THERMOGENESIS CORP
Form 10-K
September 04, 2013

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, 2013

Commission File Number: 000-16375

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

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, 2012 (the last trading day of the second quarter) was $13,762,000 based on the closing sale price on such day.

As of August 28, 2013, 16,660,962 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the registrant's proxy statement for its 2013 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

Table of Contents

TABLE OF CONTENTS

Table of Contents
PART I

ITEM 1. BUSINESS

Business Overview

ThermoGenesis Corp. (the "Company", "we", "our") is a leading designer and supplier of clinical technologies for processing, storage and administration of stem cells used in the practice of regenerative medicine. Regenerative medicine is an emerging field using cell-based therapies to treat a number of clinical 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, peripheral 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 growing market.

Regenerative medicine represents a new paradigm in human health and the treatment of disease and injury. It is uniquely capable of altering the fundamental mechanisms of disease and through translational medicine, we are better understanding our body's ability to heal itself. Harnessing, concentrating and directing that ability for the treatment of acute and chronic conditions has demonstrated curative potential never before seen.

We believe our enabling tools and technologies are foundational to the automation and commercialization of regenerative medicine practiced at the point-of-care. However, global regulatory bodies are increasing their oversight and placing a greater burden of proof on device manufacturers to demonstrate the safety, consistency, predictability and effectiveness of in-vivo use from the cells produced by our devices. In a laboratory or manufacturing setting the consistency and predictability are controlled by the rigorous validated procedures and test methods around their Good Manufacturing Practices ("cGMP"). A point-of-care product is used by and in a physician managed environment where the safety and well-being of the patient is the key principle. Therefore enabling the physician to ensure a point-of-care product delivers a clinically effective cell therapy meeting current cGMP quality standards requires rigorous precision and consistent control mechanisms of all variables at the patient bed side during a procedure, including but not limited to cell temperatures, dosing, cell viability, and viscosity. All of these control processes must be simple, rapid, and cost effective to become a routine treatment modality.

To capture the true potential of our technological assets and know-how across the entire value stream of regenerative medicine, we believe we must broaden our clinical capabilities and extend our presence into point-of-care to ensure a level of consistency and control across multiple indications and delivery settings. In doing so, we will evolve into a fully integrated regenerative medicine company capable of developing and delivering safe and consistently efficacious, commercially viable autologous cell therapies physicians can deliver with ease, in less than 60 minutes, at the patient's bed-side. We believe this transformation will substantially expand the company's addressable markets to include billion dollar patient populations within the vascular and orthopedic markets.

Table of Contents

Consistent with this strategy, on July 15, 2013, we entered into an Agreement and Plan of Merger and Reorganization with TotipotentRX Corporation ("TotipotentRX"), a privately held California Corporation, and its principle shareholders. TotipotentRX specializes in developing cell-based therapies in the field of regenerative medicine and is the exclusive provider of cell-based product and services to the Fortis Healthcare System. The combined company, which will be called Cesca Therapeutics, is expected to become one of the first fully integrated regenerative medicine companies in the world, developing clinically validated, commercially scalable, point-of-care cell therapies for major therapeutic markets, including orthopedic, cardiovascular and neurologic indications. Our consummation of the merger with TotipotentRX is subject to, among other things, approval by our stockholders and TotipotentRX shareholders.

Our Solutions

We believe our automated products significantly enhance the safety, reproducibility 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 to the development of 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 efficiency 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 2013:

·Received Registration Approval for AXP in China

Our AXP received registration approval from China's State Food & Drug Administration enabling the Company to initiate commercial distribution in China.

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

We signed an exclusive, subject to existing distributors and customers, agreement to distribute the AXP Disposable Blood Processing Set in China and several southeast Asian countries.

·AXP System Selected by New Customers in United Kingdom and Portugal

Our AXP system was selected by United Kingdom's NHS Blood and Transplant ("NHSBT") which manages six cord blood collection facilities and operates a cord blood bank laboratory under a five-year exclusive agreement and Crioestaminal, a leading cord blood stem cell bank in Portugal.

·Sold ThermoLine Product Line to Helmer Scientific

The sale of our ThermoLine plasma freezer and thawer product line was part of our growth strategy to focus our core business on developing enabling technologies for the stem cell regenerative medicine market.

·Signed New Cord Blood Products Distribution Agreements

We signed three integrated distribution agreements with Concessus, HVD Biotech Vertriebs GmbH and Comercia Exportacao e Importacao de Materials Medicos to provide a customer-centric focus that incorporates sales, service and support for our cord blood product portfolio.

Table of Contents
Market Overview

Regenerative Medicine Market
The regenerative medicine market continues to experience meaningful advances in clinical efficacy, the number of FDA therapeutic product approvals 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 the 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, modify, cryopreserve, store or administer cells as the therapeutic agent. These cells can be stem cells, modified autologous cells, i.e. cell vaccines, and cell carrier packages for therapeutic cytokines and growth factors, i.e. platelets. Key success factors include:

·Target or purified cell recovery rates
·Efficiency of cell processing, including time
·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 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, predictable recovery rates, and speed of processing. These market requirements must be considered and translated into product features and benefits for successful market adoption.

