 2012, foreign sales were $8,240,000 or 43% of net revenues. For fiscal 2011, foreign sales were $9,655,000 or 41% of net revenues. For fiscal 2010, foreign sales were $9,261,000 or 40% of net revenues.

Our AXP and MXP bag sets are manufactured by a contract supplier in Costa Rica and our manual cord blood disposable bag set that can be used with the BioArchive System is manufactured by a contract supplier in Mexico.

Where you can Find More Information

The Company is required to file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other information with the Securities and Exchange Commission ("SEC"). The public can obtain copies of these materials by visiting the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549, by calling the SEC at 1-800-732-0330, or 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, the Company will make copies available to the public free of charge through its website, www.thermogenesis.com. The information on the Company's website is not incorporated into, and is not part of, this annual report.

ITEM 1A. RISK FACTORS

An investment in ThermoGenesis' 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 report. The risks and uncertainties described below are not the only ones facing ThermoGenesis. Additional risks and uncertainties that we are not aware of or focused on or that we currently deem immaterial may also impair ThermoGenesis' business operations. This 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 Business

Our Future Revenue Growth is Dependent on our New Products Being Accepted and Our Existing Products being Accepted for New Indications or into New Markets and We Are Not Sure They Will Be Accepted. The acceptance of our products into new markets or for new indications will depend upon the medical community and third-party payers accepting the products as clinically useful, reliable, accurate, and cost effective compared to existing and future products or procedures. Acceptance will also depend on our ability to adequately train technicians on how to use our existing and future products. Even if our products are released for sale, their use may not be recommended by the medical profession or hospitals unless acceptable reimbursement from healthcare and third party payers is available. Failure of these products to achieve significant market share could have material adverse effects on our long term business, financial condition, and results of operation.

Outcomes of Pending or Future Clinical Trials or Evaluations May be Negative and the Regenerative Medicine Market May not Expand, or May Not Expand in the Areas Targeted by our Products. The marketing and sales of new products may depend on successful clinical trial or evaluation outcomes in the regenerative medicine areas targeted by our products and the approval of regulators. Clinical trials also represent a significant expenditure of resources. Negative clinical trial results in connection with our products or in the areas targeted by the Company could negatively impact regulatory approval or market acceptance of our products. Unfavorable clinical trials or failure of

study results to obtain regulatory approval or target areas with successful clinical trials, could have material adverse effects on our long term business, financial condition, and results of operations.

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A Significant Portion of our Revenue is Derived from Customers in Foreign Countries. We may Lose Revenues, Market Share, and Profits due to Exchange Rate Fluctuations, Political and Economic Changes Related to our Foreign Business. In the year ended June 30, 2012, sales to customers in foreign countries comprised approximately 43% of our revenues. This compares to 41% in fiscal 2011. 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 our foreign customers are willing to pay, and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial position and results.

The Loss of a Significant Distributor or End User Customer may Adversely Affect our Financial Condition and Results of Operations. Revenues from one significant distributor comprised 29% of our revenues for the year ended June 30, 2012 and approximately 80% of the significant distributor's revenue came from one customer. The loss of a large end user customer or distributor may decrease our revenues.

We are Heavily Reliant on a Single Distributor to Market and Sell our AXP Products. We are Heavily Reliant on a Single Distributor to Market and Sell our MXP and Res-Q Systems. We have limited control over our distributor's sales and marketing efforts. Although we have added distributors in other territories and other indications, we must manage our distribution network effectively to gain additional revenue and gross profit. Since the AXP System and Res-Q products are a significant portion of our revenues and projected revenue growth, a delay or failure by our distributors to successfully market these products may decrease our future revenues and competitive advantage.

Our Inability to Successfully Identify and Complete Acquisitions or Successfully Integrate Any New Products Could Have a Material Adverse Effect on Our Business. Our current business strategy includes the acquisition of other companies, technologies and products that position us to move into greater markets and larger revenue streams. Promising acquisitions are difficult to identify and complete for a number of reasons, including competition among prospective buyers and the need for regulatory, including antitrust, approvals. We would seek to acquire based on time and risks associated with moving towards our strategic markets, as opposed to the risks and costs associated with trying to organically grow or develop those components. We may not be able to identify and successfully complete transactions. Any acquisitions we may complete may be made at a substantial premium over the fair value of the net identifiable assets. Further, we may not be able to integrate any acquired businesses successfully into our existing businesses, make such businesses profitable, or realize anticipated cost savings or synergies, if any, from these acquisitions, which could adversely affect our business.

