

INSMED INC  
Form 10-Q  
May 09, 2006

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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(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

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**INSMED INCORPORATED**

(Exact name of registrant as specified in its charter)

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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)

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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.

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INSMED INCORPORATED

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REPORT: FORM 10-Q

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## 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
<b>Assets</b>		
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
<b>Liabilities and stockholders equity</b>		
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	<b>54,579</b>	10,529
Total liabilities and stockholders' equity	<b>\$ 62,640</b>	\$ 22,870

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)**

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

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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, 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)

	<b>For the Three months Ended March 31, 2005</b>
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
<b>Total:</b>	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	
<b>Options outstanding at March 31</b>	<b>6,639,630</b>	<b>3.08</b>	<b>4.61</b>
<b>Exercisable at March 31, 2006</b>	<b>3,443,098</b>	<b>4.37</b>	<b>4.31</b>

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.

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## 8. Legal Proceedings

### *Infringement Claims*

Insmmed are currently defending infringement claims brought against us. On December 20, 2004, Tercica and Genentech filed a complaint against Avecia Limited and us in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court alleging infringement of EP patent No. 571,417, or the 417 patent. The 417 patent has claims directed to particular uses of a combination of IGFBP-3 and IGF-1. In the complaint, Tercica asked the court for an injunction to restrain allegedly infringing activity, for a declaration that the 417 patent is valid and infringed, for an order requiring the delivery or destruction of allegedly infringing articles and materials and for an inquiry into possible economic damages. In May 2005, Insmmed filed for summary judgment to dismiss the complaint. The Company's motion for summary judgment was denied and a trial date in this litigation has not been set.

In addition, on December 23, 2004, Genentech and Tercica sued us for infringement of U.S. Patent Nos., 5,187,151 and 6,331,414 in the United States District Court for the Northern District of California. These patents are directed to certain methods of using rhIGF-1/rhIGFBP-3 and methods of producing rhIGF-1, respectively. On February 16, 2005, Tercica filed an amended complaint, adding an infringement allegation against us with respect to U.S. Patent No. 5,528,287, or the 287 patent. The claims of the 287 patent are directed to DNA encoding BP53 (i.e. IGFBP-3) and recombinant constructs, transformed host cells and methods for using the same. Genentech and Tercica claim that the production or use of IPLEX, a complex of rhIGF-1/rhIGFBP-3, will infringe these patents. Insmmed moved to dismiss the amended complaint for lack of jurisdiction and on other grounds. At a hearing on the motion on April 15, 2005, the court granted the Company's motion and dismissed the case with leave for plaintiffs to refile the complaint. A second amended complaint was filed on April 22, 2005 by Genentech and Tercica against us that, among other things added Celtrix Pharmaceuticals, a wholly-owned subsidiary, as a defendant. Insmmed moved to dismiss the portion of the second amended complaint that relates to the 287 patent. On June 29, 2005, the Court denied the Company's motion to dismiss. On July 14, 2005, Insmmed filed the Company's answer and counterclaims, in which Insmmed denied infringement and sought a declaratory judgment that the asserted patents are not infringed, are invalid, and/or are unenforceable. The reply to the counterclaims by Genentech and Tercica was filed on August 5, 2005. On October 17, 2005, Tercica and Genentech filed a third amended complaint adding Insmmed Therapeutic Proteins, the Company's wholly-owned subsidiary, as a defendant. The answer and counterclaims in response to the third amended complaint were filed by us on October 27, 2005. Briefing on patent claim construction issues and summary judgment motions is set to be completed by May 5, 2006, with a claim construction hearing scheduled for May 19, 2006. Discovery is ongoing and a trial date is scheduled for November 2006.

On May 27, 2005, Genentech and Tercica filed a motion for preliminary injunction seeking an order barring us, until trial, from making, using or selling IPLEX with respect to its allegations of infringement of U.S. Patent Nos. 6,331,414 and 5,187,151, and requesting that Insmmed be required to share any Orphan Drug Exclusivity it obtains with Tercica. Insmmed filed an opposition to the motion for a Preliminary Injunction on June 10, 2005. On June 16, 2005, Genentech and

Tercica withdrew their motion for a preliminary injunction, but reserved the right to refile the motion for a preliminary injunction. Insmmed cannot predict whether Genentech and Tercica will seek a preliminary injunction at another time.

*Deceptive Promotional Statements and Unfair Business Practices Claims*

On December 6, 2005, Tercica filed a complaint against us in the United States District Court for the Northern District of California alleging Insmmed made deceptive promotional statements and engaged in unfair business practices related to Tercica's product, Increlex, allegedly in violation of the California Business and Professions Code and the Federal Lanham Act. Tercica amended the complaint on December 15, 2005. Tercica is requesting injunctive and monetary relief.

