THERMOGENESIS CORP Form 10-K September 11, 2009

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-K

# ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the Fiscal Year Ended: June 30, 2009

Commission File Number: 333-82900 ThermoGenesis Corp.

(Exact name of registrant as specified in its charter)

Delaware 94-3018487

(State of incorporation)

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

2711 Citrus Road Rancho Cordova, California 95742

(Address of principal executive offices) (Zip Code)

(916) 858-5100

(Registrant s telephone number, including area code)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes b 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 p 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. 

§ Yes

§ 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 registrant was required to submit and post such files.) Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer b Non-accelerated filer\* o Smaller reporting company o

\*(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) of Yes b No

The aggregate market value of the common stock held by non-affiliates as of December 31, 2008 (the last trading day of the second quarter) was \$24,092,023, based on the closing sale price on such day.

As of August 31, 2009, 56,092,960 shares of the registrant s Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the registrant s proxy statement for its 2009 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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#### PART I

# ITEM 1. BUSINESS

## **Business Overview**

Our mission is to design, develop and commercialize medical products that enable the collection, processing and cryopreservation of stem cells and other cellular tissues used in the practice of regenerative medicine. Regenerative medicine is an emerging field that, among other things, aims to repair or restore lost or damaged tissue and cell function using cell-based therapies. Our current products automate the volume reduction and cryopreservation process of adult stem cell concentrates from cord 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. The Company was founded in 1986 and is located in Rancho Cordova, California.

Our business model is based on the sale of medical devices and the recurring revenues generated from the companion single-use, sterile disposable products. Our products are currently sold in 34 countries throughout the world. Our end user customers include private and public cord blood banks, surgeons, hospitals and research institutions. Our worldwide commercialization strategy is based primarily on the utilization of distributors, with some direct selling in the U.S.

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

#### **Our Solutions**

We provide the tools necessary for the collection, separation, expansion, storage and delivery of stem cells from adult tissue sources including cord blood, bone marrow, (later) adipose and placenta. These tools are being used by health care providers in both the laboratory and point of care setting. Our competitive advantage is achieved through applying our advanced engineering capabilities to develop a complete tool box for the healthcare providers advancing regenerative medicine. Our solutions enable our customers to automate their processes, comply with quality regulations and achieve high stem cell yields. We believe our products significantly enhance the safety and viability of stem cell and regenerative medical products and will ultimately expand the use and success of those products in clinical treatment through their ease of use and high cell recovery rates.

#### **Kev Events**

The following are key events that occurred in fiscal 2009:

Key Management Changes

The following key management changes were made:

On April 14, 2009, J. Melville Engle was named Chief Executive Officer. Mr. Engle has more than 30 years of management experience in the healthcare industry and has served as President or Chief Executive Officer of three companies.

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o Also on April 14, 2009, Matthew T. Plavan was named Chief Operating Officer. He also retained the position of Executive Vice President, Chief Financial Officer. Mr. Plavan joined the Company in 2005.

Launch of MXP and Spine Smith Agreement

In September 2008, we signed an agreement with Celling Technologies, a subsidiary of SpineSmith LLC (Celling), to distribute our MarrowXpress (MXP) product line. The distribution rights are for the field of orthopedic applications. In December 2008, we launched the MXP, our first product used for isolating stem cells from bone marrow.

Suspension of Vantus Veterinary Launch

In fiscal 2008, we formed a wholly-owned subsidiary, Vantus Veterinary Stem Cell Laboratories (Vantus). Its initial focus was the banking (equipment and services) of equine stem cells for use in treatment of orthopedic injuries in the performance equine market. The current economic downturn significantly impacted the equine market and, as such, in fiscal 2009 we postponed our launch activities until the market and distribution opportunities improve.

# **Market Overview**

During the past year, the regenerative medicine market has experienced significant changes from a macroeconomic, political, and commercialization perspective.

Overall worldwide economic conditions have significantly worsened since the summer of 2008. The fiscal crisis reduced the availability of funds for the purchase of capital equipment and forced healthcare entities to reduce their research, capital and operating budgets accordingly. These cutbacks impacted our ability during the year to sell our larger capital equipment devices at the levels experienced in preceding years.

From a political standpoint, the election of President Obama resulted in increased awareness of regenerative medicine, primarily with embryonic stem cells. On March 9, 2009, President Obama signed the stem cell executive order lifting the ban on federal funding for promising embryonic stem cell research. In January 2009, the U.S. Food and Drug Administration (FDA) granted clearance for Geron to commence safety trials for its human embryonic stem cell-based therapy. Their Phase I multi-center trial was established to show the safety of its product for patients with complete subacute spinal cord injury. We believe the change of policy in Washington D.C., and the latest clearance from the FDA, will lead to an overall increased public awareness of adult stem cells and the potential of embryonic stem cells. In addition to increasing research activities, the regenerative medicine market has witnessed the establishment of various commercial partnerships. For example, in 2008, Cytori Therapeutics and GE Healthcare (GEHC) announced a partnership to commercialize Cytori s Celution System in Europe.

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

- o Stem cell recovery rates
- o Efficiency of cell processing
- Cost of care
- o Product quality and efficacy
- o Purity, viability and potency of stem cells

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Cells are processed in both the laboratory setting 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, Good Manufacturing Practices (GMP) processing, objective quality assurance and the ability to process multiple samples at one time. Requirements for the point of care include sterile field packaging, portability, minimal processing steps and speed of processing. These market requirements must be considered and translated into product features and benefits for successful market adoption.

The availability of stem cells at the point of care enables physicians to apply cells across an array of applications in an already-crowded operating room setting. Physicians may also choose to study patient outcomes to understand the benefit of stem cells under their own independently-sponsored and regulated studies. Such research efforts are growing and already represent studies in diverse areas such as wound healing, radiation injury, breast reconstruction and augmentation, cardiovascular applications, peripheral vascular disease and liver disease among many others. We expect the breadth of these applications will grow significantly as physicians continue to adopt cell-based regenerative medicine into their treatment strategies based on the availability of safe, clinical grade cells at the point of care.

#### **Market Size**

Market estimates for the regenerative medicine market include pathologies that affect vast numbers of people of all age groups. A well known industry analyst, Robyn Young, predicts the U.S. regenerative medicine market will grow from \$87 million in 2008 to over \$8.1 billion by the year 2018. The following chart highlights the disease states that are expected to be impacted by the advent of stem cell therapies.

Source: Robyn Young, Stem Cell Summit, 2009, pg. 16. Industry Market Drivers

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

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

Political actions

Government funding

Clinical outcomes

Corporate investment

Awareness of availability

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Growing endorsement by doctors

Increase in prevalence of conditions treated

New sources of stem cells

#### **Scientific Overview**

#### **Stem Cells**

Stem cells have the remarkable potential to develop into many different cell types and serve as a repair system for the body. They can theoretically divide without limit to replenish other cells as long as the person or animal is alive. When a stem cell divides, each new cell has the potential to either remain a stem cell or become another type of cell with a more specialized function, such as a muscle, a red blood, or a brain cell.

There are two main types of stem cells: embryonic and adult. An embryonic stem cell is a primitive cell derived from a 5-day pre-implantation embryo that has the potential to become a cell from a wide variety of specialized cell types. Adult stem cells are found in human tissue and can renew and differentiate themselves to yield the major specialized cell types of that tissue. Adult stem cells are thought to reside in a specific area of each tissue where they may remain non-dividing for many years until they are activated by disease or tissue injury. The Company s current products address therapies with adult stem cells only. Initially, researchers greatest hope was for stem cells derived from embryos. However, while embryonic stem cell therapies may offer great promise, companies are unlikely to see embryonic stem cell treatments marketed for serious conditions for many years.

It is reported that stem cells can be found in umbilical cord blood, bone marrow, brain, peripheral blood, fat, blood vessels, amniotic fluid, skeletal muscle, skin, placenta, menstrual blood and liver. Historically, our products have only been used in cord blood applications. However, in fiscal 2009, the Company successfully introduced its first bone marrow stem cell product, MXP. We are currently evaluating opportunities for our technology in the adipose stem cell market.

#### **Stem Cell Therapy**

Adult stem cell research is primarily focused on the isolation, characterization, purity, plasticity and clinical uses of adult-derived, pluripotent stem cells from a variety of human tissues. There are two principal types of adult stem cells being investigated today for medical application: hematopoietic stem cell and mesenchymal stem cells. Hematopoietic adult stem cells are capable of restoring the ability of a patient s bone marrow to produce healthy blood cells and are routinely used in the treatment of cancer. Mesenchymal stem cells are being intensively investigated for their ability to promote healing of tissues by modulation of inflammatory and immunologic responses and by promoting the growth of blood vessels in ischemic tissues.

Stem cell therapy can be used to:

Regenerate bone marrow damaged by high-dose chemotherapy or radiation therapy used to treat patients with a variety of cancers such as leukemia and lymphoma;

Provide genetically healthy and functioning bone marrow to treat patients with more than 60 life threatening genetic diseases such as sickle cell anemia and immunodeficiency; and

Regenerate and repair tissue including the treatment of myocardial infarction, peripheral limb ischemia and non-union bone fractures.

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Perhaps the most important potential application of human stem cells is the generation of cells and tissues that could be used for new regenerative medicine cell based therapies. Today, donated organs and tissues are often used to replace ailing or destroyed tissue, but the need for transplantable tissues and organs far outweighs the available supply. Directed to differentiate into specific cell types, stem cells offer the possibility of a renewable source of replacement cells and tissues that could possibly treat conditions including Parkinson s and Alzheimer s diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis.

## **Product Overview**

We provide proprietary tools and technologies to enable highly effective separation and cryopreservation of biological fluids including peripheral, bone marrow and umbilical cord blood at a competitive cost.

The **AutoXpress Platform or AXP** is a medical device with an accompanying disposable bag set that isolates and retrieves stem cells from umbilical cord blood. The AXP provides cord blood banks with a system to isolate and capture adult stem cells with lower labor costs and a reduced risk of contamination, under GMPs. Our market for the AXP includes both private and public cord blood banks. At a private bank, an individual pays to have cord blood stem cells from their offspring collected and stored, while a public bank owns cord blood stem cells donated by individuals, which are then available to the public for transplantation. The product is an automated, closed, sterile system that volume-reduces cord blood to a user defined volume in 30 minutes, able to retain over 97% of the mononuclear cells. Self-powered and microprocessor-controlled, the AXP contains flow control optical sensors which achieve precise separation.

The AXP is sold in 20 countries. The product has been commercially available since 2006, marketed under a Master File with the FDA. In 2007, the Company received 510(k) clearance from the FDA for use in the processing of cord blood for cryopreservation.

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

	2005	2009	CAGR
Public	118	169	9.4%
Private	91	220	24.7%
Total Banks	209	389	16.8%

The **MarrowXpress**, an extension of the AXP, isolates and retrieves 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 mononuclear cells. Self-powered and microprocessor-controlled, the MXP 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.

The **BioArchive**® **System** is an automated cryogenic system used in stem cell therapy to cryopreserve and archive stem cells for future transplant and treatment. Launched in fiscal 1998, over 200 BioArchive Systems have been purchased by over 90 umbilical cord blood stem cell

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banks in over 30 countries worldwide to archive, cryopreserve and store stem cell preparations extracted from human placentas and umbilical cords for future use.

The BioArchive System can store over 3,600 stem cell samples. It is the only fully-automated system commercially available 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.

The **Res-Q** product is also used for bone marrow stem cell processing. Launched in July 2009, the Res-Q can be used in a clinical laboratory or can be used inter-operatively at the point of care. The technology is a next generation, centrifuge-based disposable device designed for the isolation and extraction of specific stem cell populations at the point of care. Res-Q is a rapid, reliable, and easier-to-use product which achieves a higher recovery rate of stem cells from bone marrow. The key advantages of the Res-Q 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 as little as 15 minutes. As cell processing for regenerative medicine applications becomes more readily accepted, we believe the features and benefits of the Res-Q position the product for broad-based adoption.