Risks Related to Our Operations

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 devote 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.

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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 United States 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 increases 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 our 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 European Union 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 European Union 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. 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. Other countries, such as China, have enacted or may enact laws or regulations similar to RoHS. While we have implemented a compliance program to ensure our product offering meets 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. Additionally, if we were found to be non-compliant with any such rule or regulation, we could be subject to fines, penalties and/or restrictions imposed by government agencies that could adversely affect our operating results.

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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. There are no assurances we will be successful 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 Disposable Products and Custom Components May Impact the Production Schedule. The Company obtains certain disposable products and custom components from a limited number of suppliers. If the supplier raises the price or discontinues production, the Company 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.

Our AXP Revenue is Indirectly Subject to Customer and Distributor Inventory Requirements and Continuity of Inventory Purchasing. The GEHC AXP distribution agreement expires July 31, 2013, with automatic one year renewals, unless terminated by either party at any time with a 90 day advance notice. Contract termination would cause the sale of AXP disposable product inventory by GEHC, which would result in a surplus of product availability in the market. During the sell-off of product inventory by GEHC, our revenues could decline significantly, which would have a material adverse effect on our financial performance during those periods. We estimate the amount of such a revenue decline could be up to $1.5 million per quarter over two consecutive quarters. If termination occurred, we would attempt to mitigate the financial impact on working capital requirements by seeking other distribution partners, modifying customer contracts or seeking additional debt or equity financing.

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Failure to Meet Certain Financial Covenants could Decrease our AXP Revenues. Under certain license and escrow agreements, if we fail to meet certain financial covenants, other companies 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.

Failure to Retain or Hire Key Personnel May Adversely Affect Our Ability to Sustain or Grow Our Business. Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, clinical, regulatory, sales, marketing and managerial personnel. Our future success partially depends upon the continued services of key technical and senior management personnel. Our future success also depends on our continuing ability to attract, retain and motivate highly qualified managerial and technical personnel. The inability to retain or attract qualified personnel could have a significant negative effect upon our efforts and thereby materially harm our business and future financial condition.

All of our Operations are Conducted at a Single Location. Any Disruption at our Facility could Delay Revenues or Increase our Expenses. All of our operations are conducted at a single location although we contract the manufacturing of certain devices, disposables and components. We take precautions to safeguard our facility, 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.

Risks Related to Our Industry

We and our Customers are Subject to Various Political, Economic and Regulatory Changes in the Healthcare Industry that Could Force us to Modify how we Develop and Price our Components, Affect our Manufacturing Capabilities and Services, and Could Harm our Business. The healthcare industry is highly regulated and is influenced by changing political, economic and regulatory factors. Federal and state legislatures have periodically considered programs to reform or amend the U.S. healthcare system at both the federal and state levels. Regulations affecting the healthcare industry in general, and the medical device industry in particular, are complex, change frequently and have tended to become more stringent over time. In addition, these regulations may contain proposals to increase governmental involvement in healthcare, lower reimbursement rates or otherwise change the environment in which healthcare industry participants, including medical device companies, operate. A change in regulations could impair our ability to operate profitably. In addition, any failure by us to comply with applicable government regulations could also result in the cessation of portions or all of our operations, impositions of fines and restrictions on our ability to continue or expand our operations.

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 inappropriately interpret these quality system requirements and regulations may subject the Company to delays in production while it corrects deficiencies found by the FDA, the State of California, or the Company’s 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) product 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.

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Future Regulatory Changes May Affect Our Business. On August 3, 2010, the FDA released for public comment two internal working group reports with numerous recommendations (1) to improve the 510(k) process, and (2) to utilize science in regulatory decision making in ways that encourage innovation yet maintain predictability. In addition, the Institute of Medicine ("IOM") has conducted an independent evaluation of the 510(k) program. We anticipate significant changes will result in the way 510(k) programs will operate and the data requirements, including clinical data, to obtain 510(k) clearance or PMA approval. We cannot predict what effect these reforms will have on our ability to obtain 510(k) clearances or PMA approvals in a timely manner or the effect on our business

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 U.S. 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 Will be Subject to Regulation in Foreign Countries. In cooperation with our distribution partners, we intend to 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.

