INSMED INC
Form 10-Q/A
June 10, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Mark One)

x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2005

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)	54-1972729 (I.R.S. employer identification no.)
4851 Lake Brook Drive Glen Allen, Virginia 23060 (Address of principal executive offices)	(804) 565-3000 (Registrant s telephone number including area code)

Indicate by check X 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: x No ¨

Indicate by check X whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes: x No ¨

As of May 6, 2005, the latest practicable date, there were 44,987,287 shares of Insmed Incorporated common stock outstanding.

Explanatory Note:

This amendment to the Quarterly Report on Form 10-Q amends the Quarterly Report on Form 10-Q of Insmed Incorporated (the Company) for the period ended March 31, 2005, filed with the Securities and Exchange Commission on May 10, 2005, solely to amend the disclosure provided in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations. Except for the forgoing amended disclosures, the information in this Form 10-Q/A has not been updated to reflect events that were not required to be disclosed in the filing which is being amended hereby.

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REPORT: FORM 10-Q

PART I. FINANCIAL INFORMATION

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PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2005	December 31, 2004
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	**$ 35,771**	$ 9,222
Restricted Cash	**285**	285
Other current assets	**100**	174
Total current assets	**36,156**	9,681
Long-term assets:		
Restricted Cash - long term	**3,118**	3,303
Deferred financing costs	**1,827**	
Property and equipment, net	**24**	27
Total assets	**$ 41,125**	$ 13,011
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 1,541**	$ 2,621
Accrued project costs	**759**	884
Payroll liabilities	**1,407**	1,183
Interest payable	**80**	
Restructuring reserve	**360**	360
Total current liabilities	**4,147**	5,048
Long-term liabilities:		
Convertible Debt	**35,000**	
Debt discount	**(16,369)**	
Net convertible debt	**18,631**	
Asset retirement obligation	**591**	443
Restructuring reserve-long-term portion	**207**	285

Total liabilities	**23,576**	5,776
Stockholders equity:		
Common stock; $.01 par value; authorized share 500,000,000; issued and outstanding shares, 44,987,287 in 2005 and 44,893,496 in 2004	**450**	449
Additional capital	**236,592**	220,515
Accumulated deficit	**(219,493)**	(213,729)
Net stockholders equity	**17,549**	7,235
Total liabilities and stockholders equity	**$ 41,125**	$ 13,011

See accompanying notes to the condensed consolidated financial statements.

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INSMED INCORPORATED

Condensed Consolidated Statements of Operations

(in thousands, except per share data - unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Revenues	**$ 57**	$ 61
Operating expenses:		
Research and development	**4,287**	3,855
General and administrative	**1,293**	1,041
Total operating expenses	**5,580**	4,896
Operating loss	(5,523)	(4,835)
Interest income	**64**	76
Interest expense	**(305)**	
Net loss	**$ (5,764)**	$ (4,759)
Basic and diluted net loss per share	**$ (0.13)**	$ (0.12)
Shares used in computing basic and diluted net loss per share	**44,986**	38,395

See accompanying notes to the condensed consolidated financial statements.

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INSMED INCORPORATED

Consolidated Statements of Cash Flows

(in thousands - unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Operating activities		
Net loss	**$ (5,764)**	$ (4,759)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	**226**	14
Changes in operating assets and liabilities:		
Other assets	**74**	(159)
Accounts payable	**(1,080)**	1,114
Accrued project costs	**(125)**	(907)
Payroll liabilities	**224**	154
Restructuring reserve	**(78)**	(76)
Asset Retirement Obligations	**148**	
Interest payable	**80**	
Net cash used in operating activities	**(6,295)**	(4,619)
Financing activities		
Proceeds from issuance of convertible debt with detachable stock warrants	**35,000**	
Proceeds from issuance of common stock	**87**	
Costs incurred in conjunction with issuance of debt	**(2,428)**	
Cash restricted to restricted letters of credit	**185**	
Net cash provided by financing activities	**32,844**	
Increase (decrease) in cash and cash equivalents	**26,549**	(4,619)
Cash and cash equivalents at beginning of period	**9,222**	29,526
Cash and cash equivalents at end of period	**$ 35,771**	$ 24,907

See accompanying notes to the condensed consolidated financial statements.

