

INSMED INC
Form 10-Q
May 09, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2006

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-30739

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia
(State or other jurisdiction of
incorporation or organization)

4851 Lake Brook Drive

54-1972729
(I.R.S. Employer

Identification No.)

(804) 565-3000

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Glen Allen, Virginia 23060
(Address of principal executive offices)

(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. (Check one):

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:

As of April 30, 2006, the latest practicable date, there were 100,150,700 shares of Insmmed Incorporated common stock outstanding.

INSMED INCORPORATED

INDEX

REPORT: FORM 10-Q

PART I. FINANCIAL INFORMATION

ITEM 1	Financial Statements	
	<u>Condensed Consolidated Balance Sheets at March 31, 2006 (unaudited) and December 31, 2005</u>	3
	<u>Condensed Consolidated Statements of Operations for the Three Month Periods Ended March 31, 2005 and March 31, 2006 (unaudited)</u>	4
	<u>Consolidated Statements of Cash Flows for the Three Month Periods Ended March 31, 2005 and March 31, 2006 (unaudited)</u>	5
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
ITEM 2	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
ITEM 3	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	17
ITEM 4	<u>Controls and Procedures</u>	17

PART II. OTHER INFORMATION

ITEM 1	<u>Legal Proceedings</u>	18
ITEM 2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
ITEM 3	<u>Defaults Upon Senior Securities</u>	18
ITEM 4	<u>Submission of Matters to a Vote of Security Holders</u>	18
ITEM 5	<u>Other Information</u>	18
ITEM 6	<u>Exhibits</u>	18
	<u>SIGNATURE</u>	19
	CERTIFICATIONS	

PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	(Unaudited)	
	March 31, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,207	\$ 18,835
Restricted cash	285	285
Other current assets	33	83
Total current assets	59,525	19,203
Long-term assets:		
Restricted cash - long term	2,830	3,118
Deferred financing costs, net	270	532
Property and equipment, net	15	17
Total long-term assets	3,115	3,667
Total assets	\$ 62,640	\$ 22,870
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 2,243	\$ 968
Accrued project costs & other	4	1,990
Payroll liabilities	926	1,574
Interest payable	28	52
Restructuring reserve	204	286
Total current liabilities	3,405	4,870
Long-term liabilities:		
Convertible debt	6,013	11,438
Debt discount	(2,539)	(5,001)
Net convertible debt	3,474	6,437
Asset retirement obligation	1,182	1,034
Total liabilities	8,061	12,341
Stockholders equity:		
Common stock; \$.01 par value; authorized shares 500,000,000; issued and outstanding shares, 100,150,700 in 2006 and 66,525,792 in 2005	1,001	665
Additional paid-in capital	321,663	264,522
Accumulated deficit	(268,085)	(254,658)

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Net stockholders' equity	54,579	10,529
Total liabilities and stockholders' equity	\$ 62,640	\$ 22,870

See accompanying notes to the condensed consolidated financial statements.

INSMED INCORPORATED
Condensed Consolidated Statements of Operations**(in thousands, except per share data - unaudited)**

	Three Months Ended March 31	
	2006	2005
Revenues	\$ 54	\$ 57
Operating expenses:		
Research and development	7,174	4,287
Selling, General and administrative	3,800	1,293
Total operating expenses	10,974	5,580
Operating loss	(10,920)	(5,523)
Interest income	312	64
Interest expense	(2,819)	(305)
Net loss	\$ (13,427)	\$ (5,764)
Basic and diluted net loss per share	\$ (0.17)	\$ (0.13)
Shares used in computing basic and diluted net loss per share	79,987	44,986

See accompanying notes to the condensed consolidated financial statements.

