THERMOGENESIS CORP Form 10-Q May 10, 2007

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

b Quarterly Report Pursuant to Section 13 quarterly period ended March 31, 2007.	or 15(d) of the Securities Exchange Act of 1934 for the
•	or
o Transition Report Pursuant to Section 13 transition from to	or 15(d) of the Securities Exchange Act of 1934 for the
Commission File	Number: 333-82900
	enesis Corp.
(Exact name of registran	t as specified in its charter)
Delaware	94-3018487
(State of incorporation)	(I.R.S. Employer Identification No.)
2711 Ci	trus Road
	a <u>, California 95742</u>
(Address of principal ex	ecutive offices) (Zip Code)
<u>(916) 8</u>	<u>858-5100</u>
` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` `	number, including area code)
Indicate by check mark whether the registrant (1) has filed Securities Exchange Act of 1934 during the preceding 12 required to file such reports), and (2) has been subject to s b Yes	uch filing requirements for the past 90 days.
Indicate by check mark whether the registrant is a large ac	
filer. See definition of accelerated filer and large accelerated	
	erated filer o Non-accelerated filer
Indicate by check mark whether the registrant is a shell co o Yes	mpany (as defined in Rule 12b-2 of the Exchange Act).
Indicate the number of shares outstanding of each of the is date.	suer s classes of common stock, as of the latest practicable
Class	Outstanding at May 3, 2007
Common stock, \$.001 par value	55,306,175

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# PART I FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# ThermoGenesis Corp. Condensed Balance Sheets (Unaudited)

(in thousands, except share and per share amounts) ASSETS	M	arch 31, 2007	J	une 30, 2006
Current assets: Cash and cash equivalents Short-term investments Accounts receivable, net of allowance for doubtful accounts of \$66 (\$17 at June 30,	\$	9,582 25,184	\$	3,527 35,472
2006)		4,108		3,773
Inventories		4,635		2,792
Other current assets		379		462
Total current assets		43,888		46,026
Equipment at cost less accumulated depreciation of \$3,147 (\$3,024 at June 30, 2006) Other assets		1,529 104		1,489 88
	\$	45,521	\$	47,603
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities: Accounts payable	\$	2,146	\$	1,931
Accrued payroll and related expenses  Deferred revenue		324 721		417 718
Other current liabilities		938		618
Total current liabilities		4,129		3,684
Deferred revenue  Long-term portion of capital lease obligations and note payable		1,816 13		1,921 26
Long-term portion of capital lease obligations and note payable		13		20
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; 55,301,175 issued				
and outstanding (54,882,952 at June 30, 2006) Paid in capital in excess of par		55 117,523		55 115,769
Accumulated deficit		(78,015)		(73,852)
Total stockholders equity		39,563		41,972

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\$ 45,521 \$ 47,603

See accompanying notes to financial statements. Page 3

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# ThermoGenesis Corp. Condensed Statements of Operations (Unaudited)

		Three Months Ended March 31,				Nine Months Ended March 31,		
(in thousands, except share and per share amounts)		2007		2006		2007		2006
Product and other revenues Milestone payments and license fees	\$	4,791 419	\$	3,063 185	\$	11,891 1,340	\$	8,117 374
Net revenues		5,210		3,248		13,231		8,491
Cost of product and other revenues Cost of milestone payments and license fees		3,346 92		1,932		8,741 217		5,466
Cost of revenues		3,438		1,932		8,958		5,466
Gross profit		1,772		1,316		4,273		3,025
Expenses:								
Selling, general and administrative		2,201		1,771		6,813		5,101
Research and development		1,034		705		2,969		2,955
Total operating expenses		3,235		2,476		9,782		8,056
Interest and other income, net		426		268		1,346		370
Net loss		(\$1,037)		(\$892)		(\$4,163)		(\$4,661)
Per share data:								
Basic and diluted net loss per common share		(\$0.02)		(\$0.02)		(\$0.08)		(\$0.10)
Shares used in computing per share data	5	5,266,175	5	1,584,192	5	55,103,539	4	17,822,518
See accompanying	See accompanying notes to financial statements. Page 4							

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# ThermoGenesis Corp. Condensed Statements of Cash Flows (Unaudited) Nine Months Ended March 31, 2007 and 2006

