

THERMOGENESIS CORP

Form 10-Q

November 08, 2006

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549
FORM 10-Q**

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2006.

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition from _____ to _____.

Commission File Number: 333-82900

ThermoGenesis Corp.

(Exact name of registrant as specified in its charter)

Delaware

(State of incorporation)

94-3018487

(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)

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 12 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 whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 1, 2006
Common stock, \$.001 par value	54,940,675

ThermoGenesis Corp.
INDEX

	Page Number	
<u>Part I Financial Information</u>		
<u>Item 1.</u>	<u>Financial Statements</u>	3
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition & Results of Operations</u>	11
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	19
<u>Item 4.</u>	<u>Controls and Procedures</u>	19
<u>Part II Other Information</u>		
<u>Item 1.</u>	<u>Legal</u>	20
<u>Item 1A.</u>	<u>Risk Factors</u>	20
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
<u>Item 3.</u>	<u>Defaults upon Senior Securities</u>	20
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	20
<u>Item 5.</u>	<u>Other Information</u>	20
<u>Item 6.</u>	<u>Exhibits</u>	20
<u>Signatures</u>		21
<u>EXHIBIT 31.1</u>		
<u>EXHIBIT 31.2</u>		
<u>EXHIBIT 32</u>		

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****ThermoGenesis Corp.
Condensed Balance Sheets (Unaudited)**

(in thousands, except share and per share amounts)	September 30, 2006	June 30, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,675	\$ 3,527
Short-term investments	31,697	35,472
Accounts receivable, net of allowance for doubtful accounts of \$33 (\$17 at June 30, 2006)	3,349	3,773
Inventories	3,231	2,792
Other current assets	418	462
Total current assets	45,370	46,026
Equipment at cost less accumulated depreciation of \$3,133 (\$3,024 at June 30, 2006)	1,446	1,489
Other assets	96	88
	\$ 46,912	\$ 47,603
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,918	\$ 1,931
Accrued payroll and related expenses	301	417
Deferred revenue	698	718
Other current liabilities	916	618
Total current liabilities	3,833	3,684
Deferred revenue	1,753	1,921
Long-term portion of capital lease obligations and note payable	22	26
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.001 par value; 2,000,000 shares authorized; none outstanding		
Common stock, \$0.001 par value; 80,000,000 shares authorized; 54,934,175 issued and outstanding (54,882,952 at June 30, 2006)	55	55
Paid in capital in excess of par	116,197	115,769
Accumulated deficit	(74,948)	(73,852)

Total stockholders' equity	41,304	41,972
	\$ 46,912	\$ 47,603

See accompanying notes to financial statements.

Page 3

Table of Contents

ThermoGenesis Corp.
Condensed Statements of Operations (Unaudited)

(in thousands, except share and per share amounts)	Three Months Ended September 30,	
	2006	2005
Product and other revenues	\$ 3,819	\$ 2,086
Milestone payments and license fees	486	30
Net revenues	4,305	2,116
Cost of product and other revenues	2,529	1,529
Cost of milestone payments and license fees	64	
Cost of revenues	2,593	1,529
Gross profit	1,712	587
Expenses:		
Selling, general and administrative	2,312	1,584
Research and development	962	1,073
Total operating expenses	3,274	2,657
Interest and other income, net	466	54
Net loss	(\$ 1,096)	(\$ 2,016)
Per share data:		
Basic and diluted net loss per common share	(\$ 0.02)	(\$ 0.04)
Shares used in computing per share data	54,903,767	45,917,502

See accompanying notes to financial statements.

