THERMOGENESIS CORP
Form 425
November 07, 2013

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 6, 2013

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

Delaware	000-16375	94-3018487
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[x] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 8 - Other Events
Item 8.01 Other Events.

ThermoGenesis (the "Company") is providing this information both to update investors on the status of the Company's proposed merger with TotipotentRX, including its filing of a Registration Statement on Form S-4 with the Securities and Exchange Commission and to address the recent publication of certain information regarding ThermoGenesis and TotipotentRX and their businesses.

ThermoGenesis and TotipotentRX continue to prepare and complete the steps necessary to consummate their merger. The time required to complete the Registration Statement includes a multi-year initial audit of a private entity with foreign subsidiaries financial statements and the development of pro-forma combined financial statements to be included in the Registration Statement. No material issues affecting the proposed merger have arisen and ThermoGenesis will file the Registration Statement as soon as practicable.

In addition to certain financial and other information contained in the Registration Statement soon to be filed, ThermoGenesis will provide a detailed description of TotipotentRX's business, the historical background on discussions between the two companies, and management's rationale for the merger. To further educate investors regarding the proposed merger, the detailed description of TotipotentRX's business will discuss its historical clinical research and clinical trial activities and the results of the trials performed since their inception. Management believes this information will be comprehensive and highly informative regarding the value of TotipotentRX to ThermoGenesis, building upon the information previously disclosed about the merger. Moreover, management further believes that the information contained therein will serve to address certain concerns raised recently in the press through online blogs and other forms of publication, regarding the stem cell markets in general and the proposed merger in particular. These concerns include questions regarding the clinical utility of stem cell treatments, the conduct of clinical trials in India and the results of TotipotentRX's clinical initiatives to date.

In addition to the Registration Statement, ThermoGenesis has prepared the attached Question and Answer ("Q&A") document. Although we believe many of the concerns raised and questions recently asked in online media are relevant and justified, we disagree with a number of the conclusions being drawn and the inferences being made. We appreciate this opportunity to dispel some of the confusion in the field and our market strategies. Healthcare regulations differ from one country to another and they continue to evolve at different speeds. ThermoGenesis remains committed to complying with all appropriate regulations and keeping the safety of the patient foremost. Hence the reason ThermoGenesis has undertaken to obtain therapeutic approvals through FDA compliant pathways.

As a general policy, neither ThermoGenesis nor TotipotentRX publicly comments on rumors and other circulated information, and by preparing this Q&A, neither ThermoGenesis nor TotipotentRX assumes a duty to update such information.

Questions and Answers Regarding ThermoGenesis and TotipotentRX

Q: What are the general standards for a clinical trial and are they different for cell therapy?

A: The general standard for the design of a complete, three phase clinical trial includes the following elements: (1) it is controlled; (2) it is randomized; (3) it is blinded; (4) it is protocol-driven; (5) it has a determinant; and (6) its results are published. The primary goal in Phase I of a clinical trial is to prove safety in humans, not to prove efficacy. To prove efficacy, not safety, requires using controls, randomization and blinding (steps 1-3 above). ThermoGenesis' and TotipotentRX's 10 registry, pilot and Phase I trials are safety studies. Therefore, they are not subject to factors (1), (2) and (3) listed above.

Q: Why are TotipotentRX trials not registered on the Clinical Trials Registry - India ("CTRI")?

A: At the time of TotipotentRX initiating its trials, autologous cell therapies were not regulated by Drugs Controller General of India ("DCGI"), nor has a law been passed by parliament granting DCGI jurisdiction over autologous cells. Moreover, despite a specific request by TotipotentRX, CTRI would not publish TotipotentRX's submissions for registration. Subsequently, in October 2010, the Health Minister of India in Executive Order No. V.25011/375/2010-HR clarified that the jurisdiction of regulating stem cell1 research falls to the National Apex Committee for Stem Cell Research and Therapy ("NAC-SCRT"). Any restricted stem cell usage (embryonic or allogeneic cells) requires NAC-SCRT's prior approval, and any permissible (i.e. minimally manipulated autologous cells) stem cell research requires only notification. TotipotentRX's and ThermoGenesis' clinical programs, whether investigator initiated or TotipotentRX sponsored, falls under this Executive Order, and in the absence of codified parliamentary law specific to cell therapy, TotipotentRX followed the Executive Order by submitting notification to the Chairman of the NAC-SCRT. Presently DCGI does regulate the devices to carry out such procedures. In addition, TotipotentRX and/or ThermoGenesis have at all points in time maintained DCGI registration approval for the importation and the sale of the Res-QTM 60 ("Res-Q") (device) for intra-operative preparation of autologous bone marrow derived stem cells and the AXP® AutoXpress® Platform (AXP) (device) for peripheral and cord blood processing without restriction2 and, on advice of Indian counsel, were not obligated to file applications of concentrating autologous bone marrow or peripheral blood derived cells under a clinical trial. You may obtain a copy of the Executive Order by contacting ThermoGenesis, Investor Relations, 2711 Citrus Road Rancho Cordova, CA 95742.