Our **Thermoline** product line includes the ultra-rapid plasma Thermoline Freezer and ultra-rapid plasma Thermoline Thawer. We offer two models of plasma freezers which vary primarily by capacity and condenser type. The Thermoline freezer optimizes plasma freezing through its unique liquid heat transfer and uniform freezing technologies that can freeze units of blood plasma in approximately 30 minutes. These products are suited for medium to large laboratories.

We also offer three models of blood components thawers which vary primarily by capacity. The product s unique flexible membrane technology allows for a closed thawing system. These instruments can be used for rapid (less than 12 minutes) homogeneous thawing of plasma and glycerolized frozen red blood cells.

The **CryoSeal** Fibrin Sealant (CryoSeal) System is an automated system used to prepare an autologous hemostatic surgical sealant from a patient s own blood or from a single donor in approximately one hour. We received FDA approval to market the CryoSeal in liver resection surgeries in July 2007. The CryoSeal serves the wound care market. Our intention is to divest this product line in fiscal 2010.

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The Company s sales by geographic region are as follows for the years ended June 30:

	2009	2008	2007
U.S.	\$ 11,489,000	\$12,901,000	\$ 8,579,000
Europe	2,510,000	5,565,000	4,625,000
Asia	3,544,000	2,125,000	2,588,000
South America	1,859,000	1,208,000	802,000
Other	397,000	147,000	157,000
	\$ 19,799,000	\$ 21,946,000	\$ 16,751,000

# **Sales and Distribution Channels**

Our products are sold to customers in the U.S. and international markets. In most major markets our sales are derived from a relatively small customer base, primarily from cord blood banks or direct distributors.

## **United States**

AXP: Exclusively sold and distributed by GEHC. Our major customers are Cord Blood Registry (CBR) and New York Blood Center (NYBC).

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MXP and Res-Q Systems: Sold by Celling for orthopedic applications. The MXP System was launched in December 2008 and the Res-Q System in July 2009.

Other products, such as the BioArchive System: Sold on a direct basis by our sales force.

#### **International**

Internationally, we sell our products through GEHC or independent distributors. GEHC is the exclusive distributor of the AXP except for Central and South America, China (except Hong Kong) and Russia/CIS. Our independent distributors generally cover one country each.

# **Competition**

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

Competitors/Markets AXP	Area of Focus	Geographic Distribution
BioSafe/Sepax	Processing of cord blood	Direct in Europe and U.S.
BioE/Prepacyte-cb	Modified manual processing of cord blood	Worldwide via local distribution networks
MXP		
BioSafe/Sepax	Laboratory processing of bone marrow aspirate	Direct in Europe and U.S.
COBE/Spectra	Laboratory processing of bone marrow aspirate	Worldwide
Ficoll/Paque	Manual processing of bone marrow aspirate	Worldwide distribution through GEHC
Res-Q		
Harvest/SmartPReP	Point of care and laboratory processing of bone marrow aspirate	U.S distribution through Oteotech, India distribution through LifeCell, otherwise direct
BioMet/MarrowStem	Point of care processing of bone marrow aspirate	Direct
BioArchive		
Chart	Cryopreservation of cells and tissue	Worldwide via local distribution networks
	BioRepository (Storage of cell lines, primarily in vials)	
	BioPharma (Storage of drugs or vaccines, primarily in vials)	

Cord blood banks

Taylor Wharton Cryopreservation of cells and tissue. Worldwide via local distribution

networks

BioRepository

BioPharma

Cord blood banks

**Thawers** 

Helmer Blood banks, blood centers and Worldwide via Baxter in Europe.

hospital blood banks

Biotechnology Medical Services in the Middle East, local distributors and direct

Windaic East, local distributors and direc

Thermo Fisher Blood banks, blood centers and Worldwide

Scientific/Cyto Therm hospital blood banks

**Freezers** 

Harris Source plasma companies and Worldwide via local distribution

recovered plasma suppliers networks

Jewett Source plasma companies and Worldwide via local distribution

recovered plasma suppliers networks

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# **Research and Development**

The Company s research and development activities are focused principally on the development of new products that serve the regenerative medicine market and on significant upgrades to our existing products. Specific activities in fiscal 2009 included the development of our Res-Q product for bone marrow applications and the commencement of second generation AXP and MXP improvements. Activities planned for fiscal 2010 include completion of second generation product enhancements, the development of Res-Q for indications beyond orthopedics and other related projects. Research and development expense reflects the cost of these activities, as well as the costs to obtain regulatory approvals of new products and processes and to maintain the highest quality standards with respect to existing products. We have no customer-sponsored research and development expense.

# **Manufacturing**

Our long-term manufacturing strategy is to utilize high quality, low cost contract manufacturers to provide the routine production of our products. The Company currently outsources the manufacture of the majority of our disposable products. However, the Company currently manufactures or assembles all of its major instruments and medical devices. During fiscal 2009, we initiated the process to outsource the manufacturing of our devices, beginning with the Thermoline products. It is our intent to transition substantially all our device manufacturing to contract manufacturers over the next few years. In conjunction with our outsourcing efforts and the divestiture of our surgical wound care business, we expect to streamline our supply chain and improve our order fulfillment process through vendor consolidation and third party logistics providers. In parallel with this effort, we plan on adding an in-house pilot manufacturing capability to ensure that initial production scale-up batches meet product requirements and manufacturability standards.

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

# **Ouality Strategy**

Our quality strategy is based on three key tenets:

Doing things right the first time

Meeting customer expectations

Continuous improvement

We embrace the notion that quality must be a key component of everything we do. Our management and employees are measured and evaluated based on our quality performance. The foundation of our quality strategy is our quality system.

Our quality system is based on a process approach to quality management. Any activity that receives inputs and converts them to outputs is considered a quality process. We have identified and currently manage numerous linked processes. Often the output from one process directly forms the input to the next. Our quality system defines the parameters under which we conduct our business. The quality system embeds our quality policy and describes how we will consistently provide our customers with products and services that meet their expectations. Our quality system, and the obligations defined within it, is applicable to all our divisions, subsidiaries, operating facilities, and functions. The principles embodied in this quality system are viewed worldwide as a means of ensuring our products are produced in an acceptable manner.

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Our quality system has been created to be harmonized with 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 Federal Food, Drug, and Cosmetic Act and 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 Quality System Regulations (QSR) which include requirements relating to manufacturing processes, extensive testing, control documentation and other quality assurance procedures. Our facilities have undergone International Organization of Standards (ISO) 13485:2003 and Medical Device Directive (MDD) inspections and we have obtained approval to CE-Mark our products. UL/CSA approval has also been obtained for our CryoSeal, BioArchive, MXP and AXP products. We are in the process of obtaining the CE Mark for Res-Q. 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 can generate data that will help fuel adoption of our product offerings. We have a quality and regulatory compliance management system that complies with the requirements of the ISO 13485: 2003 standard, the FDA s QSR (21 CFR 820), the European Union Medical Device Directive (93/42/EEC), 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 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 of our research, 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. 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.

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, such as the CryoSeal System, 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 (Phase III) to establish the safety and efficacy of the medical device for the intended indication; and

Submission and approval of a Premarket Application (PMA) 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.

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

Medical device clinical trials are typically conducted as a Phase III clinical trial. A Phase II 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) for approval of the marketing and commercialization of the medical device in the U.S. The FDA may deny the approval of a PMA 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 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.

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

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

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.

In February of 2008, the Company initiated a voluntary recall for its AXP processing bag sets. The product was recalled as a result of the omission of endotoxin testing during lot release testing. The Company developed a process, with the approval of the FDA and other regulatory agencies, to assess

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each manufactured lot and perform the appropriate testing. To date, all but one lot have been cleared through the testing process and a single sample remains to be obtained for the final lot before the recall can be completed and closed.

In October 2008, the Company initiated a voluntary recall for six lots of AXP processing bag sets. The product was recalled due to a nonconforming component which had the potential to release particulates from that component in the sterile, non-pyrogenic fluid path. Customers and physicians were notified of the issue and actions were implemented to prevent particulates from being passed into patients during transplant procedures. The FDA considered this recall to be complete and a formal request for closure of the recall was made in June 2009.

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 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 R&D biological lab.

Internationally, we are required to comply with a multitude of other regulatory requirements. To legally market our medical devices in Canada, for example, we fall under the auspices of Health Canada and the Canadian Medical Device Regulations. Health Canada reviews medical devices to assess their safety, effectiveness, and quality before allowing them to be authorized for sale in Canada. The Therapeutic Products Directorate (TPD) undertakes a variety of activities, including the promulgation of policies and regulations to support its role as the federal regulatory authority for the sale of medical devices in Canada. In Canada, manufacturers must receive a medical device license for certain health products defined as a device under the Canadian Food and Drugs Act before they can be sold on the Canadian market. To determine which devices need a license, medical devices are categorized based on the risks associated with their use. Prior to selling a device in Canada, manufacturers of Class II, III and IV devices must obtain a medical device license. Although Class I devices do not require a license, manufacturers, distributors, and importers are required to obtain an establishment license. Health Canada requires medical device manufacturers to use a quality system certificate as evidence of compliance to the appropriate regulatory quality system requirement and Health Canada will only accept quality system certificates that have been issued by special third party recognized auditing organizations (registrars) under the Canadian Medical Devices Conformity Assessment System (CMDCAS). The Medical Devices Regulations require class II, III and IV medical devices to be designed and/or manufactured under ISO 13485:2003.

In the European Union, 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 European Union, 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. To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they can be granted approval (known as shonin ). The Japanese government, through the Ministry of Health, Labor, and Welfare (MHLW) regulates medical devices under the Pharmaceutical Affairs Law (PAL).

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#### **Patents and Proprietary Rights**

The Company believes that patent protection is important for products and potential segments of its current and proposed business. In the U.S., the Company currently holds 22 patents, and has three patents pending to protect the designs of products which the Company intends to market. There can be no assurance, however, as to the breadth or degree of protection afforded to the Company or the competitive advantage derived by the Company from current patents and future patents, if any. Although the Company believes that its patents and the Company s existing and proposed products do not infringe upon patents of other parties, it is possible that the Company s existing patent rights may be challenged and found invalid or found to violate proprietary rights of others. In the event any of the Company s products are challenged as infringing, the Company would be required to modify the design of its product, obtain a license or litigate the issue. There is no assurance that the Company would be able to finance costly patent litigation, or that it would be able to obtain licenses or modify its products in a timely manner. Failure to defend a patent infringement action or to obtain a license or implementation of modifications would have a material adverse effect on the Company s continued operations.

While patents have been issued or are pending, the Company realizes, (a) that the Company will benefit from patents issued only if it is able to market its products in sufficient quantities of which there is no assurance; (b) that substitutes for these patented items, if not already in existence, may be developed; (c) that the granting of a patent is not a determination of the validity of a patent, such validity can be attacked in litigation or the Company or owner of the patent may be forced to institute legal proceedings to enforce validity; and (d) that the costs of such litigation, if any, could be substantial and could adversely affect the Company.

## **Licenses and Distribution Rights**

In September 2008, the Company and Celling signed a distribution agreement for the Company s MXP and Res-Q 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 on July 29, 2009 to provide shared funding for clinical studies to demonstrate the clinical effectiveness of the products in orthopedic applications.

In May 2008, the Company and GEHC amended their International Distribution Agreement, effective July 1, 2008. Under the terms of the amendment, GEHC no longer sells the BioArchive System and related disposables. GEHC remains the exclusive distributor for the AXP product line for cord blood applications in North America, Europe and Asia (excluding China). The amendment also includes price increases for the AXP disposable bag sets sold to GEHC. The expiration date of the original agreement remains December 31, 2010, and will be automatically renewed for additional two year periods unless terminated by one of the parties 12 months prior to the end of the then current term. Under the original agreement, signed October 13, 2005, the Company received fees for the rights granted under the agreement. The amounts received are being recognized as revenue on the straight-line method over the initial 5-year term of the contract. During fiscal 2009, distribution rights for the AXP in Japan were returned to the Company by GEHC.