Page 4

Table of Contents

ThermoGenesis Corp.
Condensed Statements of Cash Flows (Unaudited)
Three Months Ended September 30, 2006 and 2005

(in thousands)	2006	2005
Cash flows from operating activities:		
Net loss	(\$1,096)	(\$2,016)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111	93
Stock based compensation expense	342	231
Amortization of premium on short-term investments	(377)	
Net change in operating assets and liabilities:		
Accounts receivable	424	692
Inventories	(455)	186
Other current assets	44	102
Other assets	(8)	
Accounts payable	(13)	(624)
Accrued payroll and related expenses	(116)	(99)
Deferred revenue	(188)	(30)
Other current liabilities	298	(77)
Net cash used in operating activities	(1,034)	(1,542)
Cash flows from investing activities:		
Capital expenditures	(52)	(40)
Purchase of short-term investments	(7,848)	
Maturities of short-term investments	12,000	
Net cash provided by (used in) investing activities	4,100	(40)
Cash flows from financing activities:		
Payments on capital lease obligations and note payable	(4)	(36)
Exercise of stock options and warrants	86	171
Net cash provided by financing activities	82	135
Net increase (decrease) in cash and cash equivalents	3,148	(1,447)
Cash and cash equivalents at beginning of period	3,527	9,568
Cash and cash equivalents at end of period	\$ 6,675	\$ 8,121

Supplemental non-cash flow information:

Equipment acquired by capital lease		\$	106	
Transfer of inventory to equipment	\$	36	\$	22
Transfer of equipment to inventory	\$	20	\$	63

See accompanying notes to financial statements

Page 5

Table of Contents

ThermoGenesis Corp.

Notes to Condensed Financial Statements (Unaudited)

1. Summary of Significant Accounting Policies

Interim Reporting

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. All sales, domestic and foreign, are made in U.S. dollars and therefore currency fluctuations are believed to have no impact on ThermoGenesis Corp.'s (the Company) net revenues. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three month period ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending June 30, 2007. These financial statements should be read in conjunction with the financial statements and the notes thereto included in the Annual Report on Form 10-K for the fiscal year ended June 30, 2006.

The balance sheet at June 30, 2006, has been derived from the audited financial statements at that date but does not include all the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

Revenue Recognition

The Company recognizes revenue including multiple element arrangements, in accordance with the provisions of the Securities and Exchange Commission's (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*. 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's 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. If an undelivered element exists, the Company will determine the fair value of the undelivered element and subtract the fair value of the undelivered element from the total consideration under the arrangement. The residual amount is the Company's estimate of the fair value of the delivered element. 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. 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.

Milestone payments the Company receives under collaborative 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. The direct costs, primarily labor, of product development contracts are deferred until the development revenue is recognized.

Table of Contents

ThermoGenesis Corp.

Notes to Condensed Financial Statements (Unaudited) (Continued)

1. Summary of Significant Accounting Policies (Continued)

Revenue Recognition (Continued)

Revenues from the sale of the Company's products are recognized upon transfer of title. The Company generally ships products F.O.B. shipping point at its office. There is no conditional evaluation on any product sold and recognized as revenue. All foreign sales are denominated in U.S. dollars. 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 the distributor places the product with an end-user. 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, or 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. 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. 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. Amounts billed in excess of revenue recognized are recorded as deferred revenue on the balance sheet.

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, warrants and common stock restricted awards that were not included in diluted net loss per common share were 2,953,633 and 2,883,816 as of September 30, 2006 and 2005.

Table of Contents**ThermoGenesis Corp.****Notes to Condensed Financial Statements (Unaudited) (Continued)****1. Summary of Significant Accounting Policies (Continued)****Recent Accounting Pronouncements**

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB No. 108) to provide guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. Under SAB No. 108, companies should evaluate a misstatement based on its impact on the current year income statement, as well as the cumulative effect of correcting such misstatements that existed in prior years existing in the current year's ending balance sheet. SAB No. 108 will become effective for the Company in its fiscal year ending June 30, 2007. We are currently evaluating the impact of the provisions of SAB No. 108 on our financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 157, *Fair Value Measurements* (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosure about fair value measurements. SFAS No. 157 applies under other accounting standards that require or permit fair value measurements. Accordingly, SFAS No. 157 does not require any new fair value measurement. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of the provisions of SFAS No. 157 on our financial statements.

