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THERMOGENESIS CORP

Form S-3

November 21, 2005

As filed with the Securities and Exchange Commission on November 21, 2005

Registration No. _____

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

Form S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

THERMOGENESIS CORP.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

94-3018487

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

2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100
(Address and telephone number of principal executive offices)

Philip H. Coelho
Chief Executive Officer
2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100
(Name, address and telephone number of agent for service)

Copies to:
David C. Adams, Esq.
Mark Lee, Esq.
Bullivant/Houser/Bailey P.C.
1331 Garden Highway, Suite 300
Sacramento, California 95833
Telephone: (916) 442-0400

Approximate date of commencement of the proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. []

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list

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the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If delivery of the Prospectus is expected to be made pursuant to Rule 434, please check the following box. []

CALCULATION OF REGISTRATION FEE			
Title of each class of securities to be registered	Amount to be registered(1) (3)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(2)
Common Stock, \$0.001 par value	\$75,000,000	-	\$75,000,000

(1) There are being registered an indeterminate number of shares of common stock of the Registrant as shall have an aggregate offering price not to exceed \$75,000,000. The proposed maximum offering price per share shall be determined from time to time by the Registrant in connection with the issuance of any securities under the registration statement. Also includes additional shares of common stock that may be issued as a result of stock splits, stock dividends or similar transactions.

(2) Calculated in accordance with Rule 457(o) of the Securities Act of 1933, as amended ("Securities Act").

(3) Includes such indeterminate number of shares of common stock as may from time to time be issued at indeterminate prices, subject to the aggregate threshold dollar amount registered.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission (the "Commission"), acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The Company may not sell these securities until the registration statement filed with the Commission becomes effective, and only then pursuant to a prospectus supplement. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted or would be unlawful prior to registration or qualification under the securities laws of any such state.

SUBJECT TO COMPLETION, DATED NOVEMBER 21, 2005.

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PROSPECTUS

\$75,000,000

THERMOGENESIS CORP.
Common Stock

By this prospectus, we may offer a number of shares of our common stock up to an aggregate of \$75,000,000 in one or more transactions. We will provide specific terms for any sale of common stock in supplements to this prospectus. You should read this prospectus and any prospectus supplement, as well as the documents incorporated or deemed to be incorporated by reference in this prospectus, carefully before you invest. This prospectus may not be used to offer and sell the shares of common stock unless accompanied by a prospectus supplement.

Our common stock is traded and listed on the NASDAQ SmallCap Market, under the symbol "KOOL." On November 18, 2005, the last reported sale price for the common stock was \$5.01 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK.
SEE "RISK FACTORS" AT PAGE 2.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE SALES OF SECURITIES UNLESS ACCOMPANIED BY THE APPLICABLE PROSPECTUS SUPPLEMENT.

The date of this Prospectus is _____, 2005

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PROSPECTUS SUMMARY

Forward-Looking Statements

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This Prospectus contains or incorporates "forward-looking statements," which include statements about our business strategy, our growth strategy, our product development and marketing efforts and anticipated trends in our business, which are not historical facts. We may also make additional forward-looking statements from time to time in filings that we make with the Commission. When we use words like "believe," "expect," "anticipate," "project," and similar expressions, this should alert you that the statement is forward-looking. Forward-looking statements speak only as of the date made, based largely on expectations. These expectations are generally subject to a number of risks and uncertainties, some of which cannot be predicted or quantified and which are beyond our control. Future events and actual results may differ materially from the anticipated results expressed in, contemplated by, or underlying our forward-looking statements. Statements in this Prospectus, and in documents incorporated by reference into this Prospectus, including those set forth in the caption "Risk Factors" describe factors, among others, that could contribute to or cause differences. In light of these risks and uncertainties, we cannot give any assurances that the forward-looking information will in fact transpire or prove to be accurate in the future.