Although Insmmed deny any liability, no assurances can be given as to the outcome of this action. An unfavorable settlement or decision could affect the Company's ability to make, use or sell the Company's products, and would have a material adverse effect on the Company's business, financial condition and results of operations. Any liability resulting from this action may exceed the Company's financial resources. Insmmed have requested that the court dismiss the action on a number of bases, including that Tercica failed to state a claim under the Federal Lanham Act and the court lacks personal jurisdiction over us. Insmmed plan to seek attorneys' fees from Tercica if the case is successfully concluded.

Insmmed cannot predict with certainty the outcome of these proceedings. Insmmed note however, that an adverse ruling could materially and adversely impact the Company's ability to make, use or sell the Company's products.

**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, 2005.

**Overview**

Insmmed Incorporated is a biopharmaceutical company focused on the development and commercialization of drug products for the treatment of metabolic diseases and endocrine disorders. Currently, the Company's 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 IPLEX and formerly called SomatoKin®), rhIGFBP-3 and INSM-18. We are actively developing these drugs to treat indications in the metabolic and oncology fields.

We have not been profitable and have accumulated a deficit of approximately \$268 million through March 31, 2006. 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, the Company's expenditures will increase as development of the Company's 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. All of the Company's research and development expenditures, whether conducted by the Company's own staff or by external scientists on the Company's behalf and at the Company's expense, are recorded as expenses as incurred. 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.

The Company's leading product, IPLEX, was approved in December 2005 for the treatment of Severe Primary IGFD. IPLEX has also been granted Orphan Drug Designation for the treatment of Severe Primary IGFD indication and other indications. Substantially all of the Company's research and development expenditures for fiscal 2005 and 2006 have been related to IPLEX.

The Company's research and development efforts for other products 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. These products are either in preclinical stages or, Phase I and II clinical trials. All of the Company's research and development expenditures related to these early-stage products and the Company's efforts associated with IPLEX are significantly interrelated as they are all associated with drugs that modulate IGF-I activity in the human body. A significant finding in any one drug for a particular indication may provide benefits to the Company's efforts across all of these products. All of these products also share a substantial amount of the Company's common fixed costs such as salaries, facility costs, utilities and maintenance. Given the small portion of research and development expenses that are related to products other than IPLEX we have determined that very limited benefits would be obtained from implementing cost tracking systems that would be necessary to allow for cost information on a product-by-product basis.

In the near term, Insmmed intends to focus substantially all of its research and development resources on the expansion of IPLEX into other indications. The Company's plans to expand IPLEX into additional indications are expected to represent the Company's main research and development focus in 2006. The Company's thrust to develop the Company's other early-stage products will continue but we expect those efforts to account for a much smaller portion of Insmmed's research and development expenditures. These estimates are based on currently available information and, due to a number of factors, no assurance can be provided that this project will not take longer to complete or cost more than we have currently estimated.

The Company's clinical trials with respect to IPLEX are subject to numerous risks and uncertainties that are outside of the Company's control, including the possibility that necessary

regulatory approvals may not be obtained. For example, the duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

the number of patients that ultimately participate in the trial;

the duration of patient follow-up that is determined to be appropriate in view of results;

the number of clinical sites included in the trials;

the length of time required to enroll suitable patient subjects; and

the efficacy and safety profile of the product candidate.

The Company's clinical trials may also be subject to delays or rejections based on the Company's inability to enroll patients at the rate that we expect or the Company's inability to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for the Company's planned clinical trials.

Moreover, all of the Company's product candidates and particularly those that are in the preclinical or early clinical trial stage must overcome significant regulatory, technological, manufacturing and marketing challenges before they can be successfully commercialized. Some of these projects may never reach the clinical trial stage of research and development. As preclinical studies and clinical trials progress, we may determine that collaborative relationships will be necessary to help us further develop or to commercialize the Company's product candidates, but such relationships may be difficult or impossible to arrange. The Company's projects or intended projects may also be subject to change from time to time as we evaluate the Company's research and development priorities and available resources.

Any significant delays that occur or additional expenses that we incur may have a material adverse affect on the Company's financial position and require us to raise additional capital sooner or in larger amounts than is presently expected. In addition, as a result of the risks and uncertainties related to the development and approval of the Company's drug candidates and the additional uncertainties related to the Company's ability to market and sell these products once approved for commercial sale, we are unable to provide a meaningful prediction regarding the period in which material net cash inflows from any of these projects are expected to become available.

### **Results of Operations**

Revenues for the three months ended March 31, 2006 were \$54,000, compared with revenues of \$57,000 for the corresponding period in 2005. The net loss for the three months ended March 31, 2006 was \$13.4 million, or \$0.17 per share, compared to the net loss of \$5.8 million, or \$0.13 per share, reported for the corresponding period in 2005. At March 31, 2006, cash and cash equivalents were \$59.2 million, an increase of \$40.4 million from December 31, 2005, as capital was raised through the issue and sale of Insmed stock.