On August 22, 2006, the Company announced that GEHC and CBR, the world s largest family cord blood bank, signed a multi-year contract to supply CBR with the Company s AXP Platform and disposables. 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. This agreement also initiates the development of an advanced cord blood stem cell container.

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In July 2006, the Company entered into a Product Development and Supply Agreement with Biomet. Under the development phase of this agreement, Biomet paid the Company \$1.1 million in milestone payments to develop a fibrinogen concentration kit. The Company will grant intellectual property license rights to Biomet and its affiliates to manufacture, use and sell the product for use in surgical hemostats, graft delivery systems and surgeries. The Company has the right of first offer to manufacture the product; and if the Company does not manufacture the product, Biomet will pay a royalty. The agreement has a term of 5 years.

In July 2005, the Company entered into a non-exclusive, five-year distribution agreement with Biomet to supply Biomet with the Company s existing CE-Marked Thrombin Processing Device for sale in Europe for all applications and worldwide for spinal applications in order to allow them to immediately begin marketing their platelet gel product. Previously, Biomet had been selling bovine thrombin with their platelet gel product.

On March 28, 2005, the Company entered into a five-year Distribution and License Agreement with Asahi Kasei Medical Co., Ltd. (Asahi). Under the agreement, the Company granted Asahi exclusive rights to sell the CryoSeal System in Japan. This agreement replaces the parties prior Distribution and Manufacturing License Agreement for the CryoSeal System. The agreement also granted Asahi the right to manufacture the processing disposables and thrombin reagent for production of Thrombin Activation Device (TAD) in Japan. Asahi paid a non-refundable fee upon signing the agreement. The amounts received are being recognized as revenue on the straight-line method over the initial 5-year term of the contract. Asahi has the non-exclusive right to manufacture and sell the TAD Stand Alone in Japan. Asahi has a right of first refusal to expand the territory to include South Korea, North Korea, Taiwan, the Philippines, Thailand, Singapore, India and Malaysia. In June 2008, the parties extended the contract for an additional two years. The agreement shall be automatically renewed for one year terms unless Asahi terminates.

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, and in May 2000, the Company negotiated rights to directly co-market the bag sets in Europe in exchange for an additional royalty fee, while continuing to utilize Pall Europe s distribution centers.

#### **Backlog**

Our backlog was \$0.5 million and \$2.3 million as of June 30, 2009 and 2008, 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.

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#### **Employees**

As of June 30, 2009, the Company had 81 employees, 33 of whom were engaged in manufacturing and quality control, 21 in research and new product development, regulatory affairs, clinical and scientific affairs, 14 in sales, marketing and customer service and 13 in administration. The Company also utilizes temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are represented by a collective bargaining agreement, nor have we experienced any work stoppage.

# FINANCIAL INFORMATION ON FOREIGN SALES AND OPERATIONS

For fiscal year 2009, foreign sales were \$8,310,000 or 42% of net revenues. For fiscal year 2008, foreign sales were \$9,045,000 or 41% of net revenues. For fiscal year 2007, foreign sales were \$8,172,000 or 49% of net revenues. In June 2008, the Company entered into a contract with Nipro Corporation to manufacture AXP disposable bag sets. The manufacturing facility and Nipro Corporation headquarters are located in Japan.

## 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 management is not aware of or focused on or that management currently deems immaterial may also impair ThermoGenesis business operations. This report is qualified in its entirety by these risk factors.

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

# Risks Related to Our Business

Our New Products Are at Initial Market Introduction, and We Are Not Sure the Market Will Accept Them. The market acceptance of our new products 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. Market acceptance will also depend on our ability to adequately train technicians on how to use the AXP, MXP and Res-Q Systems and future products. Even if our new 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

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these new products to achieve significant market share could have material adverse effects on our long term business, financial condition, and results of operation.

A Significant Portion of our Revenue is to Customers in Foreign Countries. We may Lose Revenues, Market Share, and Profits due to Exchange Rate Fluctuations and Other Factors related to our Foreign Business. In the year ended June 30, 2009, sales to customers in foreign countries comprised approximately 42% of our revenues. 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.

# 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 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.

Any Failure to Achieve and Maintain the High 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. We have from time to time voluntarily recalled certain products. Despite our very high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we are unable to manufacture our products in accordance with necessary quality standards, or if we are unable to procure additional high-quality manufacturing facilities, our business and results of operations may be negatively affected.

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 Quality System Regulation 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.

Our Lack of Production Experience May Delay Producing Our New Products. We have manufactured our Blood Plasma Thawers, Freezers and BioArchive Systems for a number of years. We do not have significant experience in manufacturing the Res-Q, the CryoSeal System, the AXP and MXP devices or in

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the manufacture of disposables. There can be no assurance that our current resources and manufacturing facility can handle a significant increase in orders for either the BioArchive System or the CryoSeal System. If we are unable to meet demand for sales, we would need to contract with third-party manufacturers. No assurances can be made that such third-party manufacturers can be retained, or retained on terms favorable to us. Inability to have products manufactured by third parties at a competitive cost could erode anticipated margins for such products, and negatively impact our profitability.

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. 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, or transfer between, qualified suppliers may impact the production schedule, therefore delaying revenues, and this may cause the cost of disposables or key components to increase.

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. 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. Quality Problems with our Products or Processes could Harm our Reputation for Producing High Quality Products and Decrease our Future Revenues. Quality is extremely important to us and our customers due to the consequences of product failure. Our quality certifications and product performance during evaluations and validations are critical to the marketing success of our products. If we fail to meet our customer squality standards our reputation could be damaged and we could lose current and potential customers. Our future revenues could decline as a result. 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 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.

We are Heavily Reliant on a Single Distributor to Market and Sell our AXP Products. GEHC is the primary distributor of the AXP Platform. We have limited control over their sales and marketing efforts for these products. Since the AXP Platform products are a significant portion of our revenues and projected revenue growth, a delay or failure by our distributor to successfully market these products may decrease our future revenues and competitive advantage.

Our Business is Indirectly Subject to Customer and Distributor Inventory Requirements and Continuity of Inventory Purchasing. Our end user customers may have separate agreements with our distributors that require them to hold

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a certain level of inventory. Similarly, other customers have historically purchased ahead of their utilization to insure growth within their business, particularly for the processing of stem cells. Given the tightening of credit and other financial constraints, including downturns in collection and processing for cord blood, our customers could reduce the amount of inventory levels our distributors hold, or which they hold internally. If that were to occur, sales of our products could decline significantly, which would have a material adverse effect on our financial performance in any period where such events occur.

We are Heavily Reliant on a Single Distributor to Market and Sell our MXP and Res-Q Products. Currently, SpineSmith is sole distributor of our MXP and Res-Q products. For orthopedic applications, SpineSmith has exclusive distribution rights in the U.S. and non-exclusive in the rest of the world. We have limited control over their sales and marketing efforts for these products. While we are looking for additional distributors outside the orthopedic application, we are relying on our distributor for a significant portion of our projected revenue growth, A delay or failure by our distributor to successfully market these products may decrease our revenues and competitive advantage. 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 and attracting and retaining highly qualified personnel in these areas. 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.

#### Risks Related to Operating Results and Financial Markets

banks and hospitals. We believe these entities have been negatively affected by

We Have Incurred Net Losses since Our Inception and Expect Losses to 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, 2009, we had a net loss of \$8,550,000 and an accumulated deficit at June 30, 2009, of \$98,359,000. We will continue to incur significant costs as we develop and market our current products and related applications. Although we are executing on our business plan to develop and market launch new products, continuing losses may impair our ability to fully meet our objectives for new product sales.

We May Need to Raise Additional Capital in the Future to Fund Our Operations. We May be Unable to Raise Funds When Needed or on Acceptable Terms. During the year ended June 30, 2009, our operating activities used cash of \$8,757,000. As of June 30, 2009, we had a cash and short investments balance of \$15,631,000. Based on our cash and short-term investments 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, if actual sales do not meet expectations, or product development, marketing and production costs increase significantly, we may need to seek additional financing beyond the next 12 months. Any additional equity financings may be dilutive to our existing stockholders. The Continuing Crisis in the U.S. and World Financial and Securities Markets Could Have a Material Adverse Effect on our Customers Business and Effect our Operations and Revenues. Our products are purchased by cord blood

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the deterioration in the U.S. and global economies in several ways. For instance, cord blood banks and hospitals are facing increased pressure from reduction in donations or in government funding that support their operations. The current economic crisis heightens the risk that our customers may lack the funding or credit facilities that they may have previously used for acquiring our products. Such credit or funding restrictions could delay or lower our future revenues.

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

We and our Customers are Subject to Various Political, Economic and Regulatory Changes in the Healthcare Industry that Could Force us to Modify how we Develop and Price our Components, Manufacturing Capabilities and Services, and could Harm our Business. The healthcare industry is highly regulated and is influenced by changing political, economic and regulatory factors. Federal and state legislatures have periodically considered programs to reform or amend the U.S. healthcare system at both the federal and state levels. Regulations affecting the healthcare industry in general, and the medical device industry in particular, are complex, change frequently and have tended to become more stringent over time. In addition, these regulations may contain proposals to increase governmental involvement in healthcare, lower reimbursement rates or otherwise change the environment in which healthcare industry participants, including medical device companies, operate. While we are not aware of any legislation or regulations specifically targeting the medical device industry that are currently pending, any such regulations could impair our ability to operate profitably. In addition, any failure by us to comply with applicable government regulations could also result in the cessation of portions or all of our operations, impositions of fines and restrictions on our ability to continue or expand our operations.

# 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. Although the majority of our products related to freezing blood components are currently exempt from the requirement to file a 510(k) or PMA, that situation may change in the future if the FDA moves to regulate cell therapy products. In anticipation of possible future regulation by the FDA, the Company has filed, and is maintaining, a Master File on the BioArchive System and the AXP Platform. However, currently the BioArchive, AXP, and the ThermoLine products are being marketed and sold worldwide. Further, our products must be manufactured under principles of our quality system for continued CE-Marking so they can continue to be marketed and sold in Europe. These principles are similar to the quality system regulations of both the FDA and California Department of Health. Failure to comply with 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 European 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 from the FDA or even be temporarily shut down in manufacturing while the nonconformances are rectified.

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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 who possess greater financial resources and more personnel than we have. Our current principal market is cord blood banks. With regard to the BioArchive System and AXP Platform, numerous larger and better-financed medical device manufacturers may choose to enter this market as it develops. The CryoSeal System may face competition from major plasma fractionators that currently sell fibrin glue sourced from pooled plasma outside the U.S.

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 immediate impact in the near future.

Product Liability and Uninsured Risks May Adversely Affect the Continuing Operations. We operate in an industry susceptible to significant product liability claims. We may be liable if any of our products cause injury, illness, or death. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. We also may be required to recall certain of our products should they become damaged or if they are defective. We are not aware of any material product liability claim 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 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 Our Common Stock

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

Variations in operating results,

Regulatory actions, such as product recalls,

Governmental regulatory acts,

Biological or medical discoveries,

Changes in earnings estimates by securities analysts, and

Market conditions in our industry and the economy as a whole.

The closing price of our common stock has ranged from a high of \$6.40 to a low of \$0.31 during the five year period from July 1, 2004 to June 30, 2009. 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 our last fiscal year, 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.

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If the Price of our Common Stock Does Not Meet the Requirements of the NASDAQ Capital Market Stock Exchange, 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. On October 17, 2008, NASDAQ temporarily suspended one of the listing requirements for continued listing on the NASDAQ Capital Market that requires a company s minimum bid price to be above \$1.00 per share. This suspension was extended until July 31, 2009. As of July 31, 2009, our stock price was below \$1.00 per share. If our share price remains below \$1.00, our shares may be delisted or the Company may have to take other action to avoid delisting. 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.

# ITEM 1B. <u>UNRESOLVED STAFF COMMENTS</u>

None.

#### **ITEM 2. PROPERTIES**

The Company leases a facility with approximately 28,000 square feet of space located in Rancho Cordova, California. Approximately 50% of the facility is devoted to warehouse space and manufacturing of products, including 500 square feet for a clean room. The other 50% is comprised of office space, a biologics lab and a Research & Development lab. The lease expires in October 2011.