Summary

This summary highlights selected information from this prospectus and does not contain all of the information that is important to you. To understand the terms of any offering you should read carefully this prospectus and the prospectus supplement, as well as our periodic reports filed with the Securities and Exchange Commission that contain more detailed disclosure about our business and financial performance.

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About this Prospectus

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission ("SEC") utilizing a "shelf" registration process. Under this shelf registration process, we may sell shares of our common stock up to an aggregate of \$75,000,000 in one or more offerings. This prospectus provides you with a general description of the shares of common stock we may offer. Each time we sell shares of common stock we will provide a prospectus supplement that will contain specific information about the terms of that offer and sale. The prospectus supplement may add, update or change information contained in this prospectus. This prospectus, together with applicable prospectus supplements, includes all material information relating to this offering. Please carefully read both this prospectus and any prospectus supplement together with any additional information described below under "Where You Can Find More Information." THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

Where You Can Find More Information

Government Filings. We file annual, quarterly and special reports and other information with the Commission. You may read and copy any document that we file at the Securities and Exchange Commission's Public Reference Room at 100 F. Street, N.E., Room 1580, Washington, D.C. 20549. Please call the Commission at 1-202-551-8090 for more information about the Public Reference Room. Most of our filings are also available to you free of charge at the Securities and Exchange Commission's website at <http://www.sec.gov>.

Information Incorporated by Reference. The Commission rules and regulations allow us to "incorporate by reference" the information that we file with it. This means that we can disclose additional important information to you by referring to those documents. The information incorporated by reference is an

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important part of this Prospectus, and information that we file in the future with the Commission will automatically update and supersede this information. We have filed the following documents with the Commission and the information contained in those documents is incorporated by reference into this Prospectus:

- o Our Annual Report on Form 10-K for the fiscal year ended June 30, 2005, filed on September 12, 2005;
- o Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, filed on November 9, 2005;
- o Our Current Reports on Form 8-K filed on November 10, 2005;
- o Our Current Report on Form 8-K filed on October 18, 2005;
- o Our Proxy Statement on Schedule 14A filed on September 12, 2005;

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- o Our Proxy Statement on Schedule 14A filed on October 31, 2005.

Please note that all other documents and reports filed under Sections 13(a), 13(c), 14 or 15(d) of the Securities and Exchange Act of 1934, as amended, following the date of this Prospectus and prior to the termination of this offering will be deemed to be incorporated by reference into this Prospectus and will be made a part of it from the date of filing with the Commission.

Filings made with the Commission and other information about us can be found on our website at www.thermogenesis.com. We will provide to each person, including any beneficial owner, who is delivered a prospectus, a copy of any of the documents that are incorporated by reference free of charge. Send requests to Matthew Plavan, Assistant Corporate Secretary, ThermoGenesis Corp., 2711 Citrus Road, Rancho Cordova, CA 95742 or call (916) 858-5100.

Our Business

We are a leader in developing and manufacturing automated blood processing systems and disposables that enable the manufacture, preservation and delivery of personalized cell and tissue therapy products, or CTT products, for clinical use. Personalized CTT products are created from the blood or tissue of a single donor and administered to that donor or a matched patient. Our systems and disposables are intended for use by hospitals and blood banks in two distinct markets. In cell therapy, our products automate the isolation, capture and preservation of stem cells residing in the blood of the placenta and umbilical cord, or cord blood, after a baby is born. These cells are used to treat patients for leukemia, lymphoma and over 60 other life threatening genetic diseases. Cord blood stem cells typically result in reduced immune complications post transplant compared to adult bone marrow stem cells. In tissue therapy, our products are used for the rapid manufacture of autologous sealants or thrombin for surgical wound care. Autologous sealants have no risk of contamination by blood-borne pathogens from other donors. We believe that our significant experience and technical expertise in developing proprietary technologies for enabling personalized CTT products, coupled with our relationships with leading transplant physicians, stem cell researchers and surgeons, has enabled us to develop safer, more effective systems for these applications.