INSMED INCORPORATED

Condensed Consolidated Statements of Cash Flows

(in thousands - unaudited)

	Three Months Ended March 31	
	2006	2005
Operating activities		
Net loss	\$ (13,427)	\$ (5,764)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,726	226
Stock based compensation expense	270	
Stock options issued for services	20	
Changes in operating assets and liabilities:		
Other assets	50	74
Accounts payable	1,275	(1,080)
Accrued project costs	(1,986)	(125)
Payroll liabilities	(648)	224
Restructuring reserve	(82)	(78)
Asset retirement obligation	148	148
Interest payable	(24)	80
Net cash used in operating activities	(11,678)	(6,295)
Financing activities		
Proceeds from issuance of convertible debt with detachable stock warrants		35,000
Proceeds from issuance of common stock		
Public offering - issuance of 23 million shares	43,240	
Issuance costs	(316)	
Warrants converted into shares	8,810	
Other	28	87
Total proceeds from issuance of common stock	51,762	87
Costs incurred in conjunction with issuance of debt		(2,428)
Decrease in cash restricted to restricted letters of credit	288	185
Net cash provided by financing activities	52,050	32,844
Increase in cash and cash equivalents	40,372	26,549
Cash and cash equivalents at beginning of period	18,835	9,222
Cash and cash equivalents at end of period	\$ 59,207	\$ 35,771
<i>Supplemental information</i>		
Cash paid for interest	\$ 83	\$
See accompanying notes to the condensed consolidated financial statements.		

Insmed Incorporated

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission regulations for interim financial information. These financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. It is presumed that users of this interim financial information have read or have access to the audited financial statements contained in the Annual Report on Form 10-K of Insmed Incorporated (the Company) for the fiscal year ended December 31, 2005. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation have been included. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies

Research and Development Costs

Research and development costs consist primarily of compensation and other expenses related to research and development personnel, costs associated with pre-clinical testing and clinical trials of the Company's product candidates, including the costs of manufacturing the product candidates, litigation costs as it relates to the Company's patents and facilities expenses. Research and development costs are expensed as incurred. The Company does not have separate accounting policies for internal or external research and development and does not conduct any research and development for others.

Stock-Based Compensation

Effective January 1, 2006. The Company recognizes expense for stock-based compensation in accordance with FASB Statement 123 (R) *Share-Based Payment*. (See Note 3)

Prior to that date the Company recognized expense for stock-based compensation in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Accordingly, compensation cost was recognized for the excess, if any, of the estimated fair value of the stock at the grant date over the exercise price. Stock options granted to non-employees are accounted for in accordance with EITF 96-18, *Accounting for Equity Instruments that are issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

In accordance with FASB Statement 123 (R), *Share-Based Payment*, the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of statement 123 for all periods presented is as follows:

Stock Compensation Expense

(in thousands - except per share data)

	For the Three months Ended March 31, 2005
Net Loss	(5,764)
Net Loss Per Share (Basic and Diluted)	(0.13)
Pro-forma Fair value stock compensation expense	(560)
Pro-forma Net Income	(6,324)
Pro-forma Net Loss Per Share (Basic and Diluted)	(0.14)

3. Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued a revision of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (Statement 123(R)). Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement 123(R) was adopted by the Company on January 1, 2006. The Company adopted the fair-value-based method of accounting for share-based payments effective January 1, 2006, using the modified prospective transition method described in FASB Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. Currently, the Company uses the Black-Scholes-Merton Formula to estimate the value of stock options granted to employees and expects to continue to use this acceptable option valuation model. Under that transition method, compensation cost recognized during the three months ended March 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair valued estimated in accordance with the provisions of SFAS 123(R). Prior to January 1, 2006, the Company applied Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related Interpretations in accounting for its stock based compensation plans. Results for prior periods have not been restated. However, had the Company adopted Statement 123 (R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro-forma net income and earnings per share in Note 2 to the Company's consolidated financial statements.

As a result of adopting statement 123(R) on January 1, 2006, the Company's net loss for the three months ended March 31, 2006 is \$270,000 higher than if it had continued to account for share-based compensation under statement 123. Basic and diluted loss per share for the three months ended March 31, 2006 would have been \$0.16 per share if the Company had not adopted statement 123(R), compared to reported basic and diluted earnings per share of \$0.17 per share. Unamortized stock compensation expense as of March 31, 2006 is \$2.2 million.

4. Equity Compensation Plan Information

As of March 31, 2006, Insmed has two equity compensation plans under which it is granting stock options and shares of non-vested stock. The Company is currently granting stock-based awards through the Restated 2000 Stock Incentive Plan (the 2000 Plan) and the 2000 Employee Stock Purchase Plan (the 2000 ESPP). Both the 2000 Plan and the 2000 ESPP are administered by the Compensation Committee of the Board of Directors and the Board of Directors.