The availability of therapeutic cells, including stem cells, at the point-of-care enables physicians to apply cells across an array of applications. In the United States the regulations governing the use of tissue and cells are defined in the Public Health Services Act under Sections 351 and 361. Cells intended to treat patients which are autologous, minimally manipulated, homologous and not combined with another regulated article are categorized as 361 agents and may be prescribed by physicians without a PreMarket Approval (“PMA”) or Biological License Approval (“BLA”). All other cell products are therefore regulated as 351 tissue or cell treatments and can only be used within an approved clinical trial or as defined in the PMA/BLA license. Therefore, many physicians are now choosing to study patient outcomes to understand the benefits of the therapeutic cells under their own independently-sponsored and regulated studies. Such research efforts are growing and already include studies using cells derived from bone marrow, peripheral blood, cord blood, adipose, and placenta sources in diverse areas such as spinal fusion, non-healing fractures, wound healing, radiation injury, breast reconstruction and augmentation, cardiovascular applications, peripheral vascular disease and liver disease among many others.

In terms of the largest market opportunities, the current forecast is that commercial products will come first in orthopedics, cardiology, skin and wound healing, diabetes and central nervous system disorders. With initiatives like the Armed Forces Institute for Regenerative Medicine (“AFIRM”), the acceleration of therapy development for the treatment of wounded warriors could create more rapid adoption for general patient populations due to the significant clinical research dollars and highly-collaborative nature of the AFIRM program.[1]

4

Table of Contents

Market Size

Market estimates for regenerative medicine include pathologies that affect vast numbers of people of all age groups.

Below is illustrated the 2009 to 2018 forecast for the global markets in tissue engineering, cell therapy and transplantation, by clinical area.

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[1]Excerpts from Oct. 2012 white paper: A Private Investor Guide to Regenerative Medicine Unique Opportunities in an Emerging Field- www.regenerativemedicinefoundation.org.

Table of Contents

Regenerative medicine can capitalize on the trends surrounding cost containment. As healthcare costs rise, there has been a similar boost in efforts to limit expenses by employers, payers and the government. If regenerative medicine therapies can provide a cost-effective alternative to current treatments, physicians and hospitals might have an incentive to more readily adopt them. Again, the need for baseline clinical and cost data, and more comprehensive studies, is as critical as funding the research itself.

Overall demographics make a compelling case for examination of regenerative medicine as a field of the future. The demands of an aging population places ever increasing demands on healthcare delivery requirements and cost, and most prominently shows up as in the dramatic percentage of gross domestic product ("GDP") spending on healthcare. The U.S. alone spent an estimated $2.2 trillion, or 16% of GDP, on healthcare in 2006, a figure that is expected to reach $4.1 trillion by 2016. By 2040, the senior citizen population will double in the U.S. to about 70 million and about 25% of GDP could be devoted to healthcare by that time.[1]

Cord Blood Market

Since the first cord blood transplant was carried out in 1988, stem cells derived from umbilical cord blood have been used in more than 30,000 transplants worldwide to treat a wide range of blood diseases, genetic and metabolic disorders, immunodeficiencies and various forms of cancer. Today over 4,000 cord blood transplantations are performed annually and that number is expected to grow.

Cord blood banks now exist in nearly every developed country, as well as several developing nations.

Cord blood banking can be divided into 3 segments; private, public and public/private (hybrid) with private companies serving individual families and public banks serving the broader public. The hybrid private/public banks use revenue generated from patrons from their private sector to fund a public bank.

The number of units a cord bank receives is somewhat related to how many sites from which they receive units. Some cord blood banks may receive units only from nearby hospitals and birthing centers, while others allow mail-in units from a wide geographic region via courier services.

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 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.

Table of Contents

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 now been purchased by over 110 umbilical cord blood banks in over 35 countries for the archiving, cryopreservation and storage of 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.

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.

Sales and Distribution Channels

We market and sell our products primarily through independent distributors. During fiscal 2013, we employed new integrated distribution arrangements whereby our suite of cord blood products are distributed into specific territories by a single distributor. The new arrangements have improved the customer experience by streamlining their product, service and support needs through a single point of contact.

Table of Contents

Business Development

We continue to have encouraging discussions with multiple potential partners aimed at identifying and developing growth opportunities beyond our current product offerings and geographies. These include leveraging our technology platforms to create new products for our existing markets, cord blood and bone marrow processing and adjacent markets such as adipose tissue processing. In addition, we seek to develop products that serve more of 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 stockholder value through the advancement of existing products into new applications and through the development and commercialization of new products. See Item 1A “Risk Factors”.

Competition

The regenerative medicine and medical device industries are characterized by rapidly evolving technology and intense competition from medical device companies, pharmaceutical companies and stem cell companies operating in the field of cardiac, vascular, orthopedics and neural medicine. The primary competitors for our current product mix include automated cell processing systems from BioSafe, TerumoBCT (formerly COBE), non automated processing from Terumo Cardiovascular Systems, Biomet, CytoMedix and cell cryopreservation storage systems from Chart Industries and Taylor-Wharton.

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 element 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 60 BMC safety/efficacy for CLI (Ph1b study)	Underway – Follow up observations
Celling Technologies, LLC “Celling”/ UC Davis	Res-Q	Non-union bone fractures	Purpose is to establish Res-Q 60 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

Table of Contents

Research and Development

Our research and development activities in fiscal 2013 focused on developing or expanding contract manufacturing capabilities for low cost disposables and building on our product quality leadership position. Significant investments were also made to support product registration in China, Taiwan, India and South Korea. In fiscal 2014, the Company plans to introduce new features and enhancements to the AXP and MXP platforms. Research and development expenses were $2,991,000, $3,729,000 and $3,003,000 for the years ended June 30, 2013, 2012 and 2011, respectively. These totals include expenses related to engineering, regulatory, scientific and clinical affairs.