Our principal executive offices are located at 2711 Citrus Road, Rancho Cordova, California 95742. Our telephone number is (916) 858-5100.

RISK FACTORS

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Investment in our common stock involves risk. You should carefully consider the risks we describe in our reports filed with the Securities and Exchange Commission (SEC) from time to time which are incorporated by reference herein, and those that may be set forth in any prospectus supplement, before deciding to invest.

USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we expect to use the net proceeds from the sale of our common stock for working capital, to fund our future growth plans, and for other general corporate

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purposes and capital expenditures related to our growth. We may also use a portion of the net proceeds to acquire or invest in businesses, products or technologies that complement our existing business. From time to time, we engage in preliminary discussions and negotiations with various businesses in order to explore the possibility of strategic partnering or investment.

DESCRIPTION OF OUR BUSINESS

BUSINESS OVERVIEW

We are a leader in developing and manufacturing automated blood processing systems and disposables that enable the manufacture, preservation and delivery of personalized cell and tissue therapy products, or CTT products, for clinical use. Personalized CTT products are created from the blood or tissue of a single donor and administered to that donor or a matched patient. Our systems and disposables are intended for use by hospitals and blood banks in two distinct markets. In cell therapy, our products automate the isolation, capture and preservation of stem cells residing in the blood of the placenta and umbilical cord, or cord blood, after a baby is born. These cells are used to treat patients for leukemia, lymphoma and over 60 other life threatening genetic diseases. Cord blood stem cells typically result in reduced immune complications post transplant compared to adult bone marrow stem cells. In tissue therapy, our products are used for the rapid manufacture of autologous sealants or thrombin for surgical wound care. Autologous sealants have no risk of contamination by blood-borne pathogens from other donors. We believe that our significant experience and technical expertise in developing proprietary technologies for enabling personalized CTT products, coupled with our relationships with leading transplant physicians, stem cell researchers and surgeons, has enabled us to develop safer, more effective systems for these applications.

In recent years, our revenue primarily has been generated from the sale of our BioArchive System and related disposables. However, we currently are developing and commercializing new automated systems that enable the manufacture of personalized CTT products. Our products and products in development are described below.

- o The BioArchive System is an automated cryogenic system used in cell therapy to cryopreserve and archive cord blood stem cells for future transplant. We have sold 117 BioArchive Systems to date to major cord blood banks and stem cell research institutes in 26 countries. We have recently signed a global distribution agreement with GE Healthcare granting them exclusive rights to distribute the BioArchive System and related disposables.
- o The AutoXpress, or AXP, System is our newly developed automated system and disposable intended for use in cell therapy to isolate and capture

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stem cells from cord blood. Our agreement with GE Healthcare also grants them exclusive rights to distribute the AXP System and disposables, and we expect sales to begin in the first quarter of 2006.

- o The CryoSeal Fibrin Sealant, or FS, System is an automated system used in wound care to prepare an autologous hemostatic surgical sealant from

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a patient's own blood in approximately one hour. We have completed our pivotal 150 patient U.S. clinical trial and are preparing our PMA submission. In addition, we have received the CE Mark, and in Japan our distribution partner, Asahi Medical, filed their PMA equivalent in March 2005.

- o The Thrombin Processing Disposable, or TPD, is used in wound care to isolate activated thrombin from the patient's blood plasma in less than 30 minutes. Thrombin is used as a topical hemostatic agent for minor bleeding sites, to treat pseudo aneurysms and to release growth factors from platelets. We have signed non-exclusive distribution agreements with Biomet, Medtronic and Asahi Medical for sales of our TPD.

BACKGROUND

Industry

CTT is a broad and rapidly growing field of medicine that requires the collection, purification, manipulation, storage and administration of stem cells, proteins and growth factors tailored to individual patients. Personalized CTT products are created from the blood or tissue of a single donor, administered to that donor or a matched patient, and used either for the treatment of leukemia, lymphoma and over 60 other life threatening diseases, or for surgical wound care. Critical factors in providing effective personalized CTT products are that they be precisely identified and tracked from their source to the receiving patient and that every manufacturing step, such as harvesting, processing, freezing, transporting, matching and delivering, preserves the viability and sterility of the product.