Q: Is ABO incompatibility still an issue in allogeneic bone marrow transplant, and why do you see MXP® MarrowXpress® ("MXP") being important in this application?

A. Yes, ABO incompatibility remains an issue in bone marrow transplants. Major ABO incompatibility bone marrow transplants increase the median time patients continue to require packed red blood cell ("RBC") transfusions post their bone marrow transplant, meaning the engraftment of RBCs and platelets from the transplant in ABO mismatch recipients is delayed. Delays in engraftment decrease a patient's survival odds. Also the co-morbidity risks (Transfusion Related Associated Lung Injury, etc.) and costs of regular blood transfusions post-transplant, including and until engraftment is achieved3, is expensive and with the increased risk of transfusion related injuries and their subsequent high mortality rates it is advisable to find ways of improving engraftment rates if possible.

The transplant of major and bi-directional ABO incompatible units without depletion of the donor's RBCs and plasma proteins likely impacts the overall survival, relapse rate, and acute/chronic graft-versus-host disease4 in the ABO mismatched transplant recipient.

Depletion of ABO donor incompatible RBCs and plasma prior to transplant is completed today by bone marrow transplant centers through traditional equipment/methods (Cobe instrumentation, chemical sedimentation, etc.),

usually resulting in significant loss of critical stem cells, generally in the range of 40-60%. This can delay the time to engraftment putting the patient at risk of serious or life threatening complications. The MXP technology, as optimized for this procedure, results in minimal stem cell losses, in the 20-25% range, significantly increasing the odds that successful engraftment will happen and sooner. TotipotentRX has reported their interim results in using AXP in this application, and this information is publicly filed. Both TotipotentRX and ThermoGenesis believe the use of MXP in bone marrow transplant centers for challenging mismatched pediatric and adult cases will have a meaningful impact on engraftment rates. It is estimated that as many as 40% of all bone marrow transplant recipients receive ABO mismatched donor units.

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Q: Can you give an update on TotipotentRX's critical limb ischemia ("CLI") clinical trial?

A: TotipotentRX concluded the final patient follow-up of its phase I study in late June 2013. It is their policy to conclude the study and have finalized data analyzed for statistical significance by cohort segmentation prior to announcing definitive results. A properly structured, statistically analyzed report will take approximately four months to complete per normal course and include the following essential steps and internal quality control:

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1 Per the Indian Council of Medical Research and Department of Biotechnology Guidelines 2007 (the current Standard for cell therapy in India), minimally manipulated stem cells clinical trials can be conducted under Institutional Ethics Board and Institutional Committee for Stem Cell Research and Therapy. Such trials must be reported to the NAC-SCRT. The NAC-SCRT was not formed until October 2010, so a three-year gap in the process existed. All trials are reported to the NAC-SCRT as mandated by the Standard and Executive Order.

2 Res-Q 60 BMC Registration Certificate MD-826 issued March 10, 2011 for the intra-operative preparation of autologous concentrated bone marrow stem cells.

3 Blin et al, Impact of Donor-Recipient Major ABO Mismatch on Allogeneic Transplantation Outcome According to Stem Cell Source, Biol Blood Marrow Transplant 16:1315-1323, 2010

4 Booth et al, Clinical Guide to ABO-incompatible allogeneic stem cell transplantation, Biol Blood Marrow Transplant 19(8): 1152-8, 2013

1) Electronic databases for warehousing and analyzing the clinical data are built to FDAs requirement. Presently, Indian law requires hard copy records for clinical trials, which requires substantial time to hard code and quality control into the electronic data files.
2) Independent readers of the radiography studies are queued up to analyze each imaging study (in this case angiograms), and their interpretations are quality controlled by one or more additional readers.
3) The trial data is sorted into cohorts.
4) The data statistics are calculated by biostatisticians.
5) Report drafting - internal quality control is completed and final review by the study investigators.

Q: What is the purpose of the cautionary disclaimer related to the use of certain imaging equipment in TotipotentRX's Acute Myocardial Infarction Rapid-Delivery of Stem cell Therapy ("AMIRST") case study?