Manufacturing

Our long-term manufacturing strategy continues to be utilizing high quality, low cost contract manufacturers for production of routine products while maintaining in-house manufacturing capabilities for complex, low volume devices that depend upon core technologies. The Company has completed virtually all of its major outsourcing programs.

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") 13485:2012 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: 2012 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.

Table of Contents

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 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"), and in certain jurisdictions having authorization for the trial under investigational use. Medical device trials which are conducted inside the U.S. are subject to FDA preapproval under either 21 C.F.R. Part 812, known as IDE application, or 21 C.F.R. Part 312, known as Investigation New Drug ("IND") application. Clinical trials conducted outside the U.S., and the data collected therefrom, are allowed per the requirements outlined in 21 C.F.R. Part 312.120.

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.

Table of Contents

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 substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate. 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.

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.

Table of Contents

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. The Company has received notices of issuance for three of the pending U.S. applications. It is Company policy to seek foreign patent protection in relevant markets around the world.

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.

Licenses and Distribution Rights

Cord Blood Registry Systems, Inc. (“CBR”)

On July 26, 2013, we entered into an extension addendum to the License and Escrow Agreement to amend and reduce the minimum cash and short-term investments balance to $3,500,000 at any month end through October 31, 2013. Thereafter, it reverts back to $6,000,000 at any month end.

On February 6, 2013, we entered into an amendment to the License and Escrow Agreement to amend and reduce the financial covenants that we must meet in order to avoid an event of default. The modified covenants include a minimum cash and short-term investments balance of not less than $4,000,000 at any month end through June 30, 2013, which reverts back to $6,000,000 at any month end, and a quick ratio of 1.75 to 1 at the end of any month.

The Company is in compliance with the covenants at June 30, 2013.

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 to 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. Originally, default occurred 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.

12

Table of Contents

On August 22, 2006, the Company announced that GE Healthcare ("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.

Golden Meditech

In August 2012, the Company entered into a Product Purchase and International Distributor Agreement with 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.

Asahi

Effective June 30, 2012 Asahi exercised its option to purchase certain intellectual property rights 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 intellectual property rights were sold for $2,000,000 which was received in August 2012.

In June 2010, the Company and Asahi entered into an 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-Q 60 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 five years, subject to an extension right of an additional three years.

Table of Contents

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. Effective December 25, 2012, the agreement was terminated. As the distribution agreement has terminated, Nanshan is no longer eligible to earn additional shares of common stock.

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.

GEHC

In January 2012, the Company and GEHC signed an amendment, effective August 1, 2012. Under the terms of the 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 amendment will automatically renew for one year terms unless terminated by either party with 90 days notice. On August 26, 2013, the Company sent GEHC a 90 day notice of termination, which terminates the agreement effective November 24, 2013.

In January 2010, the Company and GEHC also signed an amendment to extend their Amended and Restated International Distribution Agreement, effective February 1, 2010. Under the terms of the amendment, the contract ran through July 31, 2012, GEHC continued 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 amendment provided incentives for both parties related to sales success, product quality and delivery. 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 May 2010, the Company and GEHC signed a non-exclusive distribution agreement for the Res-Q 60 BMC System. Under the agreement, GEHC had 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.

Table of Contents

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. The Company and Fenwal are in discussions to terminate the agreement

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 received 75% and the Company 25%.

Table of Contents

Backlog

Our backlog was $319,000 and $1,528,000 as of June 30, 2013 and 2012, 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, 2013, the Company had 66 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 administration and 10 in sales, marketing and customer service. 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.

Foreign Sales and Operations

For fiscal 2013, foreign sales were $9,934,000 or 55% of net revenues. 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.

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.

Table of Contents

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 Proposed Merger with TotipotentRX is Subject to Various Closing Conditions, and the Failure to Complete the Merger with TotipotentRX could Negatively Impact Us. The TotipotentRX Merger is subject to the satisfaction of a number of conditions, including, but not limited to approval by our stockholders and TotipotentRX's shareholders. No assurance can be given that the TotipotentRX Merger will occur on the terms and timeline currently contemplated or at all. If the proposed TotipotentRX Merger is not completed, the share price of our common stock may decline to the extent that the current market price of our common stock reflects an assumption that the TotipotentRX Merger will be completed. Further, a failed TotipotentRX Merger may result in negative publicity and a negative impression of us in the investment community since we have spent a substantial amount of effort, time and money to explain the benefits of the TotipotentRX Merger.

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.

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, 2013, sales to customers in foreign countries comprised approximately 55% of our revenues. This compares to 43% in fiscal 2012. 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 four significant distributors comprised 56% of our revenues for the year ended June 30, 2013 and a significant portion of our largest distributor's revenue came from one customer. The loss of a large end user customer or distributor may decrease our revenues.

Table of Contents

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 Res-Q products are a significant portion of our 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.

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 the employees, consultants, sales agents or distributors of our Company 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

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.

Table of Contents

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 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. 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.