(in thousands)	2007	2006
Cash flows from operating activities:		
Net loss	(\$4,163)	(\$4,661)
Adjustments to reconcile net loss to net cash used in operating activities:	(+ 1,- ==)	(+ 1,000)
Depreciation and amortization	347	277
Stock based compensation expense	614	831
Accretion of discount on short-term investments	(969)	
Loss on sale of equipment	9	
Net change in operating assets and liabilities:		
Accounts receivable	(335)	(118)
Inventories	(1,911)	572
Other current assets	83	220
Other assets	(16)	
Accounts payable	215	(723)
Accrued payroll and related expenses	(93)	(58)
Deferred revenue	(102)	2,306
Other current liabilities	320	17
Other liabilities		49
Net cash used in operating activities	(6,001)	(1,288)
Cash flows from investing activities:		
Capital expenditures	(328)	(285)
Purchase of investments	(37,743)	(19,611)
Maturities of investments	49,000	, ,
Net cash provided by (used in) investing activities	10,929	(19,896)
Cash flows from financing activities:		
Payments on capital lease obligations and note payable	(13)	(109)
Issuance of common stock	(13)	32,564
Exercise of stock options and warrants	1,140	335
Net cash provided by financing activities	1,127	32,790
Net increase in cash and cash equivalents	6,055	11,606
Cash and cash equivalents at beginning of period	3,527	9,568
Cash and cash equivalents at end of period	9,582	\$ 21,174

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Supplemental non-cash flow information: Equipment acquired by capital lease		\$ 106
Transfer of inventory to equipment	\$ 124	\$ 94
Transfer of equipment to inventory	\$ 56	\$ 63
See accompanying notes to financial statements Page 5		

# 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 nine month period ended March 31, 2007 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. Revenues from the sale of the Company s products are recognized when persuasive evidence of an arrangement exists, delivery has occurred (or services have been rendered), the price is fixed or determinable, and collectibility is reasonably assured. 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. Amounts billed in excess of revenue recognized are recorded as deferred revenue on the balance sheet. The Company s foreign sales are generally through distributors. There is no right of return provided for distributors. For sales of products made to distributors, the Company considers a number of factors in determining whether revenue is recognized upon transfer of title to the distributor, or when payment is received. These factors include, but are not limited to, whether the payment terms offered to the distributor are considered to be non-standard, the distributor history of adhering to the terms of its contractual arrangements with the Company, the level of inventories maintained by the distributor, whether the Company has a pattern of granting concessions for the benefit of the distributor, and whether there are other conditions that may indicate that the sale to the distributor is not substantive. The Company currently recognizes revenue primarily on the sell-in method with its distributors.

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

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

### Revenue Recognition (Continued)

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

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

Milestone payments the Company receives under collaborative arrangements are recognized as revenue upon achievement of the milestone events, which represent the culmination of the earnings process, and when collectibility 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.

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

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

# Segment Reporting

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

### 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 2,766,349 and 3,074,369 as of March 31, 2007 and 2006.

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

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

### Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. (FIN) 48, Accounting for Uncertainty in Income Taxes. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in a company s financial statements in accordance with FASB No. 109, Accounting for Income Taxes. Specifically, the pronouncement prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition of uncertain tax positions. The interpretation is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact that FIN No. 48 will have on its financial statements. In September 2006, the SEC issued SAB No. 108, Considering the Effects of Prior Year Misstatements when Ouantifying 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. The Company does not anticipate the adoption of SAB No. 108 will have a material impact on its 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. The Company is currently evaluating the impact of the provisions of SFAS No. 157 on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 allows entities to voluntarily choose to measure many financial assets and financial liabilities at fair value. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact, if any, the adoption of SFAS No. 159 will have on its financial statements.

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

### 2. Investments

Investments consisted of the following at March 31, 2007:

		Gross	Gross	
	Amortized	Unrealized	Unrealized	Estimated
(in thousands)	Cost	Gains	Losses	Fair Value
March 31, 2007				
U.S. government and agency securities	\$25,184	\$ 1	(\$8)	\$25,177

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 have been in a continuous unrealized loss position for less than 12 months, are \$8 and \$17,717 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.