2. Short-term Investments

Short-term investments consisted of the following at September 30, 2006:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
September 30, 2006				
U.S. government and agency securities	\$31,697	\$ 10	(\$9)	\$31,698

The aggregate amount of unrealized losses and fair value of U.S. government and agency securities, which are not deemed to be other-than-temporarily impaired and less than twelve months, are \$9 and \$7,955 respectively. The unrealized loss on these investments are temporary, as the duration of the decline in the value of the investments has been short; the extent of the decline, both in dollars and percentage of cost is not considered significant; and the Company has the ability and intent to hold the investments until at least substantially all of the cost of the investments is recovered.

Maturity Date:	Amortized Cost	Estimated Fair Value
Less than 90 days	\$23,789	\$23,798
Due in 91-365 days	7,908	7,900
	\$31,697	\$31,698

Table of Contents

ThermoGenesis Corp.
Notes to Condensed Financial Statements (Unaudited) (Continued)

3. Inventories

Inventories consisted of the following at:

(in thousands)	September 30, 2006	June 30, 2006
Raw materials	\$ 1,983	\$ 1,603
Work in process	1,385	1,433
Finished goods	641	530
Reserve	(778)	(774)
	\$ 3,231	\$ 2,792

Included in the Company's inventory reserve at September 30, 2006 and June 30, 2006 were \$464 and \$459, respectively, related to CryoSeal® FS System inventory products, which is based on inventory levels in excess of forecasted demand for the product. The remainder of the reserve relates to certain BioArchive® System and ThermoLine inventory which have been identified as slow-moving or potentially obsolete.

4. Commitments and Contingencies**Warranty**

The Company offers a one-year warranty for parts only on all of its non-disposable products. The Company estimates the costs that may be incurred under its basic limited warranty and records a liability in the amount of such costs at the time product revenue is recognized. Factors that affect the Company's warranty liability include the number of installed units, historical and anticipated rates of warranty claims, and cost per claim. The Company periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary.

Changes in the Company's product liability during the period are as follows:

(in thousands)	
July 1, 2006 balance	\$ 74
Warranties issued during the period	47
Settlements made during the period	(7)
Changes in liability for pre-existing warranties during the period, including expirations	(24)
Balance at September 30, 2006	\$ 90

Table of Contents**ThermoGenesis Corp.****Notes to Condensed Financial Statements (Unaudited) (Continued)****5. Stockholder s Equity****Stock Based Compensation**

Effective July 1, 2005, the Company adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized in fiscal year 2007 and 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of July 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of Statement 123, and (b) compensation cost for all share-based payments granted subsequent to July 1, 2005, based on the grant-date fair value estimated in accordance with the provisions of Statement 123(R). As a result, a non-cash charge of \$339,000 and \$195,000 was charged to compensation expense during the first quarter of fiscal 2007 and 2006, respectively.

The following is a summary of option activity for the Company s stock option plans:

(in thousands, except shares, share price and term)	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at June 30, 2006	2,539,321	\$2.72	3.34	\$3,737
Granted	45,000	\$3.95		
Forfeited or Expired	(3,550)	\$3.85		
Exercised	(40,000)	\$2.18		
Outstanding at September 30, 2006	2,540,771	\$2.75	3.2	\$3,131
Vested and Expected to Vest at September 30, 2006	2,507,615	\$2.74	3.2	\$3,109
Exercisable at September 30, 2006	1,856,864	\$2.46	2.9	\$2,745

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 for the 2,034,574 options that were in-the-money at September 30, 2006.

Table of Contents

**ThermoGenesis Corp.
Management's Discussion and Analysis of
Financial Condition and Results of Operations**

for the Three Months Ended September 30, 2006 and 2005

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

This report contains forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. When used in this report, the words anticipate, believe, estimate, expect and similar expressions as they relate to the Company or its management are intended to identify such forward-looking statements. The Company's actual results, performance or achievements could differ materially from the results expressed in, or implied by these forward-looking statements. The Company wishes to caution readers of the important factors, among others, that in some cases have affected, and in the future could affect the Company's actual results and could cause actual results for fiscal year 2007, and beyond, to differ materially from those expressed in any forward-looking statements made by, or on behalf of, the Company. These factors include without limitation, the ability to obtain capital and other financing in the amounts and at the times needed to complete clinical trials and product marketing for new products, market acceptance of new products, regulatory approval and time frames for such approval of new products and new claims for existing products, realization of forecasted income and expenses, initiatives by competitors, price pressures, the risks associated with initiating manufacturing for new products, and the risk factors listed from time to time in the Company's Securities and Exchange Commission (SEC) reports, including, in particular, the factors and discussion in the Company's Form 10-K for its last fiscal year.