Table of Contents

Compliance with Government Regulations Regarding the Use of "Conflict Minerals" may Result in Additional Expense and Affect our Operations. The SEC recently adopted a final rule to implement Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which imposes new disclosure requirements regarding the use of "conflict minerals" mined from the Democratic Republic of Congo and adjoining countries. These minerals include tantalum, tin, gold and tungsten. The new requirements will require due diligence efforts on our part in fiscal 2014 and thereafter, and we will also be required to comply with the initial disclosure requirements that become effective in May 2014. We may incur significant costs associated with complying with the new disclosure requirements, including but not limited to costs related to determining which of our products may be subject to the new rules and source of any "conflict minerals" used in those products. Additionally, implementing the new requirements could adversely affect the sourcing, supply and pricing of materials used in the manufacture of our products. We may also face reputational challenges if we are unable to verify through our compliance procedures the origins for all metals used in our products.

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.

Table of Contents

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

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.

Table of Contents

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.

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.

Table of Contents

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, 2013, we had a net loss of $3,086,000 and an accumulated deficit at June 30, 2013, of $114,191,000. 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.

ThermoGenesis Intends to Raise Additional Capital to Fund its Operations and in Furtherance of its Business Plan. We intend to raise additional capital to expand our offerings in regenerative medicine, in anticipation of our proposed merger with TotipotentRX and for working capital. The proposed financing may include shares of common stock and warrants to purchase shares of common stock or a combination of both. Any additional equity financing will be dilutive from an ownership perspective 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 2014 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.

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 ("GAAP") 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.

Table of Contents

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,
- Clinical trial results,
- 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.

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.

Table of Contents

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. 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

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.

On October 24, 2012, Harvest Technologies Corp. filed suit against us in the case Harvest Technologies Corp. v. ThermoGenesis Corp., 12-cv-01354, U.S. District Court, District of Delaware (Wilmington) claiming our Res-Q 60 System infringes certain Harvest patents. The Company has been served, and on April 11, 2013, we filed an answer and counter-claims in response. The counter-claims are based on anti-trust and other alleged improper conduct by Harvest and further seek declarations that the Res-Q 60 System does not infringe the patents and that the patents are invalid. The Company intends to vigorously defend itself against the Harvest claims, while aggressively pursuing its separate claims against Harvest.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents
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 2013	High	Low	Fiscal 2012	High	Low
First Quarter (Sep. 30)	$1.29	$0.87	First Quarter (Sep. 30)	$2.13	$1.20
Second Quarter (Dec. 31)	$1.01	$0.67	Second Quarter (Dec. 31)	$1.29	$0.71
Third Quarter (Mar. 31)	$1.00	$0.82	Third Quarter (Mar. 31)	$1.15	$0.70
Fourth Quarter (June 30)	$1.53	$0.77	Fourth Quarter (June 30)	$0.95	$0.80

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 274 stockholders of record on June 30, 2013 (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.

Table of Contents

THERMOGENESIS CORP.
FIVE-YEAR REVIEW OF SELECTED FINANCIAL DATA

	Year Ended June 30,				
Summary of Operations	2013	2012	2011	2010	2009
Net revenues	$ 17,963,000	$ 19,023,000	$ 23,400,000	$ 23,088,000	$ 19,799,000
Cost of revenues	(11,598,000)	(12,690,000)	(14,563,000)	(15,643,000)	(14,106,000)
Gross profit	6,365,000	6,333,000	8,837,000	7,445,000	5,693,000
Sales and marketing	(2,955,000)	(2,761,000)	(3,195,000)	(2,889,000)	(3,808,000)
Research and development	(2,991,000)	(3,729,000)	(3,003,000)	(5,013,000)	(5,222,000)
General and administrative	(5,645,000)	(5,222,000)	(5,474,000)	(4,797,000)	(5,441,000)
Gain on sale of product lines	2,161,000	--	--	--	--
Loss from operations	(3,065,000)	(5,379,000)	(2,835,000)	(5,524,000)	(8,778,000)
Interest and other income (expense), net	(21,000)	393,000	268,000	61,000	228,000
Net loss	$ (3,086,000)	$ (4,986,000)	$ (2,567,000)	$ (5,193,000)	$ (8,550,000)
Per share data:					
Basic and diluted net loss per common share	$ (0.19)	$ (0.30)	$ (0.17)	$ (0.37)	$ (0.61)

Balance Sheet Data	2013	2012	2011	2010	2009
Cash, cash equivalents and short term investments	$6,884,000	$7,879,000	$12,309,000	$10,731,000	$15,631,000
Working capital	$11,125,000	$14,034,000	$18,976,000	$16,587,000	$20,923,000
Total assets	$18,529,000	$21,080,000	$24,399,000	$24,030,000	$27,655,000
Total liabilities	$5,211,000	$5,182,000	$4,306,000	$6,251,000	$5,201,000
Total stockholders' equity	$13,318,000	$15,898,000	$20,093,000	$17,779,000	$22,454,000

Other Data	2013	2012	2011	2010	2009
Adjusted EBITDA[2]	$ (3,961,000)	$ (3,984,000)	$ (1,409,000)	$ (4,244,000)	$ (7,825,000)

[2]Adjusted EBITDA represents loss from operations excluding amounts for depreciation and amortization, stock-based compensation expense impairment of intangible asset and gain on sale of product lines. Adjusted EBITDA is a common measure of operating performance and helps us evaluate our performance by removing from our operating results non-cash items and items which do not relate to our core operating performance.