Cell Therapy

The human body is comprised of cells of specific tissues, such as skin, liver or blood, and stem cells that are not fully differentiated into specific tissues. Until the middle of the 1990s, researchers were familiar with two major types of stem cells, embryonic stem cells and adult stem cells. However, researchers now know that pluripotent stem cells are found in cord blood, bone marrow and other tissues of the body. Pluripotent stem cells are capable of differentiation into multiple tissues such as bone, blood, nerve and muscle. All the cells residing in blood, which are red cells, white cells and platelets, arise from a particular pluripotent stem cell called the hematopoietic stem cell. Before the discovery that there were hematopoietic stem cells in cord blood, the placenta and umbilical cord were routinely discarded as biological waste. However, these hematopoietic stem cells are harvested at no risk or pain to the donor and can be preserved in a cord blood bank for clinical use with a matched patient on short notice. Their use also results in a lower incidence of post-transplant immune complications than transplants with adult bone marrow stem cells.

Hematopoietic stem cell therapy is used to:

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- o replace diseased bone marrow with healthy, functioning bone marrow for patients with blood diseases such as aplastic anemia;

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- o replace bone marrow damaged by high-dose chemotherapy or radiation therapy used to treat patients with a variety of cancers such as leukemia and lymphoma; and
- o provide genetically healthy and functioning bone marrow to treat patients with genetic diseases such as sickle cell anemia.

With approximately four million births per year in the United States alone, cord blood represents a large, natural resource for use in the treatment of malignant and genetic diseases. Following the first successful cord blood transplant performed in 1988, awareness of the potential therapeutic value of cord blood stem cells has increased and collection and storage has grown rapidly.

We believe the number of units stored will continue to grow, due in part to the following factors:

- o increased awareness about the availability and benefits of preserving cord blood;
- o improved technology to harvest the stem cells in a sterile environment and maintain their viability for many years;
- o growing endorsement by the medical community;
- o new applications for cell therapy; and
- o new governmental legislation.

For example, in May 2005, the House of Representatives passed the National Cord Blood Stem Cell Act, which aims to store 150,000 units of cord blood in a national registry. This Act is still awaiting passage by the Senate, and there is no certainty that it ultimately will pass and be signed into law. Separately, the Health Resources and Services Administration intends to distribute funds to qualified cord blood banks to manufacture higher quality cord blood units and develop an improved system for distributing the units to matched patients. We believe that countries outside the United States are likely to follow this lead.

Wound Care

Wound care products are used in a variety of surgical procedures and applications to control bleeding, close incisions, assist in tissue fixation, create a physical barrier to prevent fluid or air passage and promote healing. With the population and number of surgeries increasing and as physicians learn about new applications and safer products, this market has potential for significant growth. Wound-healing products are evaluated by their safety, effectiveness, preparation time, ease of use and cost. In addition, the components of wound care products are very important, as different materials have different associated risks and benefits.

Current wound care products fall into the following general categories: topical hemostats, tissue sealants and platelet gels. Topical hemostats are used when bleeding is difficult to control with conventional methods, such as

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suturing, stapling or placement of pads or gauze at the bleeding site. The most common type of topical hemostatic agents are thrombin-based, which are used in procedures where blood clotting must be accelerated, in order to keep the surgery site dry. In addition, thrombin can be used by itself to control minor bleeding sites but is insufficient for more persistent bleeding sites.

The only thrombin that is available in the United States as a stand-alone product is Thrombin JMI(R), a thrombin derived from bovine, or cow, blood. This product is only sold in limited geographies outside of the United States. The market for thrombin is growing rapidly, with Thrombin JMI net sales totaling approximately \$175 million in the full year ended December 31, 2004, and already \$170 million during the nine months ended September 30, 2005.