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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, 2004. 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 our product candidates, including the costs of manufacturing the product candidates, 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 we do not conduct any research and development for others.

Stock-Based Compensation

The Company recognizes 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 is 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.

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In accordance with SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS 148), the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation is as follows:

Stock Compensation Expense

(in thousands - except per share data)

	For the Three Months Ended	
	March 31, 2005	March 31, 2004
Net Loss	(5,764)	(4,759)
Net Loss Per Share (Basic and Diluted)	(0.13)	(0.12)
Stock based employee compensation cost (under APB 25)		
Pro-forma Fair value stock compensation expense	(560)	(480)
Pro-forma Net Income	(6,324)	(5,239)
Pro-forma Net Loss Per Share (Basic and Diluted)	(0.14)	(0.14)

The fair value for these awards was estimated at the date of grant using the Black-Scholes pricing method assuming a weighted average volatility of 89%, a risk-free interest rate of 4.17%, no dividends, and a weighted-average expected life of the option of 5 years.

3. Recent Accounting Pronouncements

On December 16, 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) will be adopted by Insmed Incorporated on January 1, 2006.

The full impact of the adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company

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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 consolidated financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Insmed Incorporated expects the financial impact of Statement 123(R) to closely approximate the values that have been discussed in the footnotes on Stock Based Compensation.

4. 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 third quarter of 2002, the Company recorded a restructuring charge of $2.5 million. At March 31, 2005, approximately $0.4 million and $0.2 million of these costs remain accrued in the current and long-term portions of the restructuring reserve, respectively. These balances are expected to closely approximate the remaining costs to be incurred by the Company for lease obligations. Lease termination costs are anticipated to extend through 2006.

5. Convertible Debt Financing

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to the investors approximately $35,000,000 aggregate principal amount of 5.5% convertible notes, which notes are convertible into our common stock, par value $0.01 per share, as well as warrants to purchase, in the aggregate, 14,864,883 shares of our 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. Commencing on June 1, 2005, the notes will bear interest at a rate of 5.5% per annum and is payable quarterly commencing on March 1, 2008. The holders of the notes may convert the notes into our 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 are convertible into, in the aggregate, 27,027,027 shares of our common stock. The warrants are immediately exercisable for 14,864,883 shares of our 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 us to repurchase the notes with cash payments up on the occurrence of specified events of default and repurchase events. The investors also have the right to participate in future financings undertaken by us prior to March 16, 2005, subject to certain exceptions. In connection with issuance of the notes and warrants, we entered into registration rights agreements with the investors pursuant to which we 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.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Part I. - Item 1 of this Quarterly Report and the financial statements and notes thereto in the Company s Annual Report on Form 10-K for the year ended December 31, 2004.

Overview

Insmed Incorporated is a biopharmaceutical company focused on the development and commercialization of drug products for the treatment of metabolic diseases and endocrine disorders. Currently, our development activities focus on drugs that modulate IGF-I activity in the human body. We currently have 3 lead drug candidates, recombinant human insulin-like growth factor-I bound to recombinant human insulin-like growth factor binding protein-3 (rhIGF-I/rhIGFBP-3; also known as SomatoKine®) rhIGFBP-3 and INSM-18. We are actively developing these drugs to treat indications in the metabolic and oncology fields.

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We have not been profitable and have accumulated a deficit of approximately $219 million through March 31, 2005. We expect to incur significant additional losses for at least the next several years until such time as sufficient revenues are generated to offset expenses. In general, our expenditures will increase as development of our product candidates progresses. However, there will be fluctuations from period to period caused by differences in project-related expenditure requirements at each stage of development.