Table of Contents

Non-GAAP Measures

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

	2013	2012	2011	2010	2009
Loss from operations	$ (3,065,000)	$ (5,379,000)	$ (2,835,000)	$ (5,254,000)	$ (8,778,000)
Add (subtract):					
Depreciation and amortization	538,000	604,000	466,000	492,000	474,000
Stock-based compensation expense	563,000	791,000	960,000	518,000	479,000
Impairment of intangible asset	164,000	--	--	--	--
Gain on sale of product lines	(2,161,000)	--	--	--	--
Adjusted EBITDA	$ (3,961,000)	$ (3,984,000)	$ (1,409,000)	$ (4,244,000)	$ (7,825,000)

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 REPORT ON FORM 10-K WHICH ARE NOT HISTORICAL FACTS ARE FORWARD-LOOKING STATEMENTS AND ARE SUBJECT TO CERTAIN RISKS AND UNCERTAINTIES. THE COMPANY'S 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 THE COMPANY'S REPORTS FILED WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION.

The following discussion should be read in conjunction with the Company's consolidated financial statements contained in this report.

Table of Contents
(a) Overview

ThermoGenesis designs, develops, and commercializes devices and disposable tools for the processing, storage and administration of cell therapies. The Company was founded in 1986 and is located in Rancho Cordova, California. Our products automate the volume reduction and cryopreservation process of adult stem cells and growth factors from cord blood, peripheral blood and bone marrow for use in laboratory and point-of-care settings. Our growth strategy is to expand our offerings in regenerative medicine and partner with other pioneers in the stem cell arena to accelerate our worldwide penetration in this potentially explosive market.

Critical Accounting Policies
The Company's discussion and analysis of its financial condition and results of operations are based upon the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires the Company 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, the Company evaluates its estimates, including those related to stock-based compensation, bad debts, inventories, warranties, contingencies and litigation. The Company bases its 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.

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

Revenue Recognition
Revenues from the sale of the Company's products are recognized when persuasive evidence of an arrangement exists, delivery has occurred (or services have been rendered), the price is fixed or determinable, and collectability is reasonably assured. The Company generally ships products freight on board ("F.O.B.") shipping point. There is no conditional evaluation on any product sold and recognized as revenue. All foreign sales are denominated in U.S. dollars. Amounts billed in excess of revenue recognized are recorded as deferred revenue on the balance sheet.

The Company's sales are generally through distributors. There is no right of return provided for distributors. For sales of products made to distributors, the Company considers a number of factors in determining whether revenue is recognized upon transfer of title to the distributor, or when payment is received. These factors include, but are not limited to, whether the payment terms offered to the distributor are considered to be non-standard, the distributor history of adhering to the terms of its contractual arrangements with the Company, the level of inventories maintained by the distributor, 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 Company currently recognizes revenue primarily on the sell-in method with its distributors.

Revenue arrangements with multiple deliverables are divided into units of accounting if certain criteria are met, including whether the deliverable item(s) has value to the customer on a stand-alone basis. Revenue for each unit of accounting is recognized as the unit of accounting is delivered. Arrangement consideration is allocated to each unit of accounting based upon the relative estimated selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Estimated selling prices are determined using vendor specific objective evidence of value ("VSOE"), when available, or an estimate of selling price when VSOE is not available for a given unit of accounting. Significant inputs for the estimates of the selling price of separate units of accounting include market and pricing trends and a customer's geographic location. The Company accounts for training and installation, and service agreements as separate units of accounting.

Table of Contents

Service revenue generated from contracts for providing maintenance of equipment is amortized over the life of the agreement. All other service revenue is recognized at the time the service is completed.

For licensing agreements pursuant to which the Company receives up-front licensing fees for products or technologies that will be provided by the Company over the term of the arrangements, the Company defers the up-front fees and recognizes the fees as revenue on a straight-line method over the term of the respective license. For license agreements that require no continuing performance on the Company's part, license fee revenue is recognized immediately upon grant of the license.

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

Stock-Based Compensation

The Company calculates stock-based compensation on the date of the grant using the Black Scholes-Merton option-pricing formula. The compensation expense is then amortized over the vesting period. The Company uses the Black-Scholes-Merton option-pricing formula in determining the fair value of the Company's options at the grant date and applies judgment in estimating the key assumptions that are critical to the model such as the expected term, volatility and forfeiture rate of an option. The Company's 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.

Warranty

The Company provides for the estimated cost of product warranties at the time revenue is recognized. While the Company engages in extensive product quality programs and processes, including actively monitoring and evaluating the quality of its component suppliers, the Company's 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 the Company's estimates, revisions to the estimated warranty liability could have a material impact on the Company's financial position, cash flows or results of operations.

Inventory Reserve

The Company states inventories at lower of cost or market value determined on a first-in, first-out basis. The Company provides inventory allowances 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 reserves 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 reserves are based upon estimates about future demand from our customers and distributors and market conditions. Because some of the Company's products are highly dependent on government and third-party funding, current customer use and validation, and completion of regulatory and field trials, there is a risk that we will forecast incorrectly and purchase or produce excess inventories. As a result, actual demand may differ from forecasts and the Company may be required to record additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when products previously reserved are sold.