The 2000 Plan was originally adopted by the Board of Directors and approved by the stockholders in 2000 and its original ten-year term was extended to March 15, 2015 when the plan was last amended. Under the terms of the 2000 Plan, The Company is authorized to grant a variety of incentive awards based on Insmed common stock, including stock options (both incentive options and non-qualified options), performance shares and other stock awards. The 2000 Plan currently provides for the issuance of a maximum of 9,250,000 (adjusted for stock splits) shares of common stock. These shares are reserved for awards to all participants in the 2000 Plan, including non-employee directors.

The 2000 Employee Stock Purchase Plan (the Stock Purchase Plan) was originally adopted as of April 5, 2000 for a term of ten years and that term was extended to May 11, 2015 when the plan was last amended. The Stock Purchase Plan provides for the issuance of a maximum of 500,000 shares of Insmed common stock to participating employees.

The following table presents information as of March 31, 2006, with respect to the 2000 Plan and the 2000 ESPP.

Plan Category(1)	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans(2)
Equity Compensation Plans Approved by Shareholders:			
Amended and Restated 2000 Stock Incentive Plan	6,639,630	\$ 3.08	1,816,213(2)
2000 Employee Stock Purchase Plan, As Amended			182,182
Total:	6,639,630	\$ 3.08	1,998,395(3)

(1) The Company does not have any equity compensation plans that have not been approved by its shareholders.

(2) Amounts exclude any securities to be issued upon exercise of outstanding options, warrants and rights.

(3) To the extent that stock options or stock appreciation rights granted under the Amended and Restated 2000 Stock Incentive Plan terminate, expire, or are canceled, forfeited, exchanged or surrendered without having been exercised, or if any shares of restricted stock or performance units are forfeited, the shares of common stock underlying such grants will again become available for purposes of the Plan.

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A summary of the status of the Company's options as of March 31, 2006, and changes for the three months then ended is presented below:

Description	2006	Weighted average exercise price	Weighted average remaining contractual life in years
Options outstanding at January 1, 2006	5,924,930	\$ 3.18	
Granted	743,250	2.20	
Exercised	(23,000)	0.50	
Cancelled	(5,550)	1.65	
Options outstanding at March 31	6,639,630	3.08	4.61
Exercisable at March 31, 2006	3,443,098	4.37	4.31

The fair value of the options granted during the three months ended March 31, 2006, and 2005, was estimated at the date of grant using a Black-Scholes option-pricing model with the weighted average assumptions described below:

Assumptions	For the Three Months Ended March 31,	
	2006	2005
Dividend yield	0	0
Volatility factors of expected market price of stock	113%	89%
Risk-free interest rate	4.65%	4.2%
Expected option term (in years)	2.59	5
Forfeitures	27%	0%

The Company improved its stock compensation methodology in calculating the amount of forfeitures and the expected term of the options. Previously, forfeiture of stock option awards, either through expiration or termination, was not included in the calculation. The expected term of the option was reduced from 5.0 years to exercise to 2.6 years to exercise. The impact of these changes in methodology is offsetting. Therefore, the net dollar value impact on stock compensation expense is minimal.

5. Operational Restructuring

As a result of the September 10, 2002 decision to discontinue the INS-1 development program, the Company approved a restructuring plan to focus on its remaining drug candidates. In the first quarter of 2002, the Company recorded a restructuring charge of \$2.5 million. At March 31, 2006, approximately \$204,000 of these costs remain accrued in the current portion of the restructuring reserve. This balance is expected to closely approximate the remaining costs to be incurred by the Company for lease obligations. Lease termination costs are anticipated to extend through October 2006.