The Company leases a second facility with approximately 14,000 square feet. The two facilities are located in the same commercial complex. Approximately 30% of the second facility is devoted to warehouse space. The remaining 70% is comprised of office space. The lease expires in March 2012.

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

# **ITEM 3. LEGAL PROCEEDINGS**

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

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company did not submit any matters to security holders during the fourth quarter of its last fiscal year ended June 30, 2009.

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# **PART II**

# ITEM 5. MARKET FOR THE REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company s common stock, \$0.001 par value, is traded on the NASDAQ Capital Market 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. The ranges listed represent actual transactions, without adjustment for retail markups, markdowns or commissions, as reported by NASDAQ.

Fiscal 2009	High	Low	Fiscal 2008	High	Low
First Quarter (Sep. 30)	\$1.84	\$1.17	First Quarter (Sep. 30)	\$2.67	\$2.10
Second Quarter (Dec.			Second Quarter (Dec. 31)		
31)	\$1.28	\$0.31		\$2.59	\$1.58
Third Quarter (Mar. 31)	\$0.84	\$0.40	Third Quarter (Mar. 31)	\$2.04	\$1.35
Fourth Quarter			Fourth Quarter (June 30)		
(June 30)	\$0.77	\$0.51		\$1.70	\$1.29

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 275 stockholders of record on June 30, 2009 (not including street name holders).

The following graph compares the performance of the Company s common stock during the period June 30, 2004 to June 30, 2009, with the NASDAQ Stock Market Index and the Company s peer group of NASDAQ stocks:

## **COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among ThermoGenesis Corp., The NASDAQ Composite Index And A Peer Group

\* \$100 invested on 6/30/04 in stock or index, including reinvestment of dividends. Fiscal year ending June 30.

	6/04	6/05	6/06	6/07	6/08	6/09
ThermoGenesis Corp.	100.00	91.97	87.10	58.35	29.60	13.32
NASDAQ Composite	100.00	101.09	109.49	132.47	117.33	92.91
Peer Group	100.00	90.72	97.55	122.94	111.86	71.20

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ITEM 6. SELECTED FINANCIAL DATA

# ThermoGenesis Corp. Five-Year Review of Selected Financial Data

				Ye	ar l	Ended June 30	,			
Summary of Operations		009		2008		2007		2006		2005
Net revenues	\$ 19,7	99,000	\$	21,946,000	\$	16,751,000	\$ 12	2,048,000	\$ 1	0,177,000
Cost of revenues	(14,1	06,000)	(	(14,976,000)		(11,554,000)	(7	7,705,000)	(	7,089,000)
Gross profit	5,6	593,000		6,970,000		5,197,000	۷	1,343,000		3,088,000
Selling, general and										
administration	(9,2)	49,000)	(	(10,165,000)		(9,630,000)	(7	7,156,000)	(	5,837,000)
Research and development	(5,2)	22,000)		(7,172,000)		(4,108,000)	(4	1,157,000)	(	5,673,000)
Interest and other income, net	2	28,000		1,186,000		1,765,000		828,000		202,000
Net loss	\$ (8,5	(50,000)	\$	(9,181,000)	\$	(6,776,000)	\$ (6	5,142,000)	\$ (	8,220,000)
Per share data:										
Basic and diluted net loss per										
common share	\$	(0.15)	\$	(0.16)	\$	(0.12)	\$	(0.12)	\$	(0.18)
Balance Sheet Data	20	009		2008		2007		2006		2005
Cash, cash equivalents and short										
term investments	\$ 15,6	31,000	\$	25,287,000	\$	33,379,000	\$ 38	3,999,000	\$	9,568,000
Working capital	\$ 20,8	884,000	\$	29,978,000	\$	37,759,000	\$ 42	2,342,000	\$1	3,085,000
Total assets	\$ 27,6	555,000	\$	38,282,000	\$	43,790,000	\$47	7,603,000	\$1	7,466,000
Total liabilities	\$ 5,2	201,000	\$	7,757,000	\$	5,978,000	\$ 5	5,631,000	\$	3,435,000
Total stockholders equity  ITEM 7. MANAGEMENT S		54,000 SION A		30,525,000 ANALYSIS (		37,812,000 FINANCIAL		1,972,000 <b>NDITION</b> .		4,031,000 RESULTS

# 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 7A 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.

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#### (a) Overview

ThermoGenesis develops, manufactures, and sells medical products that enable the practice of regenerative medicine. 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 cell concentrates from cord 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.

# **Stock-Based Compensation:**

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of *Statement of Financial Accounting Standards No.* 123(R), Shared-Based Payments (FAS 123(R)). Under FAS 123(R), compensation cost is calculated 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 actual results are not consistent with the Company s assumptions and judgments used in estimating the key assumptions, the Company may be required to record additional compensation or income tax expense, which could have a material impact on the Company s financial position and results of operations.

#### Revenue Recognition:

The Company recognizes revenue including multiple element arrangements, in accordance with the provisions of the SEC s Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and the Financial Accounting Standards Board s (FASB) Emerging Issues Task Force (EITF) 00-21, *Revenue Agreements with Multiple Deliverables*. 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 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.

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The Company s foreign 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 elements are divided into separate units of accounting if certain criteria are met, including whether the delivered item has value to the customer on a stand-alone basis and whether there is objective and reliable evidence of the fair value of the undelivered items. Revenue is recognized as specific elements indicated in sales contracts are executed. If an element is essential to the functionality of an arrangement, the entire arrangement is revenue is deferred until that essential element is delivered. The fair value of each undelivered element that is not essential to the functionality of the system is deferred until performance or delivery occurs. The fair value of an undelivered element is based on vendor specific objective evidence or third party evidence of fair value as appropriate. Costs associated with inconsequential or perfunctory elements in multiple element arrangements are accrued at the time of revenue recognition. The Company accounts for training and installation as a separate element of a multiple element arrangement. The Company therefore recognizes the fair value of training and installation services upon their completion when the Company is obligated to perform such services.

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.

Milestone payments the Company receives under research and development arrangements are recognized as revenue upon achievement of the milestone events, which represent the culmination of the earnings process, and when collectability is reasonably assured. Milestone payments are triggered by the results of the Company s development efforts. Accordingly, the milestone payments are substantially at risk at the inception of the contract, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. Upon the achievement of a milestone event, which may include acceptance by the counterparty, the Company has no future performance obligations related to that milestone as the milestone payments received by the Company are nonrefundable.

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 product and other revenues, while the related costs are included in cost of product and other revenues.

#### 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

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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 product and other 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.

# (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, 2009 as Compared to the Year Ended June 30, 2008 Net Revenues:

Net revenues for the year ended June 30, 2009 were \$19,799,000 compared to \$21,946,000 for the year ended June 30, 2008, a decrease of \$2,147,000 or 10%. Our decrease in revenues is primarily a result of the slowing global economy which has impacted the majority of our product lines. The CryoSeal product line decreased \$1,477,000 from the year ended June 30, 2008. Revenues from the BioArchive product line decreased approximately \$1,000,000 as there were six fewer devices sold in fiscal 2009 as compared to fiscal 2008. The AXP product line decreased \$560,000 primarily due to the timing of bag set orders. Offsetting these decreases was an increase in revenues of \$367,000 due to the launch of the MXP in fiscal 2009 and Freezer sales increased \$370,000 primarily due to the sale of ten freezers to two different customers.

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Sales analysis for the year ending June 30:

	2009		2008	
Disposable revenues:	Φ ( 521 000		Φ ( 020 000	
AXP/MXP	\$ 6,531,000		\$ 6,828,000	
BioArchive	3,766,000		3,757,000	
CryoSeal	297,000		1,143,000	
	10,594,000	54%	11,728,000	53%
Non-disposable revenues:				
BioArchive	4,262,000	22%	5,564,000	25%
Thermoline	2,361,000	12%	2,058,000	9%
AXP/MXP	722,000	4%	594,000	3%
CryoSeal	37,000		481,000	2%
Milestone payments and license fees	676,000	3%	866,000	5%
Other	1,147,000	5%	655,000	3%
Total Company revenues	\$ 19,799,000	100%	\$21,946,000	100%

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

		June 30
	2009	2008
Asia	64	58
United States	49	46
Europe	51	47
Rest of World	38	30
	202	181

#### **Gross Profit:**

The Company s gross profit was \$5,693,000 or 29% of net revenues for the year ended June 30, 2009, as compared to \$6,970,000 or 32% for the year ended June 30, 2008. The lower gross profit was due to a lower volume of disposable products and additional inventory allowances and reserves for obsolete inventory at AXP bag set suppliers, excess AXP device inventory given the planned transition to an upgraded AXP device and excess CryoSeal inventory. These were offset by lower warranty costs for the BioArchive and CryoSeal products and lower material costs on the AXP bag sets.

#### Selling, General and Administrative Expenses:

Selling, general and administrative expenses were \$9,249,000 for the year ended June 30, 2009, compared to \$10,165,000 for the year ended June 30, 2008, a decrease of \$916,000 or 9%. The decrease is primarily due to lower salaries and benefits of \$580,000 as there were four management positions open during the year, and lower legal fees of \$325,000, as there was \$300,000 of legal fees incurred in fiscal 2008 associated with the GEHC distribution agreement negotiations and for consultation during the voluntary recall effort. Recruiting costs decreased \$275,000 in fiscal 2009 as there were expenses paid in fiscal 2008 in searches for new board members and executive officers. Additionally, stock compensation expense decreased \$220,000. These decreases were offset by an increase in severance expense of \$500,000 in fiscal 2009 primarily due to the severance accruals for the Company s former Chief Executive Officer and vice presidents of sales and marketing.

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#### Research and Development Expenses:

Research and development expenses for the year ended June 30, 2009 were \$5,222,000 compared to \$7,172,000 for fiscal 2008, a decrease of \$1,950,000 or 27%. The decrease is primarily due to a decrease in stock compensation expense of \$1,230,000 as the restricted stock awarded to the company s former Chief Technology Architect (CTA) fully vested in April 2008, a decrease of \$330,000 in expenses associated with the Vantus subsidiary which was formed in February 2008 and a reduction of \$460,000 of expenses for new product development. Management believes that product development and refinement are essential to maintaining the Company s market position. Therefore, the Company considers these costs as continuing costs of doing business. No assurances can be given that the products or markets recently developed or under development will be successful.

# Results of Operations for the Year Ended June 30, 2008 as Compared to the Year Ended June 30, 2007 Net Revenues:

Net revenues for the year ended June 30, 2008 were \$21,946,000 compared to \$16,751,000 for the year ended June 30, 2007, an increase of \$5,195,000 or 31%. The increase is primarily due to revenues from AXP disposables, which increased \$4,271,000 due to higher sales volume from existing customers. Additionally, revenues from BioArchive devices and accessories increased \$1,111,000 as there were 27 shipments of devices in fiscal 2008 compared to 20 shipments in fiscal 2007. These increases were offset by a decrease in development milestone payments and license fees of approximately \$800,000.

The following represents the Company s cumulative BioArchive Systems in the following geographies:

		June 30		
	2008	2007		
Asia	58	56		
United States	46	33		
Europe	47	40		
Rest of World	30	26		
	181	155		

The following represents the Company s revenues for disposables by product line:

	June	June 30		
	2008	2007		
AXP	\$ 6,828,000	\$ 2,557,000		
BioArchive	3,757,000	3,290,000		
TPD	257,000	493,000		
CryoSeal	886,000	365,000		
	\$11,728,000	\$6,705,000		
Percentage of total Company revenues	53%	40%		
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#### Gross Profit:

The Company s gross profit was \$6,970,000 or 32% of net revenues for the year ended June 30, 2008, as compared to \$5,197,000 or 31% for the year ended June 30, 2007. The gross margin for fiscal 2008 was impacted by the costs associated with the voluntary recall of AXP disposable bag sets. The incremental costs of \$386,000 were for testing, materials and the destruction of bag sets which were not considered resalable. No bag set lots have failed the requisite testing performed on the recalled inventory. This was offset by lower warranty costs for the CryoSeal and BioArchive devices.