Tissue sealants, which are more powerful hemostatic agents than thrombin alone, are made of either biologic or synthetic material and are used in a variety of surgical specialties and applications. They are used to close incisions, seal and secure skin flaps, reduce adhesions and promote hemostasis. Fibrin sealants make up the majority of this sub-segment. Conventional fibrin sealants are derived from large pools of up to 10,000 units of purchased human plasma and often contain animal proteins such as bovine aprotinin. While current processes attempt to remove all viral and bacterial pathogens from conventional sealants, there have been several recent peer-reviewed journal reports of the transmission of Parvovirus B-19 to surgical patients treated with these sealants. In addition, animal proteins are a potential source of agents of transmissible bovine spongiform encephalopathy, which are resistant to any methods of pathogen inactivation available to fractionators at this time.

Autologous platelet gels are made by isolating the platelets from a small amount of the patient's own blood and combining those platelets with thrombin. Thrombin causes the release of growth factors from the platelets, which then trigger wound-healing and tissue repair. Platelet gels increase the quantity and concentration of growth factors at the wound site.

OUR SOLUTION

We believe that the use of personalized CTT products will increase due to the growing evidence and understanding of their clinical benefits in treating disease. Our proprietary systems and disposables enable the manufacture, preservation and delivery of these personalized CTT products and have substantial advantages over other products and practices available today. Our products address a broad range of CTT applications in two primary areas: cell therapy and tissue therapy, including wound care.

Cell Therapy

Our BioArchive and AXP Systems and disposables are designed to ensure that the stem cells in the CTT products are successfully isolated, captured and preserved such that the cells are fully viable at time of transplant, which may be months or years after production. The BioArchive System, which can store up to 3,623 units of cord blood stem cells, is the only fully automated system that

integrates controlled rate freezing, quarantine and long term cryogenic storage. The robotic storage and retrieval of these stem cell units improves cell viability, provides precise inventory management and minimizes the possibility of human error. To date we have sold 117 BioArchive Systems to major cord blood stem cell banks and stem cell research centers in 26 countries. Cord blood stem cell units have been used to treat leukemia, lymphoma and over 60 other life threatening genetic diseases.

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More recently, we have developed the AXP System, which automates the isolation and capture of hematopoietic stem cells from cord blood into a fixed 20 ml volume. It includes a compact battery powered device and a proprietary sterile disposable bag set. The AXP replaces the current clinical process, which involves more than a dozen manual steps. The AXP System will provide cord blood banks with a reproducible and GMP-compliant solution to more successfully isolate and capture stem cells with lower labor costs and reduced contamination. We expect sales of the AXP System and disposables to begin in the first quarter of 2006 through our distribution partner, GE Healthcare.

Wound Care

In the tissue therapy market, we have developed the CryoSeal FS System and the TPD. The CryoSeal FS System manufactures fibrin sealant in a closed and sterile disposable from a single unit of the patient's own plasma in about an hour. In contrast, conventional fibrin sealants are sourced from large pools of up to 10,000 or more units of purchased plasma and often include bovine proteins, and thus remain vulnerable to contamination by infectious pathogens residing anywhere in these sources. Our CryoSeal FS System prepares the two interactive liquid components of a fibrin sealant: (1) the wound healing proteins of fibrinogen, fibronectin, Factor VIII, von Willebrands Factor and Factor XIII and (2) the activating enzyme, thrombin. When combined at the bleeding wound site, the two components form an adhesive gel that stops bleeding and bonds tissue. Once prepared, the CryoSeal fibrin sealant may be stored frozen for up to a year or used immediately as a hemostatic agent for patients undergoing surgery.

Our pivotal trial, completed in July 2005, was a 150 patient blinded, randomized multi-center clinical trial comparing the performance of CryoSeal FS to Johnson & Johnson's Instat(R) collagen sponge. The study demonstrated that patients treated with CryoSeal FS showed statistically significant reduced time to hemostasis versus the Instat(R) control group, with $p=$