A: The cautionary disclaimer in the white paper was simply a formal note in the spirit of scientific disclosure noting two types of instrumentation had been used between the early readings of the Left Ventricular Ejection Fractions ("LVEF") and the mid/final readings in the AMIRST Case Study. TotipotentRX put the language in for full transparency and disclosure.

TotipotentRX included this disclaimer specifically for the trained cardiologist reader to understand that two methods were used to measure the LVEF of this patient. However, the difference between the methods and equipment would typically give no more than a 5-10 percent variability. In this case TotipotentRX reported an improvement in LVEF of 24 percentage points (a 67.5 percent improvement), so the possible variability to one skilled in the field would not measurably negate the significance of the clinical improvements.

Q: Can you respond to the assertion that autologous bone marrow cells have failed in cardiac clinical trials to date?

A. The assertion that all autologous bone marrow cells have failed in cardiac clinical trials to date is false. Although there have been trials that have failed, they do so due primarily to poor trial design, under dosing and poor cell handling. The fact is, bone marrow cells have proven clinical utility. More specifically, the conclusion of a recent meta-analysis study is the opposite of certain assertions and citation of a single author editorial (not a scientific publication) titled Bone Marrow Tinctures for Cardiovascular Diseases, Circulation, April 2013. The latest meta-analysis per the Delawi study, Impact of Intracoronary Bone Marrow Cell Therapy on Left Ventricular Function in the Setting of ST-Segment Elevation Myocardial Infarction: A Collaborative Meta-Analysis, Delawi R et al, Eur Heart Journal, doi:10.1093/eurheartj/eht372, Sept 2013, analyzed 16 peer reviewed cell therapy trials having treated 1,641 patients in controlled studies focused on improving LVEF and found that in patients with LVEF below 40% the mean LVEF improvement after bone marrow stem cell intracoronary therapy was 5.30%, 95% CI: 4.27–6.33 [a meaningful quality of life and clinical improvement]. In addition to the learning's provided through these studies, our own experience in developing protocols and therapies have enabled us to design and develop our combination product in such a manner to mitigate against the design and performance failures of these failed studies.

Q: Is TotipotentRX aware of a January 2011 article in The Indian Express highlighting a spinal cord injury ("SCI") patient treated at Fortis Healthcare?

A: TotipotentRX is well aware of this case and the surgeon involved. This particular patient was a no-option paraplegic male who had exhausted all standards of care. The patient sought out Dr. Yashbir Dewan, a well-respected senior neurosurgeon at Fortis Hospital in New Delhi. Dr. Dewan had been interested academically and clinically in the potential stem cells might hold for sub-acute SCI patients having no option in regaining their motor skills, and on examination of this patient several different times, including a concurring opinion of the neurosurgery department head, Dr. Dewan, agreed to the patient's request for an intrathecal delivery of his own bone marrow stem cells. The patient was properly consented as required in Good Clinical Practices and per the hospital policy and the Institutional Ethics Committee. This procedure was performed in mid-2010, prior to the DCGI mandate that bone marrow processing and storage medical devices became regulated.5

Specific to the Indian Express allegations that the patient was overcharged, we cannot confirm or deny as we are not involved in the pricing of healthcare nor in the delivery/practice of medicine. However, under the Indian Council of Medical Research and Department of Biotechnology Stem Cell Guidelines, 2007, the hospital and the physician are allowed to treat patients with permissible cells (autologous cells being permissible) in non-homologous applications so long as an Independent Ethics Committee (typically called an IRB in the US) approval is in place. Dr. Dewan received approval from the local Medical Superintendent, and the Chair of the Ethics Committee to do this single no-option case. Dr. Dewan further submitted an Investigator Initiated Clinical Trial application to the Fortis Independent Ethics and Stem Cell Research Boards (per the guidelines), and received approval to conduct a 15 patient study starting in September 2011 (IEC approval: FHIRB/2011/15 and IC-SCRT approval IC-SCRT/2011/1). The Independent Ethics Board and Stem Cell Board considered among other facts the case cited in the Indian Express article, and found no reason to deny further clinical trial work by Dr. Dewan. This particular SCI trial was never sponsored by TotipotentRX or ThermoGenesis, but TotipotentRX did assist in the development of the protocol and the scientific rationale to ensure the cells were safely processed prior to the surgical procedure.