Introduction

The Company designs and manufactures medical devices and disposables for the distributed manufacturing of personalized cell therapy and surgical wound care products such as units of umbilical cord blood stem cells, fibrin sealant and thrombin. These products typically originate from the blood or tissue of the patient or a single human leukocyte antigen (HLA) typed and pathogen screened placenta or living donor. Cell therapy and surgical wound care products are broad, rapidly growing fields of medicine that involves the collection, purification, manipulation and administration of somatic stem cells, wound healing proteins or growth factors to treat malignant or genetic blood diseases or wounds incurred during surgery, tailored to individual patients. This methodology of personalized treatment is considerably different than practices with generic conventional pharmaceutical drugs. Pharmaceutical drugs are produced in large quantities and are effective on most patients with similar underlying medical conditions. Additionally, these drugs typically consist of inert materials that can be stored in medicine cabinets at room temperature. In contrast, personalized cell therapy and surgical wound care products are manufactured one at a time, are intended for a single patient and require extremely low storage temperatures (-196°C in some cases) in order to preserve the cells, blood proteins or growth factors.

The Company's products can address a broad range of cell therapy and surgical wound care treatments. Until the middle of the 1990s, researchers were familiar with only two major types of stem cells, embryonic stem cells and adult stem cells. However, recent years have seen the emergence of a category of stem cells called somatic stem cells that are found in umbilical cord blood or bone marrow and other tissues of the body. Somatic stem cells are capable of a wide range of differentiation into several highly diverse cell types such as nerve cells, muscle cells and hematopoietic cells. Somatic stem cells have come into focus as fundamental units of development and maintenance of the adult organism as well as an attractive tool for tissue regeneration.

Table of Contents

**ThermoGenesis Corp.
Management's Discussion and Analysis of
Financial Condition and Results of Operations
for the Three Months Ended September 30, 2006 and 2005 (Continued)**

Introduction (Continued)

The ability to obtain large quantities of somatic stem cells able to produce mature muscle, nerve or pancreatic cells is useful in the development of clinical treatments for genetic diseases. This clinical practice is personalized medicine which utilizes either an individual's own somatic stem cells, thus circumventing problems of immune rejection associated with implantation of allogeneic tissue or blood cells, or utilizes immunologically matched tissue or stem cells.

Cell therapy and surgical wound care products can be characterized by (1) the source of the somatic stem cells (e.g., neonatal, adult, or perhaps, in the future, embryonic) (2) the source of blood proteins or growth factors (e.g., from the patient or a matched single donor), (3) the cell progeny in the final product (e.g., hematopoietic, mesenchymal, dendritic cells, chondrocytes, etc.), (4) the disease targeted (e.g., bone marrow rescue, diabetes, myocardial infarction, Parkinson's), and (5) the type of manipulation (e.g., cell isolation, capture, expansion, gene modification, cryopreservation, cryoprecipitation or chemical fractionation). Critical factors in providing acceptable personalized cell therapy and surgical wound care 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 administering, preserves the potency of the product.

The Company's BioArchive and AXP products and intellectual property are designed to ensure that the therapeutic cells are fully functional at time of transplant, which may be months or years after production and storage. We believe that the Company's products, contain substantial advantages over other products and practices in enabling the precision manufacturing of cell therapy and surgical wound care products in a safe sterile environment which will reduce the loss of cells and loss of cell viability at each step of the process from collection to administration.