6. Convertible Debt Financing

On March 15, 2005, the Company entered into several purchase agreements with a group of institutional investors, pursuant to which the Company issued and sold to the investors approximately \$35,000,000 aggregate principal amount of 5.5% convertible notes, which notes are convertible into common stock, par value \$0.01 per share, as well as warrants to purchase, in the aggregate, 14,864,865 shares of common stock, at an exercise price of \$1.36 per share. The

principal of each note will mature and be payable in nine quarterly installments of approximately \$3,890,000 commencing on March 1, 2008. Any outstanding notes must be repaid in cash or converted by March 1, 2010. As of June 1, 2005, the holders of the notes began to receive interest payments at a rate of 5.5% per annum. Interest on the notes is payable quarterly until March 1, 2010. The holders of the notes may convert the notes into common stock at a conversion price of \$1.295 per share as adjusted in accordance with certain adjustments for stock splits, dividends and the like at any time prior to the close of business on March 1, 2010. The notes initially issued were convertible into, in the aggregate, 27,027,027 shares of common stock. The warrants initially issued were immediately exercisable for 14,864,883 shares of common stock at an exercise price of \$1.36 per share. The warrants will expire on March 15, 2010. The holders of the notes have the right to require the Company to repurchase the notes with cash payments up to the occurrence of specified events of default and repurchase events. In connection with issuance of the notes and warrants, the Company entered into registration rights agreements with the investors pursuant to which the Company agreed to file a Registration Statement under the Securities Act of 1933, registering for resale the shares of common stock issuable upon the conversion of the notes or exercise of the warrants.

Between January 1, 2006 and March 31, 2006, Insmmed received notices from holders of its 5.5% Convertible Notes due 2008-2010 electing to voluntarily convert \$5,425,000 principal amount of the notes into 4,189,189 shares of common stock at the conversion rate of one share of common stock for each \$1.295 in principal amount of the notes. Following the conversions, \$6,013,000 principal amount of the Convertible Notes remained outstanding. In addition, because certain of the Convertible Notes were converted prior to the March 1, 2006 quarterly interest payment, the Company issued an additional 29,800 shares of common stock for the forfeited cash interest payment at a conversion price of \$1.295.

The Company also received \$8,177,070 from warrant exercises that resulted in 6,012,551 shares of common stock being issued at an exercise price of \$1.36. Following the exercises there were 6,211,390 warrants remaining from the March 2005 financing.

In addition to the warrant exercises from the March 2005 financing, the Company also received \$633,332 from the exercise of warrants from the November 2004 financing that resulted in 370,370 shares of common stock being issued at an exercise price of \$1.71. Following the exercises there were 2,319,702 warrants remaining from the November 2004 financing.

7. Public Stock Offering

On March 15, 2006, Insmmed Incorporated (the Company) sold 23,000,000 shares of the Company's common stock, \$0.01 par value per share. The price to the public was \$2.00 per share, and the Underwriters purchased the shares from the Company pursuant to the Underwriting Agreement at a price of \$1.88 per share. The offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-131535) previously filed with the Securities and Exchange Commission. Net proceeds from the offering were \$43.0 million.

The AXP is an innovative product which automates the isolation and concentration of 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 has been commercially available since March 2006, marketed under a Master File with the FDA. In October 2007, the Company received 510k clearance from the FDA for the use of the AXP in the processing of cord blood for cryopreservation. The AXP Platform 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 Platform 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. In February 2008, the Company initiated a voluntary recall of certain lots of the AXP disposable bag sets as some lots of the bag sets were distributed prior to the performance of pyrogen testing. This recall was not a result of any customer complaints or reports of patient safety issues. The Company has tested approximately 50% of the recalled bag set lots, all having passed with no exceptions. The Company expects to have completed testing of the remaining available lots in the near future.

The Company is developing an extension of the AXP, the MarrowXpress Platform. This is a proprietary, automated device and companion sterile blood processing disposable for isolating stem cells from bone marrow in a closed system at or near the point of care. The initial focus will be in the use of bone marrow stem cells in the treatment of critical limb ischemia and myocardial ischemia. We are in the process of preparing a 510k submission and CE Mark application. The Company plans to sell the MarrowXpress directly to global customers.

The CryoSeal FS System (CryoSeal) 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. On July 30, 2007, the Company announced that it had received FDA clearance to market the CryoSeal FS System's autologous fibrin sealant, as an adjunct to hemostasis in liver resection surgery. In Japan, our distributor, Asahi Kasei Medical Co., Ltd. (Asahi) has completed enrollment in their pivotal clinical trial and filed their Premarket Application (PMA) approval equivalent in March 2005 with approval expected during fiscal 2009. The Company has received CE Mark approval for the system enabling its sale and use in Europe. However, we have not been able to meaningfully penetrate the market with this product and revenues have lagged expectations. Over the last several years while marketing the CryoSeal in numerous European countries, we and our distributors have faced substantial country specific regulatory, cost-reimbursement and product registration requirements that have negatively impacted our ability to sell the product and grow revenues. Compliance with these requirements has been more complicated than we anticipated, requiring far more time and the consumption of more of our resources than we originally projected.