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5 Guidelines for Import and Manufacture of Medical Devices ,Ministry of Health, Gazette notification S.O. 1468 (E) dated October 6, 2005 declared only the following sterile devices to be considered as drugs (devices are considered drugs in the Act) under Section 3(b)(iv) of the Act and therefore regulated:

1. Cardiac Stents	2. Heart Valves
3. Drug Eluting Stents	4. Scalp Vein Sets
5. Catheters	6. Orthopedic Implants
7. Intraocular Lenses	8. Internal Prosthetic Replacements
9. I.V. Cannulae	10. Bone Cement

The critical factor the Indian Express author did not consider is that physicians have full control over the care of their patients under the Practice of Medicine doctrine. This physician, his supervisors, review boards, and patient all believed this was in the best interest of the patient, and so concluded to do the procedure.

Q: How many patients has TotipotentRX/Fortis charged for their participation in clinical trials?

A: TotipotentRX and ThermoGenesis have received DCGI clearance for the use of Res-Q 60 BMC for the concentration of bone marrow stem cells intra-operatively. Therefore, TotipotentRX is authorized to charge the hospital or medical provider for the device that the physician prescribes its use.

In several of TotipotentRX's pilot trials the data is collected under physician initiated trials specific to orthopedic indications. This is similar to most companies operating in our space. In these trials, the goal is a collection of data for the physician to ascertain the benefit of one or more clinically controlled procedures/methods, and there are no restrictions for charging when the technology and surgeon are licensed. Additionally, our orthopedic indications are autologous and homologous use of stem cells (patient's own bone marrow or blood cells back into their bone tissue) and are thus unrestricted even in the US so long as specific clinical benefit claims are not made.

TotipotentRX does not charge clients for the stem cell device, process, clinical care, and for any follow-up when they are enrolled in a TotipotentRX sponsored trial.

Here is a summary of TotipotentRX financial support history:

Classification	Trial	Sponsor	Trial Type	Fees Paid By TotipotentRX
Orthopedic	AVN	Physician	Pilot	Not supported
	OA	Physician	Pilot	Not supported
	NUF	Physician	Pilot	Not supported
	Spinal Fusion	Physician	Pilot	Not supported
Dermal	Non-Healing Ulcers	Physician	Pilot	Sold at cost per IRB Directive
Vascular	AMI	TotiRX	Phase Ib	Paid by TotiRX
	CHF	TotiRX	Registry	Paid by TotiRX
	CLI	TotiRX/Thermo	Phase Ib	Paid by TotiRX
Neuro	Spinal Cord Injury	Physician	Phase Ib	Not supported
	Stroke	TotiRX/Apollo	Phase Ib	Co-Paid By TotiRX and Apollo

Q: Regarding the number of trials versus protocols, how many have been conducted in India and registered with the Clinical Trials Registry of India

A: TotipotentRX has ten clinical protocols and has conducted, or is in the process of conducting, eight clinical pilot studies or clinical trials and 1 registry study - 1 new study remains under submission to the Independent Ethics Committee. These trials are depicted in the table below:

Classification	Trial	Approvals	Trial Type	Registration
Orthopedic	AVN		Pilot	Not required

		Autologous and homologous. Approved per Res-Q 60 device approval		
	OA	Autologous and homologous. Approved per Res-Q 60 device approval	Pilot	Not required
	NUF	Autologous and homologous. Approved per Res-Q 60 device approval	Pilot	Not required
	Spinal Fusion	Autologous and homologous. Approved per Res-Q 60 device approval	Pilot	Not required
Dermal	Non-Healing Ulcers	IEC & IC-SCRT	Pilot	TIEC/2012/39/19
Vascular	AMI	TotiRX	Phase Ib	TIEC/2011/32/02
	CHF	TotiRX	Registry	TIEC/2012/39/NP/03
	CLI	TotiRX/Thermo	Phase Ib	TIEC/2010/30/04
Neuro	Spinal Cord Injury	Physician	Phase Ib	FHIRB/2011/156
	Stroke	TotiRX/Apollo	Phase Ib	Under review by IRB

TotipotentRX does not register the trials on CTRI as they are autologous (not falling under DCGI's jurisdiction at this point) and follow the Health Minister of India in Executive Order No. V.25011/375/2010-HR which gives jurisdiction to the hospital ethics review board and the institutional committee on stem cell research and therapy committee. As mentioned, the CTRI only registers trials which have DCGI clinical trial approval numbers (drugs and devices), and permissible autologous cell therapies are not under their purview.

Q: What clinical trial results has TotipotentRX/ThermoGenesis published to date?