Table of Contents

(b) Results of Operations

The following is Management's discussion and analysis of certain significant factors which have affected the Company's financial condition and results of operations during the periods included in the accompanying consolidated financial statements.

Results of Operations for the Year Ended June 30, 2013 as Compared to the Year Ended June 30, 2012

Net Revenues

Net revenues for the year ended June 30, 2013 were $17,963,000 compared to $19,023,000 for the year ended June 30, 2012, a decrease of $1,060,000, or 6%. The decrease in revenues is primarily due to the sale of the ThermoLine and CryoSeal product lines in the current fiscal year. These two product lines represented $2,240,000 in revenues for the year ended June 30, 2012 compared to $944,000 for the year ended June 30, 2013. This decrease in revenues was offset by an increase in revenues from Res-Q disposables of $403,000 primarily due to an increase in the number of bone marrow procedures performed and an increase in new customers. We anticipate the termination of the GE distribution agreement will impact our AXP revenues in the quarter ended September 30, 2013 by approximately $800,000 as GEHC sells-off their product inventory.

Sales analysis for the year ended June 30:

	2013	Percentage of Revenues		2012	Percentage of Revenues	
Disposable revenues:						
Cord Blood						
AXP	$7,133,000	40	%	$7,224,000	38	%
BioArchive	1,167,000	6	%	1,421,000	7	%
Manual	2,286,000	13	%	2,200,000	12	%
Bone Marrow						
Res-Q	2,297,000	13	%	1,894,000	10	%
MXP	17,000	--		112,000	--	
CryoSeal	118,000	--		358,000	2	%
	13,018,000	72	%	13,209,000	69	%
Non-disposable revenues:						
BioArchive	2,481,000	14	%	2,512,000	13	%
Other non-disposable	999,000	6	%	1,772,000	10	%
Other	1,465,000	8	%	1,530,000	8	%
Total Company revenues	$17,963,000	100	%	$19,023,000	100	%

The following represents the Company's cumulative BioArchive System placements in the following geographies:

	June 30,	
	2013	2012
Asia	88	86
United States	57	57
Europe	70	67
Rest of World	51	47
	266	257

Table of Contents

Gross Profit

The Company's gross profit was $6,365,000 or 35% of revenues for the year ended June 30, 2013, as compared to $6,333,000 or 33% of revenues for the year ended June 30, 2012. The increase in gross profit for the year ended June 30, 2013, is primarily due to lower inventory reserves and the mix of products sold in the prior fiscal year. We sold 25 CryoSeal devices to Asahi at cost during the quarter ended March 31, 2012. Inventory reserves recorded in the prior year were higher primarily due to the deceleration in sales of the ThermoLine freezers.

Sales and Marketing Expenses

Sales and marketing expenses were $2,955,000 for the year ended June 30, 2013, compared to $2,761,000 for the year ended June 30, 2012, an increase of $194,000 or 7%. The increase is primarily due to establishing direct representation in Asia.

Research and Development Expenses

Included in this line item are costs associated with our engineering, regulatory, scientific and clinical affairs functions. Research and development expenses for the year ended June 30, 2013, were $2,991,000, compared to $3,729,000 for fiscal 2012, a decrease of $738,000 or 20%. The decrease is primarily due to lower personnel costs primarily as a result of the January 2012 restructuring and lower costs for clinical studies, offset by an increase in consulting expenses for quality assurance and regulatory projects.

General and Administrative Expenses

General and administrative expenses were $5,645,000 for the year ended June 30, 2013, compared to $5,222,000 for the year ended June 30, 2012, an increase of $423,000 or 8%. The increase is primarily due to legal and professional fees of $835,000 associated with the proposed merger with TotipotentRX and $670,000 due to the legal diligence associated with the Res-Q patent litigation and the development of our counterclaim. These increases were offset by a decrease in severance costs of $360,000 as a result of the January 2012 restructuring.

Gain on Sale of Product Lines

During the year ended June 30, 2013, the Company recognized a gain of $2,000,000 on the sale of certain intangible assets related to the CryoSeal product line, including all associated patents and engineering files and $161,000 on the sale of the ThermoLine product line.

Adjusted EBITDA

The Adjusted EBITDA loss was $3,961,000 for the year ended June 30, 2013 compared to $3,984,000 for the year ended June 30, 2012. The adjusted EBITDA loss was consistent with the prior year as we offset a decrease in revenues from a change in the mix of products sold in our global markets with a decrease in expenses resulting from our cost reduction initiatives.

Table of Contents

Results of Operations for the Year Ended June 30, 2012 as Compared to the Year Ended June 30, 2011

Net Revenues

Net revenues for the year ended June 30, 2012, were $19,023,000 compared to $23,400,000 for the year ended June 30, 2011, a decrease of $4,377,000 or 19%. BioArchive device revenues decreased $2,600,000 as there were fewer devices sold in fiscal 2012 than in the prior year. The global economy has tightened capital budgets and lowered collection volumes which have impacted our BioArchive device sales. We also experienced a $740,000 decrease in our ThermoLine device revenues as we have stopped manufacturing devices due to our decision to divest the product line and a minimum of sales resources are devoted to the remaining devices in inventory. These decreases were offset by an increase in CryoSeal device and spare part revenues of $790,000 as we shipped a final device order of 25 units to Asahi during fiscal 2012.