Competition in Our Industry is Intense and Will Likely Involve Companies with Greater Resources than We Have. We hope to develop a competitive advantage in the medical applications of our products, but there are many competitors that are substantially larger and possess greater financial resources and more personnel than we do. Our current principal market is cord blood banks, and with regards to the BioArchive and AXP Systems, numerous larger and better-financed medical device manufacturers may choose to enter this market as it develops.

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Influence By the Government and Insurance Companies May Adversely Impact Sales of Our Products. Our business may be materially affected by continuing efforts by government, third party payers such as Medicare, Medicaid, and private health insurance plans, to reduce the costs of healthcare. For example, in certain foreign markets the pricing and profit margins of certain healthcare products are subject to government controls. In addition, increasing emphasis on managed care in the U.S. will continue to place pressure on the pricing of healthcare products. As a result, continuing efforts to contain healthcare costs may result in reduced sales or price reductions for our products. To date, we are not aware of any direct impact on our pricing or product sales due to such efforts by governments to contain healthcare costs, and we do not anticipate any impact in the near future.

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 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 for $3,000,000 and a general liability policy that includes product liability coverage of $1,000,000 per occurrence and $2,000,000 per year in the aggregate. 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 since Our Inception and Losses May Continue. Except for net income of $11,000 for fiscal 1994, we have not been profitable since our inception. For the fiscal year ended June 30, 2012, we had a net loss of $4,986,000 and an accumulated deficit at June 30, 2012, of $111,105,000. 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.

We May Need to Raise Additional Capital in the Future to Fund Our Operations. We May be Unable to Raise Funds When Needed or on Acceptable Terms. During the year ended June 30, 2011, we raised net proceeds of $3.9 million through a public offering of common stock and warrants. As of June 30, 2012, we had a cash balance of $7,879,000. Based on our cash balance, historical trends, planned cost reductions and future revenue projections, we believe our current funds are sufficient to provide for our projected needs to maintain operations and working capital requirements for at least the next 12 months. However, we may be required to seek additional capital during the next 12 months should we not be able to maintain compliance with, or obtain forbearance of financial covenants in the CBR License and Escrow Agreement or if actual sales do not meet expectations, or product development, marketing and production costs increase significantly. We may also raise money for strategic initiatives which may be dilutive. Any additional equity financings may be dilutive to our existing stockholders.

The Continuing Economic Downturn in the U.S. and World Financial and Securities Markets Could Have a Material Adverse Effect on our Customers' Business and Affect our Operations and Revenues. Our business is affected by general economic conditions and related uncertainties affecting markets in which we operate. The current economic conditions including the lingering effects of the global recession could adversely impact our business in fiscal year 2013 and beyond, resulting in:

- reduced demand for some of our products;
- increased rate of order cancellations or delays;
- increased risk of excess and obsolete inventories; and
- increased pressure on the prices for our products and services.

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Demand for most of our products depends on capital spending policies of our customers and on government funding policies. Our customers include stem cell banks (both private and non-profit), laboratories, universities, healthcare providers, government agencies and public and private research institutions. Many factors, including public policy spending priorities, available resources and product and economic cycles, have a significant effect on the capital spending policies of these entities. These policies in turn can have a significant effect on the demand for our products. Further, the current economic crisis heightens the risk that our customers may lack the funding or credit facilities that they may have previously used for acquiring our products. Such credit or funding restrictions could delay or lower our future revenues.

The Preparation of our Consolidated Financial Statements in Accordance with U.S. Generally Accepted Accounting Principles Requires Us to Make Estimates, Judgments, and Assumptions that may Ultimately Prove to be Incorrect. The accounting estimates and judgments that management must make in the ordinary course of business affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the periods presented. If the underlying estimates are ultimately proven to be incorrect, subsequent adjustments could have a material adverse effect on our operating results for the period or periods in which the change is identified. Additionally, subsequent adjustments could require us to restate our consolidated financial statements. Restating consolidated financial statements could result in a material decline in the price of our stock.

Risks Related to Our Common Stock

Trading Prices for our Common Stock Have Been, and May Continue To Be, Volatile. The trading price of our common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, many of which are beyond our control, including, among other things:

- Variations in operating results;
- Regulatory actions, such as product recalls;
- Governmental regulatory acts;
- Biological or medical discoveries;
- Changes in earnings estimates by securities analysts; and
- Market conditions in our industry and the economy as a whole.