## Selling, General and Administrative Expenses:

Selling, general and administrative expenses were \$10,165,000 for the year ended June 30, 2008, compared to \$9,630,000 for the year ended June 30, 2007, an increase of \$535,000 or 6%. The increase is due to increased legal costs primarily related to the discussions with GEHC regarding the distribution agreement and consultation during the voluntary AXP recall effort.

# Research and Development Expenses:

Research and development expenses for the year ended June 30, 2008 were \$7,172,000 compared to \$4,108,000 for fiscal 2007, an increase of \$3,064,000 or 75%. The increase is primarily due to stock compensation, salaries and consulting fees of approximately \$1,800,000 related to the CTA, a position filled by the Company s former Chief Executive Officer as of August 1, 2007. Effective May 1, 2008, the CTA resigned to become a consultant to the Company. Also adding to the increase in research and development was \$620,000 in expenses associated with the Vantus subsidiary, a \$350,000 increase in operating supplies for cell therapy research projects and payments made to UC Davis of \$130,000 in connection with an agreement to develop stem cell treatments.

# (c) Liquidity and Capital Resources

At June 30, 2009, the Company had a cash, cash equivalents, and short-term investments balance of \$15,631,000 and working capital of \$20,884,000. This compares to a cash and short-term investments balance of \$25,287,000 and working capital of \$29,978,000 at June 30, 2008. The cash was used to fund operations and other cash needs of the Company. In addition to product revenues, the Company has primarily financed operations through the private and public placement of equity securities and has raised approximately \$108 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, 2009 was \$8,757,000, primarily due to the net loss of \$8,550,000, which included the accretion of discount on short-term investments of \$161,000, offset by depreciation and stock based compensation expense of \$474,000 and \$479,000, respectively. Accounts payable used \$2,405,000 of cash due to paying vendors for purchases made late in the prior fiscal year, primarily for disposable products. Accounts receivable generated \$1,741,000 in cash for the year ended June 30, 2009. Investing activities generated \$11,041,000 of cash primarily due to short-term investments maturing.

We believe that our currently available cash, cash equivalents and short-term investments, and cash generated from operations will be sufficient to satisfy our operating and working capital requirements for at least the next twelve months. We have experienced some slowing in our customers—spending as a result of deterioration in credit markets. As we anticipate this trend to continue into fiscal 2010, we have reduced expenses without sacrificing development plans we consider essential to our near term revenue growth and do no anticipate we will have to seek additional debt or equity capital.

The Company generally does not require extensive capital equipment to produce or sell its current products. In fiscal 2007, the Company spent \$621,000 primarily for office furniture for the new leased

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facility, manufacturing equipment for the AXP product line and laboratory equipment. In fiscal 2008, the Company spent \$514,000 for development of the Company s website, laboratory equipment and manufacturing equipment. In fiscal 2009, the Company spent \$1,047,000 for quality system software, centrifuges to be placed at MXP customer sites, tooling for new products or additional vendors and computer equipment.

During the fiscal year ended June 30, 2009, revenues from one significant customer, GEHC, totaled \$7,735,000 or 39% of net revenues. During the fiscal year ended June 30, 2008, revenues from one significant customer, GEHC, totaled \$13,310,000 or 61% of net revenues. During the fiscal year ended June 30, 2007, revenues from one significant customer, GEHC, totaled \$7,502,000 or 45% of net revenues.

At June 30, 2009, the Company had two customers that individually accounted for 43% and 19% of accounts receivable. At June 30, 2008, the Company had two customers that individually accounted for 60% and 14% of accounts receivable.

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.

#### Off Balance Sheet Arrangements:

As of June 30, 2009, the Company had no off-balance sheet arrangements.

## **Contractual Obligations:**

As of June 30, 2009, the Company had the following contractual obligations and commercial commitments:

Contractual Obligations	Payments Due by Period				
		Less than		4-5	After 5
Capital Lease Obligations Operating Leases	Total \$ 9,000 1,623,000	1 year \$ 5,000 642,000	1-3 years \$ 4,000 981,000	years	years
Total Contractual Cash Obligations	\$1,632,000	\$647,000	\$985,000		
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### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices.

Our exposure to interest rate risk at June 30, 2009, is related to the investment of our excess cash into highly liquid, short-term financial investments. We invest in money market funds, certificates of deposit and U.S. Treasury obligations in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments. We do not hold auction-rate or mortgage-backed securities. Due to the short-term nature of our investments, we have assessed that there is no material exposure to interest rate risk arising from them.

All sales, including those involving foreign entities, are denominated in U.S. dollars and as a result, we have experienced no significant foreign exchange gains and losses to date. We have not engaged in foreign currency hedging activities to date, and have no intention of doing so. Our future revenues may be negatively impacted in periods of a strengthening U.S. dollar. We have not entered into any derivative financial instruments or derivative commodity instruments.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Management s Report on Internal Control Over Financial Reporting	Number 33
Reports of Independent Registered Public Accounting Firm	34
Consolidated Balance Sheets at June 30, 2009 and 2008	36
Consolidated Statements of Operations for the years ended June 30, 2009, 2008 and 2007	37
Consolidated Statements of Stockholders Equity for the years ended June 30, 2009, 2008 and 2007	38
Consolidated Statements of Cash Flows for the years ended June 30, 2009, 2008 and 2007	39
Notes to Consolidated Financial Statements 32	40

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### 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 Officer, and Executive Vice President, Chief Operating Officer and Chief Financial Officer, 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, 2009.

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.

The Company s independent registered public accounting firm has issued an attestation report on the effectiveness of the Company s internal control over financial reporting as of June 30, 2009, which appears on the following page of this Annual Report on Form 10-K.

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### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of ThermoGenesis Corp.

We have audited ThermoGenesis Corp. s internal control over financial reporting as of June 30, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). ThermoGenesis Corp. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

In our opinion, ThermoGenesis Corp. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ThermoGenesis Corp. as of June 30, 2009 and 2008, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended June 30, 2009 and the financial statement schedule listed in the Index of Item 15.(a)(2) and our report dated September 10, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP Sacramento, California September 10, 2009

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### **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, 2009 and 2008, and the related consolidated statements of operations, stockholders—equity, and cash flows for each of the three years in the period ended June 30, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15.(a)(2). These financial statements and schedule are the responsibility of the Company—s management. Our responsibility is to express an opinion on these financial statements and schedule 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ThermoGenesis Corp. s internal control over financial reporting as of June 30, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated September 10, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP Sacramento, California September 10, 2009

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## ThermoGenesis Corp. Consolidated Balance Sheets

ASSETS	June 30, 2009	June 30, 2008
Current assets: Cash and cash equivalents Short-term investments Accounts receivable, net of allowance for doubtful accounts of \$26,000 (\$31,000 at June 30, 2008) Inventories Prepaid expenses and other current assets	\$ 6,655,000 8,976,000 4,235,000 5,233,000 623,000	\$ 4,384,000 20,903,000 5,976,000 5,131,000 367,000
Total current assets	25,722,000	36,761,000
Equipment at cost less accumulated depreciation of \$3,316,000 (\$2,950,000 at June 30, 2008) Other assets	1,823,000 110,000 \$ 27,655,000	1,450,000 71,000 \$ 38,282,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities: Accounts payable Accrued payroll and related expenses Deferred revenue Other current liabilities  Total current liabilities	\$ 1,781,000 881,000 850,000 1,326,000 4,838,000	\$ 4,186,000 564,000 801,000 1,232,000 6,783,000
Deferred revenue	363,000	974,000
Commitments and contingencies (Footnote 6)		
Stockholders equity: Preferred stock, \$0.001 par value; 2,000,000 shares authorized; Series A convertible preferred stock, 1,077,540 shares issued, none outstanding at June 30, 2009 or 2008		
Common stock, \$0.001 par value; 80,000,000 shares authorized; 56,092,960 issued and outstanding (56,027,960 at June 30, 2008) Paid in capital in excess of par Accumulated deficit	56,000 120,757,000 (98,359,000)	56,000 120,278,000 (89,809,000)
Total stockholders equity	22,454,000	30,525,000

\$ 27,655,000 \$ 38,282,000

See accompanying notes.

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# ThermoGenesis Corp. Consolidated Statements of Operations

	2009	Years ended June 30 2008	2007
Revenues:	2007	2000	2007
Product and other revenues	\$ 19,123,000	\$ 21,080,000	\$ 15,093,000
Milestone payments and license fees	676,000	866,000	1,658,000
Net revenues	19,799,000	21,946,000	16,751,000
Cost of revenues:			
Cost of product and other revenues	14,106,000	14,884,000	11,294,000
Cost of milestone payments and license fees	, ,	92,000	260,000
Total costs of revenues	14,106,000	14,976,000	11,554,000
Gross profit	5,693,000	6,970,000	5,197,000
Expenses:			
Selling, general and administrative	9,249,000	10,165,000	9,630,000
Research and development	5,222,000	7,172,000	4,108,000
Total expenses	14,471,000	17,337,000	13,738,000
Loss before interest and other income, net	(8,778,000)	(10,367,000)	(8,541,000)
Interest and other income, net	228,000	1,186,000	1,765,000
Net loss	\$ (8,550,000)	\$ (9,181,000)	\$ (6,776,000)
Per share data:			
Basic and diluted net loss per common share	\$ (0.15)	\$ (0.16)	\$ (0.12)
Shares used in computing per share data	56,060,460	55,754,578	55,169,977
See accompanyin	ig notes.		

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# ThermoGenesis Corp. Consolidated Statements of Stockholders Equity

	Common	Stock	Paid in capital	Accumulated	Total stockholders
	Shares	Amount	in excess of par	deficit	equity
Balance at June 30, 2006	54,882,952	\$55,000	\$115,769,000	\$ (73,852,000)	\$41,972,000
Issuance of shares for exercise of options and warrants Issuance of common shares and compensation related to common stock restricted	601,349	1,000	1,521,000		1,522,000
awards Stock based compensation	16,223		20,000		20,000
expense			1,074,000		1,074,000
Net loss				(6,776,000)	(6,776,000)
Balance at June 30, 2007	55,500,524	56,000	118,384,000	(80,628,000)	37,812,000
Issuance of shares for exercise of options Issuance of common shares and compensation related to common stock restricted	200,651		266,000		266,000
awards, net of stock surrenders	326,785		1,138,000		1,138,000
Stock based compensation expense			490,000		490,000
Net loss				(9,181,000)	(9,181,000)
Balance at June 30, 2008	56,027,960	56,000	120,278,000	(89,809,000)	30,525,000
Issuance of common shares and compensation related to unrestricted common stock awards	65,000		36,000		36,000
Stock based compensation expense			443,000		443,000
Net loss				(8,550,000)	(8,550,000)

Balance at June 30, 2009 56,092,960 \$56,000 \$120,757,000 \$ (98,359,000) \$22,454,000

See accompanying notes.