Sales analysis for the year ended June 30:

	2012	Percentage of Revenues		2011	Percentage of Revenues	
Disposable revenues:						
Cord Blood						
AXP	$7,224,000	38	%	$7,354,000	31	%
BioArchive	1,421,000	7	%	1,398,000	6	%
Manual	2,200,000	12	%	2,162,000	9	%
Bone Marrow						
Res-Q	1,894,000	10	%	2,024,000	9	%
MXP	112,000	--		252,000	1	%
CryoSeal	358,000	2	%	607,000	3	%
	13,209,000	69	%	13,797,000	59	%
Non-disposable revenues:						
BioArchive	2,512,000	13	%	5,111,000	22	%
Other non-disposable	1,772,000	10	%	2,176,000	9	%
Other	1,530,000	8	%	2,316,000	10	%
Total Company revenues	$19,023,000	100	%	$23,400,000	100	%

The following represents the Company’s cumulative BioArchive System placements in the following geographies:

	June 30,	
	2012	2011
Asia	86	81
United States	57	56
Europe	67	64
Rest of World	47	46
	257	247

Gross Profit

The Company’s gross profit was $6,333,000 or 33% of net revenues for the year ended June 30, 2012, as compared to $8,837,000 or 38% for the year ended June 30, 2011. The lower gross profit is primarily due to the mix of products sold and an increase in inventory and warranty reserves. We delivered a final order to Asahi of 25 CryoSeal devices, at cost. Inventory reserves increased primarily due to the deceleration in sales of the ThermoLine freezers and warranty reserves increased primarily due to the AXP disposable.

Table of Contents

Sales and Marketing Expenses

Sales and marketing expenses were $2,761,000 for the year ended June 30, 2012, compared to $3,195,000 for the year ended June 30, 2011, a decrease of $434,000 or 14%. The decrease is primarily due to a decrease in commissions and a decrease in stock compensation due to the prior year amortization of the initial grant of restricted stock to Nanshan upon signing the distribution agreement.

Research and Development Expenses

Included in this line item are costs associated with our engineering, regulatory, scientific and clinical affairs functions. Research and development expenses for the year ended June 30, 2012, were $3,729,000 compared to $3,003,000 for fiscal 2011, an increase of $726,000 or 24%. The increase is primarily due to funding of clinical studies and higher salaries and benefits due to an increase in personnel.

General and Administrative Expenses

General and administrative expenses were $5,222,000 for the year ended June 30, 2012, compared to $5,474,000 for the year ended June 30, 2011, a decrease of $252,000 or 5%. The decrease is primarily due to a decrease in professional fees of $366,000 for strategic consultants and advisor expenses incurred in the prior year. Also, stock compensation expense decreased $129,000 mainly due to options granted in the prior year to the independent members of our Board of Directors. These decreases were offset by an increase in severance pay accruals as a result of the restructuring.

Interest and Other Income, Net

At June 30, 2012, we recognized other income of $327,000 due to the early termination of the Asahi Amendment. The $327,000 represented excess funds allocated to offset research and development costs we had expected to incur.

(c) Liquidity and Capital Resources

At June 30, 2013, the Company had a cash and cash equivalents balance of $6,884,000 and working capital of $11,125,000. This compared to a cash and cash equivalents balance of $7,879,000 and working capital of $14,034,000 at June 30, 2012. In addition to revenues, the Company has primarily financed operations through the private and public placement of equity securities and has raised approximately $112 million, net of expenses, through common and preferred stock financings and option and warrant exercises.

Net cash used in operating activities for the year ended June 30, 2013 was $3,082,000, primarily due to the net loss of $3,086,000, offset by depreciation and stock-based compensation expense of $538,000 and $563,000, respectively. Inventories provided $795,000 of cash due to lower levels of our BioArchive and manual disposables.

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 intend to raise capital for other purposes and may need to raise additional funds should we not be able to maintain compliance with, or obtain forbearance of, our financial covenants. See Part I Item 1-Business, CBR. In addition, should we change distributors and take on the responsibility for maintaining significant product inventory levels for certain end user customers, we may need to raise additional funding. In order to maximize the value of our clinical trials and accelerate the planned commercialization of our products in connection with the proposed merger with TotipotentRX, we intend to raise approximately $15 to $20 million for investing in the planned clinical development strategy over 36 months. Our ability to fund our longer-term cash needs is subject to various risks, many of which are beyond our control. Should we require additional funding, such as additional capital investments, we may need to raise the required additional funds through bank borrowings or public or private sales of debt or equity securities. We cannot assure that such funding will be available in needed quantities or on terms favorable to us, if at all see Part I Item 1A – Risk Factors.

Table of Contents

The Company generally does not require extensive capital equipment to produce or sell its current products. In fiscal 2011, the Company spent $266,000 for products at customer sites and tooling. In fiscal 2012 and 2013, the Company spent $545,000 and $391,000, respectively. These expenditures were primarily for tooling at contract manufacturers.

At June 30, 2013, we had four distributors that accounted for 28%, 18%, 10% and 10% of accounts receivable. At June 30, 2012, we had one distributor that accounted for 22% of accounts receivable and four distributors that individually accounted for 13%, 13%, 12% and 10% of accounts receivable.