Table of Contents

With a better appreciation today for the country specific expertise required to successfully market the CryoSeal, we are assessing strategic alternatives beyond our own regulatory and marketing capabilities to help us better navigate the regulatory and reimbursement pathways in each of our markets throughout the world. We are targeting to increase our market penetration for this product in Europe and in other areas of the world including Brazil, Korea, Mexico, Russia and Taiwan where our distributors may now register the CryoSeal following our recently received FDA approval. We believe that there is a market for our 100% autologous CryoSeal System due to its safety advantages over conventional, non-autologous fibrin sealants that carry the risk of contamination by blood-borne pathogens from other donors, and that this market may extend beyond the typical wound care applications to include use of the technology in the delivery of stem cells for cell therapeutics. Therefore, we are evaluating alternatives for commercialization of our CryoSeal System including new strategic partnering and licensing, distribution channel partners, and the potential use of the technology in the delivery of stem cells.

The Thrombin Processing Device (TPD), a product line extension of the CryoSeal System, 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 our divestiture options for the ThermoLine consistent with our strategic direction emphasizing the cell therapy and surgical wound care market. 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 consolidated financial statements.

Critical Accounting Policies

Management's discussion and analysis of its financial condition and results of operations are based upon the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to bad debts, inventories, warranties, contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Revenue Recognition:

The Company recognizes revenue including multiple element arrangements, in accordance with the provisions of the SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and the Financial Accounting Standards Board's (FASB) Emerging Issues Task Force (EITF) 00-21, *Revenue Agreements with Multiple Deliverables*. Revenues from the sale of the Company's products are recognized when persuasive evidence of an arrangement exists, delivery has occurred (or services have been rendered), the

Table of Contents

price is fixed or determinable, and collectibility is reasonably assured. The Company generally ships products F.O.B. shipping point. There is no conditional evaluation on any product sold and recognized as revenue. All foreign sales are denominated in U.S. dollars. Amounts billed in excess of revenue recognized are recorded as deferred revenue on the balance sheet.

The Company's foreign sales are generally through distributors. There is no right of return provided for distributors. For sales of products made to distributors, the Company considers a number of factors in determining whether revenue is recognized upon transfer of title to the distributor, or when payment is received. These factors include, but are not limited to, whether the payment terms offered to the distributor are considered to be non-standard, the distributor history of adhering to the terms of its contractual arrangements with the Company, the level of inventories maintained by the distributor, whether the Company has a pattern of granting concessions for the benefit of the distributor, and whether there are other conditions that may indicate that the sale to the distributor is not substantive. The Company currently recognizes revenue primarily on the sell-in method with its distributors.

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. Costs associated with inconsequential or perfunctory elements in multiple element arrangements are accrued at the time of revenue recognition. The Company accounts for training and installation as a separate element of a multiple element arrangement. The Company therefore recognizes the fair value of training and installation services upon their completion when the Company is obligated to perform such services.

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

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

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

Table of Contents

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 expense, which could have a material impact on the Company's financial position and results of operations.

Allowance for Doubtful Accounts:

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which would be charged against earnings.

Warranty:

The Company provides for the estimated cost of product warranties at the time revenue is recognized. While the Company engages in extensive product quality programs and processes, including actively monitoring and evaluating the quality of its component suppliers, the Company's warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from the Company's estimates, revisions to the estimated warranty liability could have a material impact on the Company's financial position, cash flows or results of operations.

Inventory Reserve:

The Company plans inventory procurement and production based on orders received, forecasted demand and supplier requirements. The Company writes down its inventories for estimated obsolescence or unmarketable inventories equal to the difference between the cost of inventories and its net realizable value based upon estimates about future demand from our customers and distributors and market conditions. Because some of the Company's products are highly dependent on government and third-party funding, current customer use and validation, and completion of regulatory and field trials, there is a risk that we will forecast incorrectly and purchase or produce excess inventory. As a result, actual demand may differ from forecasts, and such a difference may have a material adverse effect on future results of operations due to required write-offs of excess or obsolete inventory. This inventory risk may be further compounded for the CryoSeal family of products because they are at initial market introduction and market acceptance will depend upon the customer accepting the products as clinically useful, reliable, accurate and cost effective compared to existing and future products and completion of required clinical or field acceptance trials.