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# ThermoGenesis Corp. Consolidated Statements of Cash Flows

	2009	Years ended June 30 2008	2007
Cash flows from operating activities:			
Net loss	\$ (8,550,000)	\$ (9,181,000)	\$ (6,776,000)
Adjustments to reconcile net loss to net cash used in			
operating activities:			
Depreciation and amortization	474,000	543,000	549,000
Stock based compensation expense	479,000	1,921,000	1,094,000
Accretion of discount on short-term investments	(161,000)	(918,000)	(1,257,000)
Loss on sale/retirement of equipment		238,000	31,000
Loss on impairment of equipment	149,000		
Net changes in operating assets and liabilities:			
Accounts receivable, net	1,741,000	(2,750,000)	547,000
Inventories	(102,000)	(200,000)	(2,309,000)
Prepaid expenses and other current assets	(256,000)	48,000	47,000
Other assets	12,000	51,000	(34,000)
Accounts payable	(2,405,000)	2,112,000	143,000
Accrued payroll and related expenses	317,000	39,000	108,000
Deferred revenue	(562,000)	(633,000)	(231,000)
Other current liabilities	107,000	279,000	326,000
Net cash used in operating activities	(8,757,000)	(8,451,000)	(7,762,000)
Cash flows from investing activities:			
Purchase of short-term investments	(25,957,000)	(44,336,000)	(51,420,000)
Maturities of investments	38,045,000	52,000,000	60,500,000
Capital expenditures	(1,047,000)	(514,000)	(621,000)
Net cash provided by investing activities	11,041,000	7,150,000	8,459,000
Cash flows from financing activities:			
Exercise of stock options		266,000	439,000
Exercise of warrants			1,083,000
Repurchase of common stock		(293,000)	
Payments on capital lease obligations and note payable	(13,000)	(18,000)	(16,000)
Net cash (used in) provided by financing activities	(13,000)	(45,000)	1,506,000
Net increase (decrease) in cash and cash equivalents	2,271,000	(1,346,000)	2,203,000
Cash and cash equivalents at beginning of year	4,384,000	5,730,000	3,527,000
Cash and cash equivalents at end of year	\$ 6,655,000	\$ 4,384,000	\$ 5,730,000

Supplemental non-cash financing and investing information:

Transfer of inventories to equipment \$ 157,000 \$ 124,000

Transfer of equipment to inventories \$ 42,000 \$ 69,000

Transfer of equipment to other assets \$ 51,000

See accompanying notes. 39

## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. Summary of Significant Accounting Policies

### Organization and Basis of Presentation

The Company was incorporated in Delaware in July 1986. The Company designs, manufactures and markets automated and semi-automated devices and single-use processing disposables that enable hospitals and blood banks to manufacture a therapeutic dose of stem cells, wound healing proteins or growth factors from a single unit of cord blood or the patient s own blood in less than one hour. Initially, the Company developed medical devices for ultra rapid freezing and thawing of blood components, which the Company manufactures and distributes to blood banks and hospitals.

## **Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the parent company, ThermoGenesis Corp., and its wholly-owned subsidiary, Vantus. All significant intercompany balances and transactions have been eliminated in consolidation.

### Use of Estimates

Preparation of financial statements in conformity with U.S. generally accepted accounting principles and pursuant to the rules and regulations of the SEC requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used for, but not limited to, the allowance for doubtful accounts, slow-moving inventory reserves, depreciation, warranty costs, certain accruals and contingencies. Actual results could materially differ from the estimates and assumptions used in the preparation of our consolidated financial statements.

### Revenue Recognition

The Company recognizes revenue including multiple element arrangements, in accordance with the provisions of the SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and the Financial Accounting Standards Board's (FASB) Emerging Issues Task Force (EITF) 00-21, *Revenue Agreements with Multiple Deliverables*. 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 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 foreign 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.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 1. Summary of Significant Accounting Policies (Continued)

### Revenue Recognition (Continued)

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered item has value to the customer on a stand-alone basis and whether there is objective and reliable evidence of the fair value of the undelivered items. Revenue is recognized as specific elements indicated in sales contracts are executed. If an element is essential to the functionality of an arrangement, the entire arrangement is revenue is deferred until that essential element is delivered. The fair value of each undelivered element that is not essential to the functionality of the system is deferred until performance or delivery occurs. The fair value of an undelivered element is based on vendor specific objective evidence or third party evidence of fair value as appropriate. Costs associated with inconsequential or perfunctory elements in multiple element arrangements are accrued at the time of revenue recognition. The Company accounts for training and installation as a separate element of a multiple element arrangement. The Company therefore recognizes the fair value of training and installation services upon their completion when the Company is obligated to perform such services.

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.

Milestone payments the Company receives under research and development arrangements are recognized as revenue upon achievement of the milestone events, which represent the culmination of the earnings process, and when collectability is reasonably assured. Milestone payments are triggered by the results of the Company s development efforts. Accordingly, the milestone payments are substantially at risk at the inception of the contract, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. Upon the achievement of a milestone event, which may include acceptance by the counterparty, the Company has no future performance obligations related to that milestone as the milestone payments received by the Company are nonrefundable.

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 product and other revenues, while the related costs are included in cost of product and other revenues.

### Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. Short-term investments are comprised of certificates of deposit and marketable debt securities which are classified as held-to-maturity and have maturities greater than 90 days, but not exceeding one year.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 1. Summary of Significant Accounting Policies (Continued)

### Cash, Cash Equivalents and Short-Term Investments (Continued)

Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at acquisition cost, adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization and accretion is included in interest income. The cost of securities sold is based on the specific identification method. The fair value of debt securities are determined by quoted market prices.

### Fair Value of Financial Instruments

The carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value due to their short duration.

The Company adopted Statement of Financial Accounting Standard (SFAS) No. 157, Fair Value Measurements (SFAS No. 157) effective July 1, 2008 except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157. SFAS No. 157 applies to all financial assets and financial liabilities that are measured and reported on a fair value basis and requires disclosure that establishes a framework for measuring fair value and expands disclosure about fair value measurements. There was no impact for adoption of SFAS No. 157 to the Company s consolidated financial statements.

SFAS No. 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on management s own assumptions used to measure assets and liabilities at fair value. A financial asset or liability s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

Assets measured at fair value on a recurring basis include the following as of June 30, 2009:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value as of June 30, 2009
Cash equivalents				
Money market funds	\$1,059,000	\$	\$	\$1,059,000
Certificates of deposit	\$	\$3,096,000	\$	\$3,096,000
Short-term investments Certificates of deposit	\$ 42	\$8,976,000	\$	\$8,976,000
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# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 1. Summary of Significant Accounting Policies (Continued)

### Accounts Receivable and Allowance for Doubtful Accounts

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

### **Inventories**

Inventories are stated at the lower of cost or market and include the cost of material, labor and manufacturing overhead. Cost is determined on the first-in, first-out basis.

### **Equipment**

Equipment is recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation for office, computer, machinery and equipment is computed under the straight-line method over the estimated useful lives. Leasehold improvements are depreciated under the straight line method over their estimated useful lives or the remaining lease period, whichever is shorter.

### 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 consolidated financial position, cash flows or results of operations.

### **Stock-Based Compensation**

The Company has four stock-based compensation plans, which are described more fully in Note 7.

The Company accounts for stock-based compensation arrangements in accordance with FASB Statement No. 123(R) Share-Based Payment, which requires the measurement and recording of compensation expense using a fair-value method.

Valuation and Amortization Method The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing formula. This fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period.

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# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 1. Summary of Significant Accounting Policies (Continued)

### **Stock-Based Compensation (Continued)**

Expected Term For options which the Company has limited available data, the expected term of the option is based on the simplified method as allowed by SAB 107 and SAB 110. This simplified method averages an award s vesting term and its contractual term. For all other options, the Company s expected term represents the period that the Company s stock-based awards are expected to be outstanding and was determined based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior.

Expected Volatility The Company uses the trading history of its common stock in determining an estimated volatility factor when using the Black-Scholes-Merton option-pricing formula to determine the fair value of options granted. Expected Dividend The Company has not declared dividends and we do not anticipate declaring any dividends in the foreseeable future. Therefore, the Company uses a zero value for the expected dividend value factor when using the Black-Scholes-Merton option-pricing formula to determine the fair value of options granted.

Risk-Free Interest Rate The Company bases the risk-free interest rate used in the Black-Scholes-Merton valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with the same or substantially equivalent remaining term.

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

The fair value of the Company s stock options granted to employees for the years ended June 30, 2009, 2008 and 2007 was estimated using the following weighted-average assumptions:

	2009	2008	2007
Expected life (years)	3.0	3.1	3.5
Risk-free interest rate	1.4%	3.9%	4.7%
Expected volatility	83%	57%	54%
Dividend vield	0%	0%	0%

The weighted average grant date fair value of options granted during the years ended June 30, 2009, 2008 and 2007 was \$0.42, \$0.82 and \$1.66, respectively.

### Research and Development

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

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# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 1. Summary of Significant Accounting Policies (Continued)

#### Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The Company places its cash in checking accounts, money market funds and certificate of deposits with reputable financial institutions, which are within the Federal Deposit Insurance Corporation insurable limits. The Company has not experienced any realized losses on its deposits of cash, cash equivalents and investments.

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

### Segment Reporting

The Company operates in a single segment providing medical devices and disposables to hospitals and blood banks throughout the world which utilize the equipment to process blood components.

### **Income Taxes**

Effective July 1, 2007, we adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), an interpretation of FASB Statement No. 109 (SFAS 109). There was no impact on our financial statements upon adoption. Because of our historical significant net operating losses, we have not been subject to income tax since inception. The tax years 1993-2009 remain open to examination by the major taxing jurisdictions to which we are subject. The Company s policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged to the Company in relation to the underpayment of income taxes. There were no unrecognized tax benefits during all the periods presented.

The Company accounts for income taxes using the liability method. Under this method, deferred tax assets are based on differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. These deferred tax assets include net operating loss carryforwards, research credits and deferred revenue. The net deferred tax asset has been fully offset by a valuation allowance because of our history of losses. Utilization of operating losses and credits may be subject to annual limitation due to ownership change provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

### Net Loss per Share

Net loss per share is computed by dividing the net loss to common stockholders by the weighted average number of common shares outstanding. The calculation of the basic and diluted earnings per share is the same for all periods presented, as the effect of the potential common stock equivalents is anti-dilutive due to the Company s net loss position for all periods presented. Anti-dilutive securities, which consist of stock options and common stock restricted awards, that were not included in diluted net loss per common share, were 3,099,141, 3,014,437 and 2,995,417 as of June 30, 2009, 2008 and 2007, respectively.

### Subsequent Events

The Company has evaluated the impact of subsequent events through September 10, 2009, which is the date these financial statements were issued.

#### Reclassifications

Certain amounts in the prior year s financial statements have been reclassified to conform with the 2009 presentation.

# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 1. Summary of Significant Accounting Policies (Continued)

### **New Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 allows entities to voluntarily choose to measure many financial assets and financial liabilities at fair value. The Company adopted SFAS No. 159 effective July 1, 2008 and has not elected the fair value option for its financial instruments. The adoption of SFAS No. 159 did not have an impact on the Company s consolidated results or financial condition.

In June 2007, the FASB ratified a consensus opinion reached by the EITF on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). The guidance in EITF 07-3 requires the Company to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, the Company would be required to expense the related capitalized advance payments. The consensus in EITF 07-3 was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is applied prospectively to new contracts entered into on or after December 15, 2007. The Company adopted EITF 07-3 effective July 1, 2008. The adoption of EITF 07-3 did not have a material impact on the Company s results of operations or financial condition.

In December 2007, the FASB ratified EITF Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. EITF 07-1 shall be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. The Company is currently assessing the potential impact, if any, the adoption of EITF 07-1 may have on its consolidated financial statements. In December 2007, the FASB issued SFAS No. 141R, Business Combinations (SFAS No. 141R) which replaces SFAS No. 141. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value and requires the expensing of acquisition-related costs as incurred. SFAS No. 141(R) is effective in fiscal years beginning after December 15, 2008. The Company will assess the potential impact of the adoption of SFAS 141R if, and when, a future acquisition occurs.

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# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 1. Summary of Significant Accounting Policies (Continued)

### New Accounting Pronouncements (Continued)

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the U.S for non-governmental entities. SFAS No 162 is effective 60 days following approval by the Securities and Exchange Commission of the Public Company Accounting Oversight Board s amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company does not expect SFAS No. 162 to have a material impact on its financial statements. The Company is currently assessing the potential impact, if any, the adoption of SFAS No. 162 may have on its consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* (SFAS 165). SFAS 165 incorporates existing guidance into the accounting literature for the accounting and disclosure of events that occur after the balance sheet date but before financial statements are issued. In addition, the standard requires disclosure of the date through which a company has evaluated subsequent events. SFAS 165 became effective as of the end of the Company s fiscal year 2009, and the required disclosure has been provided in Note 1 Summary of Significant Accounting Policies of Notes to Consolidated Financial Statements. The adoption did not have a material effect on the Company s consolidated financial statements.