Cell Therapy

The BioArchive System, an automated cryogenic device, is used by cord blood stem cell banks in more than 25 countries for cryopreserving and archiving cord blood stem cell units for transplant. GE Healthcare is the global distribution partner for the BioArchive System. The BioArchive System has initially been configured to automate the cryopreservation and archiving in liquid nitrogen of units of hematopoietic stem cells sourced from umbilical cord blood. Cord blood stem cell units have been used more than 10,000 times to treat leukemias, lymphomas, diverse inherited anemias, such as sickle cell anemia and thalassemia, and other life threatening genetic diseases.

The Company completed development of the AXP System in fiscal 2006, and initiated a Master File of the product with the Food and Drug Administration (FDA). The AXP System is an innovative product which semi-automates the isolation and concentration of hematopoietic stem cells from cord blood into a fixed 20 ml volume in a functionally closed sterile environment. It includes a compact battery powered device and a proprietary disposable bag set. The AXP System replaces the current clinical process which is typically an 18-step manual method over a ninety (90) minute period with a semi-automated process requiring only thirty (30) minutes. The manual process requires the introduction of sedimentation agents or density gradient media into the cord blood and requires a clean room along with trained technicians to accomplish. The AXP System completes its processing without these agents or media with a higher cell recovery rate in a functionally closed bag set in thirty (30) minutes. Included in the set is a 25 ml freezing bag which can be archived in the BioArchive System.

Table of Contents

**ThermoGenesis Corp.
Management's Discussion and Analysis of
Financial Condition and Results of Operations
for the Three Months Ended September 30, 2006 and 2005 (Continued)**

Introduction (Continued)

To date, our BioArchive System and related products are purchased predominantly by specialized cord blood stem cell banks and stem cell research facilities. The sales of BioArchive devices have been dependent on start-up and ongoing funding costs associated with new stem cell banks as the science evolved. In more recent periods governmental funding of cord blood banks, as well as more recognized therapeutic benefits from this stem cell treatment appear to be increasing demand for cord blood stem cell transplants.

Surgical Wound Care

The CryoSeal System produces a second-generation surgical sealant which harvests the two interactive protein component solutions 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 from the patient's own blood. When combined at the bleeding wound site, the two components form an adhesive gel that stops bleeding and bonds tissue. This advanced surgical sealant may be manufactured in either hospitals or blood centers and competes with conventional fibrin sealants, sourced from pools of plasma purchased from up to ten thousand individuals. The Company completed a 150 patient blinded, randomized multi-center U.S. clinical trial for the CryoSeal System and sales in the U.S. are pending the required FDA approval following our Premarket Approval (PMA), submitted December 28, 2005. The study reached its primary end point, which was to demonstrate equivalency (i.e. that results obtained using the CryoSeal FS System were non-inferior to results achieved with the control). The data in fact demonstrated that patients treated with CryoSeal FS showed superiority (statistically significant quicker time to hemostasis) versus the control group. The Company has received CE Mark approval for the system enabling its sale and use in Europe, however sales into individual countries under cost reimbursement structures often require the existence of supporting clinical usage within the individual country. We have, through our distribution partners in Europe, initiated more aggressive marketing including a number of clinical trials. In Japan, our distributor, Asahi, has completed enrollment in their pivotal clinical trial and filed their PMA equivalent in March 2005 with approval expected in first half of calendar 2007.

The TPD, a product line extension of the CryoSeal platform, is a small stand alone disposable that isolates and captures activated autologous thrombin from approximately 11 ml of patient blood plasma. Thrombin is used as a topical hemostatic agent for minor bleeding sites, to treat pseudoaneurysms and to release growth factors from platelets.

The Company's legacy is in its ThermoLine products for ultra rapid freezing and thawing of blood components, which the Company distributes to blood banks and hospitals. We are currently evaluating continuation of the ThermoLine, or divestiture, consistent with our strategic direction emphasizing the cell therapy and surgical wound care market. Beginning in late 1993, and with accelerated research and development efforts from 1996 to present, the Company completed development of the BioArchive, AXP and CryoSeal technology platforms.