Results of Operations for the Three Months Ended March 31, 2008 as Compared to the Three Months Ended March 31, 2007***Net Revenues:***

Revenues for the three months ended March 31, 2008 were \$5,645,000 compared to \$5,210,000 for the three months ended March 31, 2007, an increase of \$435,000 or 8%. This is primarily due to an increase in shipments in the AXP product line, both devices and disposables, which contributed to an increase in revenues of approximately \$500,000. The increase in shipments is due to higher levels of production from our subcontract manufacturers for fulfillment against outstanding customer backlog.

Table of Contents

The following represents the Company's cumulative BioArchive devices sold into the following geographies through the dates indicated:

	March 31,	
	2008	2007
United States	41	31
Asia	57	54
Europe	45	40
Rest of World	29	27
	172	152

The following represents the Company's revenues for disposables by product line for the three months ended:

	March 31,	
	2008	2007
AXP	\$ 1,786,000	\$ 1,413,000
BioArchive	1,044,000	861,000
CryoSeal	166,000	42,000
TPD	52,000	126,000
	\$ 3,048,000	\$ 2,442,000
Percentage of total Company revenues	54%	47%

Gross Profit:

The Company's gross profit was \$1,501,000 or 27% of net revenues for the three months ended March 31, 2008, as compared to \$1,772,000 or 34% for the corresponding fiscal 2007 period. The decrease in gross margin is primarily due to \$386,000 in costs incurred by the Company as a result of the voluntary recall of AXP disposable bag sets. The incremental costs were for testing, materials and the destruction of bag sets which were not considered resalable. No bag set lots have failed the requisite testing performed on the recalled inventory.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were \$2,550,000 for the three months ended March 31, 2008, compared to \$2,201,000 for the comparable fiscal 2007 period, an increase of \$349,000 or 16%. The increase is due to higher legal fees, \$300,000, associated with the GE Healthcare distribution agreement negotiations and for consultation during the voluntary recall effort. In addition, website development, product brochures and other start-up activities for Vantus drove higher marketing expenses.

Research and Development Expenses:

Included in this line item are Engineering, Regulatory Affairs, Scientific and Clinical Affairs.

Research and development expenses for the three months ended March 31, 2008, were \$1,902,000 compared to \$1,034,000 for the corresponding fiscal 2007 period, an increase of \$868,000 or 84%. The increase is primarily due to stock compensation and salaries and benefits of approximately \$600,000 related to the Chief Technology Architect, a position filled by the Company's former Chief Executive Officer as of August 1, 2007 as part of the succession plan. Also, expenses associated with the Vantus subsidiary, which was formed in February 2008, contributed approximately \$300,000 to the overall increase in research and development expenses.

Table of Contents***Results of Operations for the Nine Months Ended March 31, 2008 as Compared to the Nine Months Ended March 31, 2007******Net Revenues:***

Revenues for the nine months ended March 31, 2008 were \$14,764,000, compared to \$13,231,000 for the nine months ended March 31, 2007, an increase of \$1,533,000 or 12%. The increase is primarily due to revenues from AXP disposables which increased \$1,900,000 due to higher sales volume. This was offset by a decrease in development milestone payments and license fees of approximately \$640,000.

The following represents the Company's revenues for disposables by product line for the nine months ended:

	March 31,	
	2008	2007
BioArchive	\$ 2,627,000	\$ 2,598,000
AXP	3,888,000	2,003,000
CryoSeal	746,000	297,000
TPD	256,000	338,000
	\$ 7,517,000	\$ 5,236,000
Percentage of total Company revenues	51%	40%

Gross Profit:

The Company's gross profit was \$4,620,000 or 31% of net revenues for the nine months ended March 31, 2008, as compared to \$4,273,000 or 32% for the corresponding fiscal 2007 period. The gross margin for the nine months ended March 31, 2008 was impacted by the costs associated with the voluntary recall as discussed above, offset by improvements to warranty expense for the BioArchive and CryoSeal devices.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were \$7,327,000 for the nine months ended March 31, 2008, compared to \$6,813,000 for the comparable fiscal 2007 period, an increase of \$514,000 or 8%. The increase is due to increased salaries and benefits for personnel and legal costs, \$386,000, related to the discussions with GE Healthcare regarding the distribution agreement and consultation during the voluntary recall effort.