A: TotipotentRX reports clinical trial results in international conferences through presentations or poster/abstract releases and in white papers. Since TotipotentRX has been a privately held company, they have had no obligation to report their results via press release. However, since announcing the planned merger with ThermoGenesis, both companies report data when it is available for publication.

TotipotentRX and ThermoGenesis are in the process of finalizing the full results of the CLI Phase Ib clinical trial. As mentioned above, this process takes approximately 3-4 months. It is tracking to normal and customary timelines.

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6 SCI clinical trial under Dr. Dewan was transferred to and re-approved by Max Hospitals IEC in 2012. Dr. Dewan left Fortis Healthcare in 2012 to join the new Max Neurosurgical Specialty Hospital.

Other clinical trial results reported publicly to date by TotipotentRX:

(1) Safety Study of Using Res-Q in The Operating Theater. A 35 patient study. Poster presentation at the ISCT Annual Meeting, May 2011. Ponemone V, Dewan Y, Hegde H, Bokhari S, and Reddy K.
(2) Autologous Bone Marrow Derived Stem Cell Graft Facilitate Remodeling of Non-Union Fractures. A 17 patient pilot study. Poster presentation at the ISCT Annual Meeting, May 2012. Ponemone V, Gulati R, Sharma J, Sivilotti M, Sarin A, Boruaht T, Singh M, Mattoo R, Sharma A, Bedi G, Oberoi N, Hegde H, and Harris K.
(3) Intrathecal Adminstration of Autologous Bone Marrow Cells with 10% Hematocrit/RBCs Are Clinically Safe. A 23 patient study (15 spinal cord and 8 cerebal palsy). Poster presentation at the ISCT Annual Meeting, May 2012. Ponemone V, Gulati R, Sivilotti M, Mukerjee A, Dewan Y, and Harris K.
(4) Safety Study of Autologous Bone Marrow Concentrate Enriched in Progenitor Cells (BMCePC) as an Adjuvant, in the Treatment of Acute Myocardial Infarction – A Clinical Case Study. White paper and presentation at AABB Annual Meeting, Denver 2013. Sanghi V, Ponemone V, Kar S, Bhatia M, Sethi D, Harris K, Kaul U, and Seth A.

Clinical trial results pending:

(1) CLI Phase Ib Results using Autologous Bone Marrow Concentrate enriched Progenitor Cells ("BMCePC"). Statistically powered study with full cohort analysis to be published in the near future.

Forward Looking Statement
This Form 8-K contains forward-looking statements. These statements involve risks and uncertainties that could cause actual outcomes to differ materially from those contemplated by the forward-looking statements. A more complete description of risks that could cause actual events to differ from the outcomes predicted by ThermoGenesis forward-looking statements is set forth under the caption "Risk Factors" in its annual report on Form 10-K and other reports we file with the Securities and Exchange Commission from time to time, and you should consider each of those factors when evaluating the forward-looking statements.

Non-Solicitation
This Form 8-K and the information contained herein shall not constitute an offer to sell, buy or exchange or the solicitation of an offer to sell, buy or exchange any securities, nor shall there be any sale, purchase or exchange of securities in any jurisdiction in which such offer, solicitation, sale, purchase or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Additional Information
In connection with the merger, ThermoGenesis intends to file a registration statement (including a prospectus) on Form S-4 with the Securities and Exchange Commission. Holders of ThermoGenesis common stock and TotipotentRX Corporation common stock are urged to read the proxy statement/prospectus/consent solicitation and any other relevant documents when filed because they contain important information about ThermoGenesis, TotipotentRX and the merger. A proxy statement will be sent to holders of ThermoGenesis common stock and a prospectus/consent solicitation will be sent to holders of TotipotentRX Corporation common stock. When filed, the proxy statement/prospectus/consent solicitation and other documents relating to the proposed merger can be obtained free of charge from the SEC's website at www.sec.gov. These documents can also be obtained free of charge from ThermoGenesis upon written request to ThermoGenesis, Investor Relations, 2711 Citrus Road Rancho Cordova, CA 95742. ThermoGenesis and its directors and executive officers may be deemed to be participants in ThermoGenesis' solicitation of proxies from its shareholders in connection with the proposed merger. Information regarding the participants and their security holdings can be found in ThermoGenesis' most Form 10-K filed with the SEC, which is

available from the SEC, and the proxy statement/prospectus/consent solicitation when it is filed with the SEC.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERMOGENESIS CORP.,
a Delaware Corporation

Dated: November 6, 2013 /s/ Dan T. Bessey
Dan T. Bessey
Chief Financial Officer