Table of Contents

**ThermoGenesis Corp.
Management's Discussion and Analysis of
Financial Condition and Results of Operations
for the Three Months Ended September 30, 2006 and 2005 (Continued)**

Introduction (Continued)

In our early history, our revenue was derived principally from the sale of our blood plasma freezers and thawers. With the launch of our BioArchive System in 1999, we realized revenue increases due to the sale of that equipment. The installed base of our medical devices is designed to drive increases in revenue due to the recurring sale of disposables. We anticipate similar revenue increases from disposable sales related to the CryoSeal System and AXP System when the installed base of units increases, however there is no assurance that this will occur. With our efforts increasingly directed at both the cell therapy and tissue therapy markets, and our re-evaluation of the strategic relevance of our ThermoLine business, we will continue to assess our internal resources needs and operational structure. As part of those efforts, and with additional products staging to come on the market, we plan to significantly increase our staffing levels in engineering, scientific research, sales and marketing and management during fiscal 2007 in an effort to accelerate product launches and product development, as we pursue increased revenue.

The Company has announced a number of important agreements, summarized as follows:

In March of 2005, the Company entered into a Supply Agreement with Biomet Biologicals, formerly Cell Factors Technologies, Inc., an Indiana corporation and an affiliate of Biomet, Inc. (Biomet). Under the agreement, the Company will manufacture a thrombin disposable and reagent for the Clotalyst System. The Clotalyst System is Biomet's autologous clotting factor device and blood processing disposables. The Company assumes the role of manufacturer for Biomet of the Clotalyst device and blood processing disposals for a term of five years. The agreement requires Biomet, upon FDA clearance, to purchase a minimum quantity of 20,000 devices per year. Biomet has paid a one time advance fee for engineering and development of the product.

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 TPD 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.

In October 2005, the Company entered into a five-year agreement with GE Healthcare (formerly Amersham Biosciences AB), which outlined the terms of a strategic relationship between the Company and GE Healthcare. Pursuant to this agreement, (i) GE Healthcare becomes the exclusive worldwide distributor and service provider for the Company's BioArchive and AXP products, (ii) GE Healthcare agreed to provide the Company with certain funds upon execution of the agreement and over the ensuing 15 months and (iii) GE Healthcare and the Company agreed to collaborate on certain future improvements to these product lines.

In November 2005, the Company entered into a non-exclusive, five-year distribution and product modification agreement with Medtronic to supply the CE marked TPD for sale with Medtronic's Magellan Platelet Separation Device. This agreement intends to allow the sale of an all autologous platelet gel. Initially, Medtronic will sell the TPD-enabled Magellan product in Europe and Canada.

Table of Contents

**ThermoGenesis Corp.
Management's Discussion and Analysis of
Financial Condition and Results of Operations
for the Three Months Ended September 30, 2006 and 2005 (Continued)**

Introduction (Continued)

In July 2006, the Company entered into a Product Development and Supply Agreement with Biomet. Under the development phase of this agreement, Biomet will pay the Company \$1.1 million in milestone payments to develop a fibrinogen concentration kit containing the Company's CryoSeal II 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. 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 period included in the accompanying financial statements.

Critical Accounting Policies

The Company's discussion and analysis of its financial condition and results of operations are based upon the Company's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 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 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.

Table of Contents

**ThermoGenesis Corp.
Management's Discussion and Analysis of
Financial Condition and Results of Operations
for the Three Months Ended September 30, 2006 and 2005 (Continued)**

Critical Accounting Policies (Continued)

Revenue Recognition:

The Company recognizes revenue including multiple element arrangements, in accordance with the provisions of the Securities and Exchange Commission's (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*. 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's 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. If an undelivered element exists, the Company will determine the fair value of the undelivered element and subtract the fair value of the undelivered element from the total consideration under the arrangement. The residual amount is the Company's estimate of the fair value of the delivered element. 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. 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. Milestone payments the Company receives under collaborative 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 >

(1)(2)**10.31(a)**

Form of 2008 Restricted Stock Unit Award Agreement for Executive Officers under U.S. Bancorp 2007 Stock Incentive Plan. Filed as Exhibit 10.1 to Form 8-K filed on January 17, 2008.