Research and Development Expenses:

Included in this line item are Engineering, Regulatory Affairs, Scientific and Clinical Affairs.

Research and development expenses for the nine months ended March 31, 2008, were \$5,015,000 compared to \$2,969,000 for the corresponding fiscal 2007 period, an increase of \$2,046,000 or 69%. The increase is primarily due to stock compensation, salaries and benefits of approximately \$1,500,000 related to the Chief Technology Architect, a position filled by the Company's former Chief Executive Officer as of August 1, 2007 as part of the succession plan. Also, expenses associated with the Vantus subsidiary of \$300,000 and payments made to UC Davis of \$130,000 in connection with an agreement to develop stem cell treatments contributed to the overall increase in research and development expenses.

Liquidity and Capital Resources

At March 31, 2008, the Company had cash, cash equivalents and short-term investments of \$29,043,000 and working capital of \$32,445,000. This compares to cash, cash equivalents and short-term investments of \$33,379,000 and working capital of \$37,759,000 at June 30, 2007. The cash was used to fund

Table of Contents

operations and other cash needs of the Company. In addition to product revenues, the Company has primarily financed operations through the private and public placement of equity securities and has raised approximately \$108,000,000, net of expenses, through common and preferred stock financings and option and warrant exercises.

At March 31, 2008 the Company has \$13,912,000 of short-term investments in mortgage-backed securities of government sponsored enterprises, specifically discounted notes issued by the Federal Home Loan Bank and the Federal National Mortgage Association. These securities are high-grade and all mature prior to the Company's year end of June 30, 2008. Due to the high credit quality and the maturity dates of these securities, the Company does not believe they will have a material negative impact on our financial condition.

Net cash used in operating activities for the nine months ended March 31, 2008 was \$5,074,000, primarily due to the net loss of \$6,697,000 which included the accretion of discount on short-term investments of \$782,000, offset by depreciation and stock based compensation expense of \$402,000 and \$1,618,000, respectively. Deferred revenue utilized \$545,000 of cash as a result of the amortization of previously received license fees.

We believe that our currently available cash, cash equivalents and short-term investments, will be sufficient to satisfy our operating and working capital requirements for at least the next twelve months. However, if we experience significant growth in the future, we may be required to raise additional cash through the issuance of new debt or additional equity.

Off-Balance Sheet Arrangements

As of March 31, 2008, the Company has no off-balance sheet arrangements.

Backlog

The Company's cancelable backlog at March 31, 2008 was \$4,319,000.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

All sales, domestic and foreign, are made in U.S. dollars and therefore material fluctuations in foreign currency rates are believed to have no impact on the Company's net revenues. The Company has no long-term investments or long-term debt, other than a capital lease, and therefore is not subject to interest rate risk. Management does not believe that inflation has had or will have a significant impact on the Company's results of operations. The Company is not exposed to any market risk involving activities in derivative financial instruments, other financial instruments or derivative commodity instruments.

Item 4. Controls and Procedures

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

There were no changes in the Company's internal controls over financial reporting that occurred during the three months ended March 31, 2008 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting. The Company believes that a control

Table of Contents

system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended June 30, 2007, which could materially affect our business, financial condition or future results. There have been no material changes from those risk factors. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information.

None.

Item 6. Exhibits:

- 31.1 Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

Table of Contents

ThermoGenesis Corp.

Signatures

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 thereunto duly authorized.

ThermoGenesis Corp.

(Registrant)

Dated: May 7, 2008

/s/ William R. Osgood
William R. Osgood
Chief Executive Officer
(Principal Executive Officer)

Dated: May 7, 2008

/s/ Matthew T. Plavan
Matthew T. Plavan
Chief Financial Officer
(Principal Financial Officer and Principal
Accounting Officer)

Page 21

Table of Contents

Exhibit Index

- 31.1 Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002.