Revenues from one significant distributor, GEHC, totaled $3,755,000 or 21%, $6,746,000 or 35% and $7,824,000 or 33% of net revenues during the years ended June 30, 2013, 2012 and 2011, respectively. Revenues from another distributor, Celling, totaled $2,299,000 or 13% and $1,870,000 or 10% of net revenues for the years ended June 30, 2013 and 2012, respectively. Revenues from two other distributors/customers, Golden Meditech and Golden Profit Technology, totaled $2,058,000 and $1,992,000, respectively, for the year ended June 30, 2013.

The Company manages the concentration of credit risk with these customers through a variety of methods including, letters of credit with financial institutions, pre-shipment deposits, credit reference checks and credit limits. Although management believes that these customers 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.

(d) Off Balance Sheet Arrangements

The Company has 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 SEC Act of 1934 and are not required to provide information under this item.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Table of Contents

Management's Report on Internal Control over Financial Reporting

The Company's 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 the Company's management, including the Company's Chief Executive and Financial Officers, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on criteria established in the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, the Company's management concluded that its internal control over financial reporting was effective as of June 30, 2013.

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.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of ThermoGenesis Corp.

We have audited the accompanying consolidated balance sheets of ThermoGenesis Corp. as of June 30, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ThermoGenesis Corp. at June 30, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Sacramento, California
September 3, 2013
38

Table of Contents

THERMOGENESIS CORP.
CONSOLIDATED BALANCE SHEETS

ASSETS	June 30, 2013	June 30, 2012
Current assets:		
Cash and cash equivalents	$6,884,000	$7,879,000
Accounts receivable, net of allowance for doubtful accounts of $47,000 ($30,000 at June 30, 2012)	4,898,000	4,558,000
Inventories	4,259,000	6,290,000
Prepaid expenses and other current assets	232,000	338,000
Total current assets	16,273,000	19,065,000
Equipment at cost less accumulated depreciation of $3,277,000 ($3,476,000 at June 30, 2012)	2,208,000	1,652,000
Intangible asset	--	315,000
Other assets	48,000	48,000
	$18,529,000	$21,080,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$3,106,000	$2,772,000
Accrued payroll and related expenses	477,000	607,000
Deferred revenue	377,000	424,000
Other current liabilities	1,188,000	1,228,000
Total current liabilities	5,148,000	5,031,000
Deferred revenue	55,000	55,000
Other non-current liabilities	8,000	96,000
Commitments and contingencies (Footnote 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,000,000 shares authorized, none issued and outstanding at June 30, 2013 and 2012	--	--
Common stock, $0.001 par value; 80,000,000 shares authorized; 16,557,627 issued and outstanding (16,413,066 at June 30, 2012)	16,000	16,000
Paid in capital in excess of par	127,493,000	126,987,000
Accumulated deficit	(114,191,000)	(111,105,000)
Total stockholders' equity	13,318,000	15,898,000
	$18,529,000	$21,080,000

See accompanying notes.

Table of Contents

THERMOGENESIS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended June 30,		
	2013	2012	2011
Net revenues	$ 17,963,000	$ 19,023,000	$ 23,400,000
Cost of revenues	11,598,000	12,690,000	14,563,000
Gross profit	6,365,000	6,333,000	8,837,000
Expenses:			
Sales and marketing	2,955,000	2,761,000	3,195,000
Research and development	2,991,000	3,729,000	3,003,000
General and administrative	5,645,000	5,222,000	5,474,000
Gain on sale of product lines	(2,161,000)	--	--
Total operating expenses	9,430,000	11,712,000	11,672,000
Loss from operations	(3,065,000)	(5,379,000)	(2,835,000)
Interest and other income (expense), net	(21,000)	393,000	268,000
Net loss	$ (3,086,000)	$ (4,986,000)	$ (2,567,000)
Per share data:			
Basic and diluted net loss per common share	$ (0.19)	$ (0.30)	$ (0.17)
Shares used in computing per share data	16,526,578	16,389,008	14,816,163

See accompanying notes.

Table of Contents

THERMOGENESIS CORP.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Paid in capital in excess of par	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at June 30, 2010	14,023,240	$14,000	$121,317,000	$ (103,552,000)	$17,779,000
Issuance of common shares and warrants in public offering	2,250,000	2,000	3,912,000	--	3,914,000
Issuance of common shares for exercise of options	2,917	--	7,000	--	7,000
Issuance of common shares and compensation related to restricted common stock awards	70,117	--	146,000	--	146,000
Stock-based compensation expense	--	--	814,000	--	814,000
Fractional shares issued pursuant to reverse stock split	92	--	--	--	--
Net loss	--	--	--	(2,567,000)	(2,567,000)
Balance at June 30, 2011	16,346,366	16,000	126,196,000	(106,119,000)	20,093,000
Issuance of common shares and compensation related to unrestricted common stock awards	60,000	--	88,000	--	88,000
Issuance of common shares and compensation related to restricted common stock awards	6,700	--	326,000	--	326,000
Stock-based compensation expense	--	--	377,000	--	377,000
Net loss	--	--	--	(4,986,000)	(4,986,000)
Balance at June 30, 2012	16,413,066	16,000	126,987,000	(111,105,000)	15,898,000
Issuance of common shares and compensation related to restricted common stock awards, net of stock surrenders	115,944	--	275,000	--	275,000
Stock-based compensation expense	--	--	198,000	--	198,000
	28,617	--	33,000	--	33,000

Common stock issued to directors in lieu of cash compensation		
Net loss	--	--