### 2. Short-Term Investments

The following is a summary of held-to-maturity securities:

June 30, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificate of deposit	\$ 8,976,000			\$ 8,976,000
Maturity Date: Less than 90 days Due in 91-365 days	\$ 99,000 8,877,000 \$ 8,976,000			\$ 99,000 8,877,000 \$ 8,976,000
June 30, 2008 U.S. Treasury obligations	\$ 20,903,000		\$ 13,000	\$ 20,890,000

The aggregate amount of unrealized losses and fair value of short term investments, which are not deemed to be other-than-temporarily impaired and less than twelve months are:

	Aggregate Fair Value	Unrealized Loss
June 30, 2008 U.S. Treasury Obligations	\$ 20,890,000	\$ 13,000
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# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 3. Inventories

Inventories consisted of the following at June 30:

	2009	2008
Raw materials	\$ 1,116,000	\$1,869,000
Work in process	1,871,000	1,302,000
Finished goods	2,246,000	1,960,000
	\$ 5,233,000	\$5,131,000

## 4. Equipment

Equipment consisted of the following at June 30:

	2009	2008	Estimated Useful Life
Machinery and equipment	\$ 2,955,000	\$ 2,301,000	3-10 years or lease term
Computer and software	1,171,000	1,096,000	2-5 years
Office equipment	706,000	696,000	5-10 years
Leasehold improvements	307,000	307,000	5 years or lease term
Less accumulated depreciation and amortization	5,139,000 (3,316,000)	4,400,000 (2,950,000)	
	\$ 1,823,000	\$ 1,450,000	

## 5. Other Current Liabilities

Other current liabilities consisted of the following at June 30:

	2009	2008
Accrued warranty reserves	\$ 529,000	\$ 507,000
Accrued professional fees	274,000	210,000
Other accrued liabilities	523,000	515,000
	\$ 1,326,000	\$ 1,232,000

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 6. Commitments and Contingencies

### **Operating Leases**

The Company leases its facilities pursuant to two operating leases, which contain scheduled rent increases. One facility lease expires in 2011, is non-cancelable and does not have an option to renew. The other facility lease expires in 2012, is cancelable after 36 months and does not have an option to renew. The Company recognizes rent expense on a straight-line basis over the terms of the respective facility lease. The annual future minimum lease payments for the non-cancelable operating leases are as follows:

2010	\$ 642,00	)()
2011	668,00	)()
2012	313,00	)()
T1		

Thereafter

Total \$1,623,000

 $Rent\ expense\ was\ \$751,\!000,\ \$697,\!000\ and\ \$552,\!000\ for\ the\ years\ ended\ June\ 30,\ 2009,\ 2008\ and\ 2007,\ respectively.$ 

# <u>Contingencies</u> In the normal course of operations, the Compa

In the normal course of operations, the Company may have disagreements or disputes with customers, employees or vendors. These disputes are seen by the Company s management as a normal part of business, and there are no pending actions currently or no threatened actions that management believes would have a significant material impact on the Company s financial position, results of operations or cash flow.

### Import/Export Bonds

For the year ended June 30, 2008, the Company recorded an estimated loss contingency in the amount of \$100,000 related to the breach of regulations for importing and exporting products. The Company settled the matter in fiscal 2009, paying \$32,000 in penalties and released the unused portion of \$68,000.

### **Product Recalls**

As part of its normal operations, the Company may conduct recalls of products or parts. For the year ended June 30, 2008, the Company accrued \$185,000 for payments to be paid in connection with recalls the Company had during the fiscal year. The Company settled the matter in fiscal 2009 for \$160,000 and released the unused portion of \$25,000. *Vendor Purchase Commitments* 

A product manufacturing supplier made purchases of raw materials based on company provided forecasts, which the company may be required to pay for as part of normal manufacturing processes, including scrap and obsolete parts that result from the Company s product design changes, and or discontinuation of manufacturing by a particular vendor. These are normal and standard manufacturing terms, and the company recorded an estimated loss contingency of \$160,000 as management considers it probable that the payment will be made.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 6. Commitments and Contingencies (Continued)

### **Warranty**

The Company offers a one-year warranty on all of its products. The Company warrants disposable products through their expiration date. The Company periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary.

Changes in the Company s product liability which is included in accrued liabilities during the period are as follows:

	For years ended June 30,	
	2009	2008
Beginning balance	\$ 507,000	\$ 302,000
Warranties issued during the period	267,000	404,000
Settlements made during the period	(667,000)	(643,000)
Changes in liability for pre-existing warranties during the period, including		
expirations	422,000	444,000
Ending balance	\$ 529,000	\$ 507,000

As a result of the voluntary recall of certain lots of the AXP disposable bag sets, the Company made revisions to its estimated warranty liability. These changes in estimates increased the Company s cost of revenues and net loss by \$520,000 and net loss per share of \$0.01 for the quarter ended September 30, 2008 and decreased the Company s cost of revenues and net loss by \$115,000 (no net loss per share impact) for the quarter ended December 31, 2008. There were no changes to the estimated warranty liability for the voluntary recall during the quarters ended March 31, 2009 or June 30, 2009.

In the prior fiscal year, as a result of various quality issues experienced by high usage customers of the AXP devices and docking stations, the Company made revisions to its estimated warranty liability for the year ended June 30, 2008. The Company recorded a change in estimate, which increased the Company s cost of product and other revenues and net loss (no net loss per share impact) by \$444,000.

### 7. Stockholders Equity

### Common Stock

As of June 30, 2009, the Company had 5,106,652 shares of common stock reserved for future issuance.

### Warrants

In conjunction with a private placement on March 26, 2002, five year warrants were issued, representing the right to acquire an additional 723,362 shares of common stock at \$3.07 per share. The warrants vested immediately and expired in March 2007.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 7. Stockholders Equity (Continued)

### Warrants (Continued)

A summary of warrant activity for the three years ended June 30, 2009 follows:

Balance at June 30, 2006	Number of Shares 393,362	Weighted- Average Exercise Price Per Share \$3.07
Warrants granted		
Warrants canceled	(40,862)	\$3.07
Warrants exercised	(352,500)	\$3.07

Outstanding and exercisable at June 30, 2007, 2008 and 2009

### **Stock Options**

The Amended 1994 Stock Option Plan (1994 Plan) permits the grant of stock or options to employees, directors and consultants. A total of 1,450,000 shares were approved by the stockholders for issuance under the 1994 Plan. Options are granted at prices that are equal to 100% of the fair market value on the date of grant, and expire over a term not to exceed ten years. Options generally vest ratably over a five-year period, unless otherwise determined by the Board of Directors. The 1994 Plan, but not the options granted, expired in October 2004.

The Amended 1998 Stock Option Plan (1998 Plan) permits the grant of stock or options to employees, directors and consultants. A total of 3,798,000 shares were approved by the stockholders for issuance under the 1998 Plan. Options are granted at prices that are equal to 100% of the fair market value on the date of grant, and expire over a term not to exceed ten years. Options generally vest ratably over three to five years, unless otherwise determined by the Board of Directors. The 1998 Plan, but not the options granted, expired in February 2008.

The 2002 Independent Directors Equity Incentive Plan (2002 Plan) permits the grant of stock or options to independent directors. A total of 350,000 shares were approved by the stockholders for issuance under the 2002 Plan. Options are granted at prices which are equal to 100% of the fair market value on the date of grant, and expire over a term not to exceed ten years. Options generally vest immediately, unless otherwise determined by the Board of Directors.

The 2006 Equity Incentive Plan (2006 Plan) permits the grant of options, restricted stock, stock bonuses and stock appreciation rights to employees, directors and consultants. Under the 2006 Plan, the number of shares of common stock equal to 6% of the number of outstanding shares of the Company are authorized to be issued. The number of shares available to grant for awards adjusts at the beginning of each fiscal year if additional shares of common stock were issued in the preceding fiscal year. As of June 30, 2009 there were 3,361,678 shares approved under the Plan for issuance.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 7. Stockholders Equity (Continued)

### **Stock Compensation Expense**

At June 30, 2009, the total compensation cost related to unvested stock-based awards granted to employees under the Company's stock option plans but not yet recognized was \$787,000 net of estimated forfeitures of \$122,000. This cost will be amortized on a straight-line basis over a weighted-average period of approximately two years and will be adjusted for subsequent changes in estimated forfeitures. The total fair value of options vested during the years ended June 30, 2009, 2008 and 2007 was \$342,000, \$377,000 and \$789,000.

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

Outstanding at June 30, 2008	Number of Shares 2,994,937	Av Ex	ighted- verage ercise Price 2.64	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Granted Forfeited or Expired Exercised	1,960,333 (1,875,629)	\$ \$	0.75 2.29		
Outstanding at June 30, 2009	3,079,641	\$	1.65	3.0	\$ 39,000
Vested and Expected to Vest at June 30, 2009	2,787,679	\$	1.71	3.0	\$ 34,000
Exercisable at June 30, 2009	842,453	\$	3.17	2.1	

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company s common stock. There were no options that were exercised during the year ended June 30, 2009. During the years ended June 30, 2008 and 2007, the aggregate intrinsic value of options exercised under the Company s stock option plans were \$248,000 and \$278,000, respectively, determined as of the date of option exercise.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 7. Stockholders Equity (Continued)

### **Stock Compensation Expense (Continued)**

The following table summarizes information about stock options outstanding at June 30, 2009:

Range of Exercise Prices	Number Outstanding	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
\$0.56 -	C				
\$0.77	1,642,500	3.7	\$0.68		
\$1.34 -					
\$1.83	340,000	3.2	\$1.55	73,334	\$ 1.53
\$2.06 -					
\$2.88	627,362	1.9	\$2.33	352,340	\$ 2.33
\$3.58 -					
\$5.01	449,779	2.4	\$4.13	396,779	\$ 4.09
\$5.88 -					
\$5.88	20,000	0.4	\$5.88	20,000	\$ 5.88
	3.079,641			842,453	

#### Common Stock Restricted Awards

On April 26, 2007, the Company s Chief Executive Officer (incumbent CEO) was granted 500,000 shares of restricted common stock with three year vesting. The grant had a value of \$1,700,000 based on the fair market value of the Company s stock on the grant date. The vesting is subject to acceleration upon certain conditions: (1) entry into the Employment Agreement for a term of three years, (2) Company s engagement of a new Chief Executive Officer (new CEO) and confirmation by the Board of Directors, and (3) development and Board approval of a transition plan for the new CEO and transition of the incumbent CEO to the position of CTA. However, in accordance with the 2006 Plan, performance based stock option awards must have a minimum vesting period of at least one year. The performance conditions were all satisfied by May 2008, therefore, the compensation expense of \$1,700,000 was amortized over one year of which \$1,417,000 and \$283,000 has been included in the accompanying consolidated statement of operations in fiscal 2008 and 2007, respectively. In connection with the vesting of the restricted stock, the election was made by the CTA to satisfy the applicable federal income tax withholding obligation by a net share settlement, pursuant to which the Company withheld 178,215 shares and used the deemed proceeds from those shares to pay the income tax withholding. The net share settlement is deemed to be a repurchase by the Company of its common stock. During fiscal 2007, the Company s Compensation Committee granted 10,000 shares of restricted common stock to an officer, one half vesting immediately and one half on the first anniversary of the grant date. The shares had a fair market value of \$3.40 per share on the date of grant.