Table of Contents

Exhibit Number	Description
(1)(2) 10.32(a)	Form of Restricted Stock Unit Award Agreement for Executive Officers under U.S. Bancorp 2007 Stock Incentive Plan to be used after December 31, 2008. Filed as Exhibit 10.10(a) to Form 8-K filed on January 7, 2009.
(1)(2) 10.33(a)	Form of Performance Restricted Stock Unit Award Agreement for Executive Officers under U.S. Bancorp 2007 Stock Incentive Plan to be used after December 31, 2008. Filed as Exhibit 10.1 to Form 8-K filed on March 6, 2009.
(1)(2) 10.34(a)	Form of 2010 Retention Performance Restricted Stock Unit Award Agreement for Executive Officers under U.S. Bancorp 2007 Stock Incentive Plan. Filed as Exhibit 10.1 to Form 8-K filed on February 18, 2010.
(1)(2) 10.35(a)	Form of 2007 Restricted Stock Unit Award Agreement for Non-Employee Directors under U.S. Bancorp 2007 Stock Incentive Plan. Filed as Exhibit 10.1 to Form 10-Q/A filed for the quarterly period ended September 30, 2007.
(1)(2) 10.36(a)	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under U.S. Bancorp 2007 Stock Incentive Plan to be used after December 31, 2008. Filed as Exhibit 10.11(a) to Form 8-K filed on January 7, 2009.
12	Statement re: Computation of Ratio of Earnings to Fixed Charges.
13	2009 Annual Report, pages 18 through 139.
21	Subsidiaries of the Registrant.
23	Consent of Ernst & Young LLP.
24	Power of Attorney.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. section 1350 as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Annual Report on Form 10-K of the Company for the year ended December 31, 2009, formatted in Extensible Business Reporting Language: (i) the Consolidated Balance Sheet, (ii) the Consolidated Statement of Income, (iii) the Consolidated Statement of Shareholders' Equity, (iv) the Consolidated Statement of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text.
(1)	<i>Exhibit has been previously filed with the Securities and Exchange Commission and is incorporated herein as an exhibit by reference to the prior filing.</i>
(2)	<i>Management contracts or compensatory plans or arrangements.</i>

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on February 26, 2010, on its behalf by the undersigned, thereunto duly authorized.

U.S. BANCORP

By /s/ Richard K. Davis

Richard K. Davis
Chairman, President and
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 26, 2010, by the following persons on behalf of the registrant and in the capacities indicated.

Signature and Title

/s/ Richard K. Davis

Richard K. Davis,
Chairman, President, and Chief Executive Officer (principal
executive officer)

/s/ Andrew Cecere

Andrew Cecere,
Vice Chairman and Chief Financial Officer
(principal financial officer)

/s/ Terrance R. Dolan

Terrance R. Dolan,
Executive Vice President and Controller
(principal accounting officer)

/s/ Douglas M. Baker, Jr.*

Douglas M. Baker, Jr., Director

/s/ Y. Marc Belton*

Y. Marc Belton, Director

/s/ Victoria Buyniski Gluckman*

Victoria Buyniski Gluckman, Director

/s/ Arthur D. Collins, Jr.*

Arthur D. Collins, Jr., Director

/s/ Joel W. Johnson*

Joel W. Johnson, Director

/s/ Olivia F. Kirtley*

Olivia F. Kirtley, Director

Table of Contents

Signature and Title

/s/ Jerry W. Levin*

Jerry W. Levin, Director

/s/ David B. O Maley*

David B. O Maley, Director

/s/ O Dell M. Owens, M.D., M.P.H.*

O Dell M. Owens, M.D., M.P.H., Director

/s/ Richard G. Reiten*

Richard G. Reiten, Director

/s/ Craig D. Schnuck*

Craig D. Schnuck, Director

/s/ Patrick T. Stokes*

Patrick T. Stokes, Director

* *Lee R. Mitau, by signing his name hereto, does hereby sign this document on behalf of each of the above named directors of the registrant pursuant to powers of attorney duly executed by such persons.*

Dated: February 26, 2010

By: /s/
Lee R. Mitau
Lee R. Mitau
Attorney-In-Fact
Executive Vice President,
General Counsel and Corporate Secretary