Research and Development Activities

We are engaged in the research and development of proposed drug products for the treatment of metabolic diseases and endocrine disorders. Research and development expenses consist primarily of salaries and related expenses, costs to develop and manufacture products and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

Our leading drug candidate, rhIGF-I/rhIGFBP-3, or SomatoKine®, is currently in Phase III clinical trials for the treatment of severe growth disturbance due to growth hormone insensitivity syndrome (GHIS). We have filed an New Drug Application for this drug in the GHIS indication, which was accepted for review by the United States Food and Drug Administration (FDA) on a priority review basis with a User Fee Goal Date of July 3, 2005. However, there can be no assurance that the FDA will act by this date.

We expect to continue to dedicate substantially all of our research and development expenditures on SomatoKine® for the treatment of GHIS and other indications through at least 2006. Our research and development efforts for other product candidates are in their early stages and include primarily research and development regarding rhIGFBP-3 for the treatment of various cancers and INSM-18 for the treatment of various tumors. We do not track cost information on a product-by-product basis because we have determined that very limited benefits would result and the tracking efforts would be costly and time consuming.

We estimate that our research and development expenditures to complete development of SomatoKine® in this indication will be in the range of between $20 million to $23 million for the current fiscal year. These estimates are based on currently available information and are subject to numerous risks and uncertainties, many of which are outside of our control, including, in particular, the uncertainty of the results of our Phase III clinical trial, together with the review of our NDA by the FDA. Significant delays or additional expenses in the development of SomatoKine may have a material adverse affect on our financial position. These risks and uncertainties prevent us from providing a meaningful prediction regarding the period in which material net cash inflows from any of our research and development projects are expected to become available.

Results of Operations

Revenues for the three months ended March 31, 2005 were $57,000, compared with revenues of $61,000 for the equivalent period in 2004. The net loss for the three months ended March 31, 2005 was $5.8 million, or $0.13 per share which represents an increase of $1.0 million and $0.01 per share from the net loss of $4.8 million, or $0.12 per share reported for the corresponding period in 2004. Sequentially, first quarter 2005 revenues were $34,000 higher than the $23,000 reported in the fourth quarter of 2004. At March 31, 2005, cash and cash equivalents were $35.8 million, an increase of $26.6 million from December 31, 2004, as capital was raised through a convertible debt offering.

Revenues remained consistent for the first quarter of 2005 compared to the first quarter of 2004. Sequentially the $34,000 increase in revenues was due to an annual royalty which is normally received and reported in the first quarter of each year.

The $1.0 million increase in the net loss for the first quarter 2005 compared to the corresponding period in 2004 resulted from a $0.4 million increase in research and development spending, a $0.3 million increase in general and administration costs and a $0.3 million increase in interest expense.

The $0.4 million increase in research and development costs, stemmed primarily from increased regulatory costs during the first three months of 2005 in support of our lead product SomatoKine® in the Growth Hormone Insensitivity Syndrome (GHIS) indication. The $0.3 million increase in general and administrative expenditures is due to a rise in external service costs in support of our business program. The $0.3 million in interest expense resulted from $80,000 of interest payable on the convertible debt and $225,000 to cover the accretion of the debt discount and deferred offering costs for the period from March 15, 2005 when the convertible debt was issued, through to the end of the calendar quarter March 31, 2005. The debt discount, which is a non cash item, and deferred offering costs are calculated and amortized in accordance with GAAP. The combined total of $18.4 million for the debt discount and deferred offering costs is being amortized over 60 months, the term of the convertible notes.

Liquidity and Capital Resources

At March 31, 2005, our cash and cash equivalents of $35.8 million were invested in investment grade, interest-bearing securities. Our business strategy contemplates selling additional equity and entering into agreements with corporate partners to fund research and development, and provide milestone payments, license fees and equity investments to fund operations. We will

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need to raise substantial additional funds to continue development and commercialization of our products. There can be no assurance that adequate funds will be available when we need them, or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we will be required to delay, restrict or eliminate some or all of our research or development programs, dispose of assets or technology or cease operations.