If our revenues or operating results fall below the expectations of securities analysts and investors, the price of our common stock would likely decline. In the last few years, the stock market experienced extreme price and volume fluctuations due to the unprecedented turmoil and upheaval of the credit markets and the financial services industry, which have particularly affected the market prices for emerging biotechnology and medical device companies, and has adversely affected the market price of our common stock.

If the Price of our Common Stock Does Not Meet the Requirements of the NASDAQ Capital Market Stock Exchange ("NASDAQ"), Our Shares may be Delisted. Our Ability to Publicly or Privately Sell Equity Securities and the Liquidity of Our Common Stock Could be Adversely Affected if We Are Delisted. The listing standards of NASDAQ provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. Delisting from NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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We Do Not Pay Cash Dividends. We have never paid any cash dividends on our common stock and may not pay cash dividends in the future. Instead, we intend to apply earnings 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.

ITEM 1B.UNRESOLVED STAFF COMMENTS

None.

ITEM 2.PROPERTIES

The Company leases a facility with approximately 28,000 square feet of space located in Rancho Cordova, California. Approximately 50% of the facility is devoted to warehouse space and manufacturing of products, including 500 square feet for a clean room. The other 50% is comprised of office space, a biologics lab and a Research and Development lab. Under the current amendment, the lease expires in October 2016.

At fiscal year end, the Company did not own or lease any other facilities.

ITEM 3.LEGAL PROCEEDINGS

The Company and its property are not a party to any pending material legal proceedings. In the normal course of operations, the Company may have disagreements or disputes with employees, vendors or customers. These disputes are seen by the Company’s management as a normal part of business, and there are no currently pending actions or threatened actions that management believes would have a significant material impact on the Company’s financial position, results of operations or cash flows.

ITEM 4.MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

The Company's common stock, $0.001 par value, is traded on NASDAQ under the symbol KOOL. The following table sets forth the range of high and low bid prices for the Company's common stock for the past two fiscal years as reported by NASDAQ.

Fiscal 2012	High	Low	Fiscal 2011	High	Low
First Quarter (Sep. 30)	$ 2.13	$ 1.20	First Quarter (Sep. 30)	$ 2.89	$ 1.76
Second Quarter (Dec. 31)	$ 1.29	$ 0.71	Second Quarter (Dec. 31)	$ 3.76	$ 2.32
Third Quarter (Mar. 31)	$ 1.15	$ 0.70	Third Quarter (Mar. 31)	$ 3.82	$ 1.97
Fourth Quarter (June 30)	$ 0.95	$ 0.80	Fourth Quarter (June 30)	$ 2.47	$ 1.91

The Company has not paid cash dividends on its common stock and does not intend to pay a cash dividend in the foreseeable future. There were approximately 277 stockholders of record on June 30, 2012 (not including street name holders).

ITEM 6.SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this report.

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ThermoGenesis Corp.
Five-Year Review of Selected Financial Data

	Year Ended June 30,				
Summary of Operations	2012	2011	2010	2009	2008
Net revenues	$19,023,000	$23,400,000	$23,088,000	$19,799,000	$21,946,000
Cost of revenues	(12,690,000)	(14,563,000)	(15,643,000)	(14,106,000)	(14,976,000)
Gross profit	6,333,000	8,837,000	7,445,000	5,693,000	6,970,000
Selling, general and administration	(7,983,000)	(8,669,000)	(7,686,000)	(9,249,000)	(10,165,000)
Research and development	(3,729,000)	(3,003,000)	(5,013,000)	(5,222,000)	(7,172,000)
Interest and other income, net	393,000	268,000	61,000	228,000	1,186,000
Net loss	$(4,986,000)	$(2,567,000)	$(5,193,000)	$(8,550,000)	$(9,181,000)
Per share data:					
Basic and diluted net loss per common share	$(0.30)	$(0.17)	$(0.37)	$(0.61)	$(0.66)

Balance Sheet Data	2012	2011	2010	2009	2008
Cash, cash equivalents and short term investments	$7,879,000	$12,309,000	$10,731,000	$15,631,000	$25,287,000
Working capital	$14,034,000	$18,976,000	$16,587,000	$20,923,000	$29,978,000
Total assets	$21,080,000	$24,399,000	$24,030,000	$27,655,000	$38,282,000
Total liabilities	$5,182,000	$			