	Amortized	Estimated
	Cost	Fair Value
Maturity Date:		
Less than 90 days	\$11,418	\$11,419
Due in 91-365 days	13,766	13,758
	\$25,184	\$25,177

#### 3. Inventories

Inventories consisted of the following at:

(in thousands)		March 31, 2007		
Raw materials Work in process Finished goods Reserve	\$	2,351 1,845 1,276 (837)	\$	1,603 1,433 530 (774)
1000170	\$	4,635	\$	2,792

Included in the Company s inventory reserve at March 31, 2007 and June 30, 2006 were \$565 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 inventory for other product lines which have been identified as slow-moving or potentially obsolete.

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

## 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	120
Settlements made during the period	(145)
Changes in liability for pre-existing warranties during the period, including expirations	147
Balance at March 31, 2007	\$ 196

### 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 \$32 and \$600 was charged to compensation expense for the three and nine months ended March 31, 2007 and \$237 and \$773 for the three and nine months ended March 31, 2006. Due to terminations and the corresponding forfeiture of stock options, the Company has reversed \$134 of previously recognized stock compensation expense during the quarter ended March 31, 2007. Additionally, the Company has adjusted its forfeiture rates as the actual number of awards expected to vest will likely differ from previous estimates.

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

## 5. Stockholder s Equity (Continued)

Stock Based Compensation (Continued)

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 Forfeited or Expired Exercised	295,000 (32,972) (54,500)	\$4.01 \$4.76 \$2.35		
Outstanding at March 31, 2007	2,746,849	\$2.84	2.7	\$2,661
Vested and Expected to Vest at March 31, 2007	2,657,167	\$2.80	2.7	\$2,660
Exercisable at March 31, 2007	1,889,551	\$2.50	2.4	\$2,349

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 2,045,074 options that were in-the-money at March 31, 2007. During the nine months ended March 31, 2007 and 2006, the aggregate intrinsic value of options exercised under the Company s stock option plans were \$96 and \$23 respectively, determined as of the date of option exercise. *Warrants* 

During the nine months ended March 31, 2007, 352,500 shares of common stock were issued due to the exercise of warrants.

### 6. Subsequent Events

Effective April 26, 2007, the Company s Chief Executive Officer (incumbent CEO) was granted 500,000 shares of restricted common stock with three year vesting. The grant has a value of \$1,700 based on the fair market value of the Company s stock on the grant date. The vesting is subject to acceleration upon certain conditions: (1) Company s engagement of a new Chief Executive Officer (new CEO) and confirmation by the Board of Directors, (2) development and Board approval of a transition plan for the new CEO and transition of the incumbent CEO to the position of Chief Technology Architect and (3) entry into the Employment Agreement for a term of three years. The Company is currently evaluating the accounting impact of the restricted stock grant.

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# ThermoGenesis Corp. Management s Discussion and Analysis of Financial Condition and Results of Operations for the Three and Nine Months Ended March 31, 2007 and 2006

# <u>Item 2. Management</u> s <u>Discussion and Analysis of Financial Condition and Results of Operations</u> 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 expect and similar expressions as they relate to the Company or its management are estimate, 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 involve 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.

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# ThermoGenesis Corp. Management s Discussion and Analysis of Financial Condition and Results of Operations for the Three and Nine Months Ended March 31, 2007 and 2006 (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, initiated a Master File of the product with the Food and Drug Administration (FDA) in October 2005 and submitted a 510(k) pre-market notification application to the FDA in February 2007. 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.

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# ThermoGenesis Corp. Management s Discussion and Analysis of Financial Condition and Results of Operations for the Three and Nine Months Ended March 31, 2007 and 2006 (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 Company expects to receive, but cannot guarantee, FDA approval during the quarter ended June 30, 2007. The study reached its primary end point, which was to demonstrate equivalency (i.e. 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 the second 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 or plasma. Thrombin is used as a topical hemostatic agent for minor bleeding sites, to treat pseudo aneurysms 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.

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# ThermoGenesis Corp. Management s Discussion and Analysis of Financial Condition and Results of Operations for the Three and Nine Months Ended March 31, 2007 and 2006 (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, 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 for market release, 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