Forward Looking Statements

Statements included as part of this Management s Discussion and Analysis of Financial Condition and Results of Operations, which are not historical in nature, may constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements regarding expected financial position, results of operations, cash flows, dividends, financing plans, business strategies, operating efficiencies or synergies, budgets, capital and other expenditures, competitive positions, growth opportunities for existing or proposed products or services, plans and objectives of management, demand for new pharmaceutical products, market trends in the pharmaceutical business, inflation and various economic and business trends. Such forward-looking statements are subject to numerous risks and uncertainties, including risks that product candidates may fail in the clinic or may not be successfully marketed, the Company may lack financial resources to complete development of product candidates, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends and other risks detailed from time to time in the Company s filings with the Securities and Exchange Commission. As a result of these and other risks and uncertainties, actual results may differ materially from those described in the discussion above.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at March 31, 2005, had $35.8 million invested in money market instruments and investment grade corporate debt. Such investments are subject to interest rate and credit risk. Our policy of investing in highly rated securities whose maturities at March 31, 2005 are all less than one year minimizes such risks. In addition, while a hypothetical decrease in market interest rates of 10% from March 31, 2005 levels would reduce interest income, it would not result in a loss of the principal and the decline in interest income would not be material.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Within the 90 days prior to the filing date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Chairman of the Board and Chief Executive Officer and Treasurer and Controller, of the effectiveness of the design and operation

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of the Company s disclosure controls and procedures pursuant to Rule 13a-14 under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, the Company s Chairman of the Board and Chief Executive Officer and Treasurer and Controller concluded that the Company s disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) required to be included in the Company s periodic filings with the Securities and Exchange Commission.

Changes in Internal Controls over Financial Reporting. During the period covered by this report, there have been no changes in the Company s internal controls over financial reporting or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses, that have materially affected, or are reasonably likely to materially affect, the Company s internal controls over financial reporting.

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PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On April 15, 2005, the United States District Court for the Northern District of California granted Insmed s Motion to Dismiss the First Amended Complaint filed by Tercica, Inc. and Genentech, Inc. alleging patent infringement against Insmed. The Court granted Tercica and Genentech leave to file another amended complaint within thirty days and Tercica and Genentech filed a Second Amended Complaint on April 22, 2005. On May 6, 2005, Insmed filed a Motion to Dismiss the second cause of action and to dismiss in part the third cause of action in the plaintiff s Second Amended Complaint relating to U.S. Patent No. 5,258,287 contending that Plaintiff s have failed to join all the owners of the patent as plaintiffs. Insmed has requested immediate dismissal of this particular patent on these grounds. Discovery requests have been served by the parties and a Case Management Conference, originally set for May 13, 2005 has been rescheduled by the court to June 10, 2005, the same date currently scheduled to hear Insmed s Motion to Dismiss.

The suit was originally filed by Tercica and Genentech on December 23, 2004.

Insmed cannot predict with certainty the outcome of this proceeding. We note however, that an adverse ruling could impact our ability to make, use or sell our products.

ITEM 2. CHANGES IN 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

(a) Exhibits

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31.1	Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmed Incorporated, pursuant to Securities Exchange Act Rules 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Kevin P. Tully, Chief Financial Officer, Treasurer and Controller of Insmed Incorporated, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Kevin P. Tully, Chief Financial Officer, Treasurer and Controller of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

* This certification accompanies this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of the Securities Exchange Act of 1934.

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SIGNATURE

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

INSMED INCORPORATED
(Registrant)

Date: June 10, 2005

By: /s/ Kevin P. Tully

Kevin P. Tully
Chief Financial Officer,
Treasurer and Controller