On August 9, 2004, the Company s Compensation Committee approved the grant of 50,914 shares of restricted common stock to selected members of management and key employees, excluding its executive officers, which had a fair market value of \$3.58 per share on the date of grant. These common stock restricted awards vest in three equal installments, on the date of grant and the first and second anniversary of the grant date. One third vested immediately on the grant date and the remaining value was amortized on a straight-line basis over the remaining two year service period.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 7. Stockholders Equity (Continued)

### Common Stock Restricted Awards (Continued)

The following is a summary of restricted stock activity during the years ended June 30, 2007, 2008 and 2009:

Outstanding at June 30, 2006	Number of Shares 11,000	Grant Date Fair Value \$ 40,000
Granted Vested Forfeited	510,000 (16,000)	1,734,000 (57,000)
Outstanding at June 30, 2007	505,000	1,717,000
Granted Vested Forfeited	30,000 (505,000) (30,000)	67,000 (1,717,000) (67,000)
Outstanding at June 30, 2008 and 2009		\$

#### 8. Concentrations

At June 30, 2009, the Company had two customers that individually accounted for 43% and 19% of accounts receivable. At June 30, 2008, the Company had two customers that individually accounted for 60% and 14% of accounts receivable.

Revenues from one significant customer totaled \$7,735,000 or 39% of net revenues, \$13,310,000 or 61% of net revenues and \$7,502,000 or 45% of net revenues during the years ended June 30, 2009, 2008 and 2007, respectively. The following is a summary of product revenues as a percentage of total net revenues for the Company s principal product lines:

		2009	2008	2007
BioArchive		41%	42%	48%
AXP/MXP		37%	34%	19%
ThermoLine		12%	9%	13%
CryoSeal		2%	7%	7%
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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### **8.** Concentrations (Continued)

The Company had sales to customers as follows for the years ended June 30:

2009	2008	2007
\$ 11,489,000	\$12,901,000	\$ 8,579,000
2,510,000	5,565,000	4,625,000
3,544,000	2,125,000	2,588,000
1,859,000	1,208,000	802,000
397,000	147,000	157,000
¢ 10 700 000	\$ 21 046 000	\$ 16,751,000
	\$ 11,489,000 2,510,000 3,544,000 1,859,000	\$ 11,489,000 \$ 12,901,000 2,510,000 5,565,000 3,544,000 2,125,000 1,859,000 1,208,000 397,000 147,000

The Company purchases certain of its CryoSeal disposable products from one supplier in Asia. Additionally, one supplier in Asia is one of two suppliers of the AXP disposable bagset. The Company has satisfactory relationships with these suppliers.

### 9. Income Taxes

The reconciliation of federal income tax attributable to operations computed at the federal statutory tax rate of 34% to income tax expense is as follows for the years ended June 30:

	2009	2008	2007
Statutory federal income tax benefit	\$ (2,907,000)	\$ (3,122,000)	\$ (2,304,000)
Net operating loss with no tax benefit	2,907,000	3,122,000	2,304,000
Total federal income tax	<b>¢</b>	¢	¢
Total federal illcolle tax	J)	J)	J)

At June 30, 2009, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately \$82,533,000 and \$51,070,000 respectively, that are available to offset future income. The federal and state loss carryforwards expire in various years between 2010 and 2029, and 2014 and 2019, respectively. At June 30, 2009, the Company has research and experimentation credit carryforwards of approximately \$1,155,000 for federal tax purposes that expire in various years between 2010 and 2029, and \$1,217,000 for state income tax purposes that do not have an expiration date.

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## THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### 9. Income Taxes (Continued)

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

	June 30, 2009	June 30, 2008
Deferred tax assets: Net operating loss carryforwards Income tax credits	\$ 30,862,000 1,976,000	\$ 27,502,000 1,507,000
Other  Total deferred taxes	2,527,000 35,365,000	2,761,000 31,770,000
Valuation allowance	(35,365,000)	(31,770,000)
Net deferred taxes	\$	\$

The valuation allowance increased by approximately \$3,595,000, \$3,041,000 and \$2,384,000 in 2009, 2008 and 2007, respectively. As of June 30, 2009, the Company has a benefit of approximately \$1,858,000 related to stock option deductions, which will be credited to paid-in capital when realized, of which \$1,624,000 is included in the valuation allowance.

Because of the change of ownership provisions of the Tax Reform Act of 1986, a portion of the Company s federal net operating loss and credit carryovers may be subject to an annual limitation regarding their utilization against taxable income in future periods.

### 10. Employee Retirement Plan

The Company sponsors an Employee Retirement Plan, generally available to all employees, in accordance with Section 401(k) of the Internal Revenue Code. Employees may elect to contribute up to the Internal Revenue Service annual contribution limit. Under this Plan, at the discretion of the Board of Directors, the Company may match a portion of the employees contributions.

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# THERMOGENESIS CORP. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 11. <u>Unaudited Quarterly Financial Data</u>

The following tables provide quarterly data for fiscal years ended June 30, 2009 and 2008.

	Ended September 30, 2008	Second Quarter Ended  December 31, 2008	Third Quarter Ended March 31, 2009	Fourth Quarter Ended June 30, 2009 <sup>(1)</sup>
Net revenues Gross Profit	\$ 4,502,000 \$ 1,280,000	\$ 6,126,000 \$ 2,213,000	\$ 5,148,000 \$ 1,794,000	\$ 4,023,000 \$ 406,000
Net loss	\$ (2,679,000)	\$ (1,695,000)	\$ (1,092,000)	\$ (3,084,000)
Per share data:				
Basic and diluted net loss per common share	\$ (0.05)	\$ (0.03)	\$ (0.02)	\$ (0.05)
Shares used in computing per share data	56,027,960	56,027,960	56,092,960	56,092,960
	First Quarter	Second	Third	Fourth
	First Quarter Ended	Second Quarter Ended	Third Quarter Ended	Fourth Quarter Ended
	_	Quarter	Quarter	Quarter
Net revenues	Ended September 30, 2007 \$ 3,632,000	Quarter Ended  December 31, 2007  \$ 5,487,000	Quarter  Ended  March 31, 2008  \$ 5,645,000	Quarter Ended June 30, 2008 (2) \$ 7,182,000
Net revenues Gross Profit Net loss	Ended September 30, 2007	Quarter Ended December 31, 2007	Quarter Ended March 31, 2008	Quarter Ended June 30, 2008 (2)
Gross Profit	Ended September 30, 2007 \$ 3,632,000 \$ 1,209,000	Quarter Ended  December 31, 2007  \$ 5,487,000 \$ 1,910,000	Quarter  Ended  March 31, 2008  \$ 5,645,000 \$ 1,501,000	Quarter  Ended  June 30, 2008 (2)  \$ 7,182,000 \$ 2,350,000
Gross Profit Net loss	Ended September 30, 2007 \$ 3,632,000 \$ 1,209,000	Quarter Ended  December 31, 2007  \$ 5,487,000 \$ 1,910,000	Quarter  Ended  March 31, 2008  \$ 5,645,000 \$ 1,501,000	Quarter  Ended  June 30, 2008 (2)  \$ 7,182,000 \$ 2,350,000

- During the fourth quarter of 2009, the gross margin was impacted by increases in inventory reserves and write-offs of obsolete inventory of \$1,006,000. Selling, general and administrative expenses were impacted by a severance accrual of \$175,000 and a loss on impairment of equipment of
- (2) During the fourth quarter of 2008, the Company recorded a write-off of long-lived assets of \$238,000 and a change in estimate of warranty liability of \$90,000.

\$150,000.

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

None.

### ITEM 9A. CONTROLS AND PROCEDURES

The Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Company s Principal Executive Officer along with the Company s Principal Financial Officer, of the effectiveness of the design of the Company s disclosure controls and procedures (as defined by Exchange Act Rule 13a-15(e) and 15a-15(e)) as of the end of the Company s fiscal year pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Company s Principal Executive officer along with the Company s Principal Financial Officer concluded that the Company s disclosure controls and procedures are effective.

## Management s Report on Internal Control over Financial Reporting

The report of management required under 9A is considered in Item 8 Part II of this Annual Report on Form 10-K under the heading Management s Report on Internal Control over Financial Reporting.

## **Attestation Report of Independent Registered Public Accounting Firm**

The attestation report required under this Item 9A is contained in Item 8 of Part II of this Annual Report on Form 10-K under the heading Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting.

### **Changes in Internal Control over Financial Reporting**

There were no changes in the Company s internal controls over financial reporting that occurred during the fiscal quarter ended June 30, 2009, that have materially affected, or are reasonably likely to materially affect its internal controls over financial reporting. The Company believes that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

### ITEM 9B. OTHER INFORMATION

None.

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### **PART III**

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders. We have adopted a Code of Ethics applicable to all employees including our CEO and CFO. A copy of the Code of Ethics is available at www.thermogenesis.com.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

## ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND</u> RELATED

### STOCKHOLDER MATTERS

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

## ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

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## **PART IV**

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

		Page Number
(a) (1)	Financial Statements	
	Reports of Independent Registered Public Accounting Firm	34
	Consolidated Balance Sheets at June 30, 2009 and 2008	36
	Consolidated Statements of Operations for the years ended June 30, 2009, 2008 and 2007	37
	Consolidated Statements of Stockholders Equity for the years ended June 30, 2009, 2008 and 2007	38
	Consolidated Statements of Cash Flows for the years ended June 30, 2009, 2008 and 2007	39
	Notes to Consolidated Financial Statements	40
_	ement s Report on Internal Control over Financial Reporting is contained as part of this report upols and Procedures.	nder Item 9A
(a) (2)	Financial Statement Schedules	
	Schedule II, Valuation and Qualifying Accounts & Reserves	65
	All other financial statement schedules have been omitted because they are not required or not	applicable.
(b)	Exhibits	
	Exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index on the next pagincorporated herein by this reference.  60	e, which are

### **Table of Contents**

### **Exhibit Description**

- 3.1 (a) Amended and Restated Certificate of Incorporation (1)
  - (b) Revised Bylaws (2)
- 10.1 (a) License Agreement with Pall/Medsep Corporation (3)
  - (b) Securities Purchase Agreement dated March 10, 2004 (form) (4)
  - (c) Amended 2002 Independent Directors Equity Incentive Plan (5)
  - (d) Distribution and License Agreement with Asahi Kasei Medical Co., Ltd. (6)
  - (e) Supply Agreement with Cell Factors Technology, Inc. (7)
  - (f) Employment Agreement for Matthew Plavan (16)
  - (g) International Distribution Agreement with Amersham Biosciences AB (8)
  - (h) OEM Supply Agreement with Medtronic, Inc. (9)
  - (i) Employment Agreement with John Chapman (10)
  - (j) Product Development and Supply Agreement with Biomet Biologics (11)
  - (k) First Amendment License Agreement (Clotalyst) (12)
  - (1) Amended & Restated International Distribution Agreement with GE Healthcare (13)
  - (m) Employment Agreement with J. Melville Engle (15)
- 14 Amended and Restated Code of Ethics (14)
- 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
- 31.1 Rule 13(a) 14(a)/15(d) 14(a) Certification (Principal Executive Officer)
- 31.2 Rule 13(a) 14(a)/15(d) 14(a) Certification (Principal Financial Officer)
- 32 Section 1350 Certifications

### **Footnotes to Exhibit Index**

- (1) Incorporated by reference to ThermoGenesis proxy statement for the Special Meeting hold on December 5, 2005.
- (2) Incorporated by reference to Form 10-KSB for the year ended June 30, 1994.
- (3) Incorporated by reference to Form 8-K dated April 14, 1997.
- (4) Incorporated by reference to Form 8-K dated March 10, 2004.

- (5) Incorporated by reference to Form 8-K dated December 15, 2004.
- (6) Incorporated by reference to Form 8-K dated March 28, 2005.
- (7) Incorporated by reference to Form 8-K dated March 29, 2005.
- (8) Incorporated by reference to Form 8-K dated October 13, 2005.
- (9) Incorporated by reference to Form 8-K dated November 4, 2005.
- (10) Incorporated by reference to Form 10-K for the year ended June 30, 2006.
- (11) Incorporated by reference to Form 8-K dated August 3, 2006.
- (12) Incorporated by reference to Form 10-K for quarter ended March 31, 2007.
- (13) Incorporated by reference to Form 8-K dated May 7, 2008
- Incorporated by reference to ThermoGenesis proxy statement for the Annual Meeting held on October 28, 2005.
- (15) Incorporated by reference to Form 8-K dated April 15, 2009.

(16) &nbs