Revenues remained consistent for the first quarter of 2006 compared to the corresponding period of 2005.



The \$7.7 million increase in the net loss for the first quarter of 2006 as compared to the first quarter of 2005 was due to a \$2.9 million increase in research and development expense, a \$2.5 million increase in selling, general and administration expense and a \$2.5 million rise in interest expense, partially offset by a \$0.2 million increase in interest income.

The rise in research and development expenses for the three months ended March 31, 2006 as compared to the corresponding period of 2005 was mainly due to higher manufacturing expenses at the Company's production facility in Boulder, Colorado, as we added personnel and scaled up production in support of the Company's IPLEX product launch. We also incurred higher litigation expenses associated with the previously mentioned patent lawsuits. The rise in selling, general and administration expenses for the three months ended March 31, 2006 is mainly due to the initial hiring of the commercial team and associated marketing expenses in preparation for the Company's commercial launch of IPLEX in the second quarter of 2006. The increase in interest expense is due to a \$2.7 million increase in non-cash amortization of the March 2005 convertible debt discount, offset by a \$0.2 million reduction in actual cash interest payments, as the conversion of the March 2005 notes and warrants, which were exercised during the first quarter of 2006, resulted in an acceleration of the debt discount and a reduction in interest paid. The increase in interest income for the quarter resulted from the higher level of cash on hand for investment.

As of March 31, 2006, the Company had total cash and cash equivalents of \$59.2 million which represents an increase of \$40.4 million from December 31, 2005. This net increase is due to the \$52.1 million in net cash provided by financing activities during the quarter, which was partially offset by the \$11.7 million in net cash used during the quarter in support of the Company's business operations. The \$52.1 million of cash from financing activities was generated from a combination of \$43.0 million in net proceeds from the March 2006 financing, \$8.8 million from the exercise of warrants and \$0.3 million from a reduction in a restricted letter of credit.

### **Liquidity and Capital Resources**

At March 31, 2006, the Company's cash and cash equivalents of \$59.2 million were invested in investment grade, interest-bearing securities. The Company's 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 need to raise substantial additional funds to continue development and commercialization of the Company's 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 the Company's research or development programs, dispose of assets or technology or cease operations.

**Contractual Obligations**

The following table provides a summary of certain of the Company's significant contractual obligations as of March 31, 2006.

**Contractual Obligations**

(in thousands)

	Total	Payments Due by Years			
		2006	2007 - 2009	2010 - 2012	Beyond 2013
Long term debt(1)	\$ 7,005	\$ 248	\$ 6,080	\$ 677	\$
Operating lease obligations	3,145	984	1,944	217	
	\$ 10,150	\$ 1,232	\$ 8,024	\$ 894	\$

- (1) Long-term debt obligations reflect the future interest and principal payments of the Company's convertible notes outstanding as of March 31, 2006. These notes become due in quarterly installments beginning on March 8, 2008 if not converted to common shares at an earlier date.

**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, 2006, had \$59.2 million invested in money market instruments and investment grade corporate debt. Such investments are subject to interest rate and credit risk. The Company's policy of investing in highly rated securities whose maturities at March 31, 2006 are all less than one year minimizes such risks. In addition, while a hypothetical decrease in market interest rates of 10% from March 31, 2006 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.* 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 Principal Financial Officer, of the effectiveness of the design and operation 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 Principal Financial Officer 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, except as described below, in the Company's internal controls over financial reporting. Effective February 20, 2006, Kevin P. Tully was reappointed as Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer) of the Company to serve until his successor is duly designated and has qualified or until his earlier resignation or removal. Michael Duncan assumed the role of Controller and relinquished his responsibilities as principal financial officer and principal accounting officer. No other factors that could significantly affect internal 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.

**PART II**

**OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

There have been no material changes in the Company's pending legal proceedings as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

**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**

- 10.1 Underwriting Agreement, dated as of March 9, 2006, by and among Insmmed Incorporated and the Representatives on behalf of the several Underwriters (each named therein) (previously filed as Exhibit 1.1 to Insmmed Incorporated's Current Report on Form 8-K on March 10, 2006 and incorporated herein by reference).
- 31.1 Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmmed Incorporated, pursuant to Securities Exchange Act Rules 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.
- 31.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer of Insmmed Incorporated, pursuant to Securities Exchange Act Rules 13a-14(a) and amended-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.
- 32.1 Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.\*
- 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.\*

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\* This certification accompanies this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2003 and shall not be deemed filed by the Company for purposes of the Securities Exchange Act of 1934.

**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: May 09, 2006

By: /s/ Kevin P. Tully  
Kevin P. Tully  
EVP & Chief Financial Officer

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