INSMED INC
Form 10-Q
November 09, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2007

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	**54-1972729**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
8720 Stony Point Parkway	**(804) 565-3000**

Richmond, Virginia 23235
(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: x 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 x 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 x

As of November 1, 2007, the latest practicable date, there were 121,824,889 shares of Insmed Incorporated common stock outstanding.

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INSMED INCORPORATED

FORM 10-Q

For the Quarterly Period Ended September 30, 2007

PART I. FINANCIAL INFORMATION

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PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except share and per share data)

	(unaudited) September 30, 2007	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 18,913	$ 24,112
Restricted cash	492	407
Accounts receivable, net	25	241
Inventories		576
Other current assets	239	87
Total current assets	19,669	25,423
Long-term assets:		
Restricted cash long term	2,326	2,708
Investments	399	
Deferred financing costs, net	184	209
Property and equipment, net	4	8
Total long-term assets	2,913	2,925
Total assets	$ 22,582	$ 28,348
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 736	$ 7,187
Accrued project costs & other	601	1,115
Payroll liabilities	1,284	1,302
Interest payable	23	23
Deferred rent	54	54
Convertible debt	1,708	
Debt discount	(578)	
Net convertible debt	1,130	
Total current liabilities	3,828	9,681
Long-term liabilities:		
Convertible debt	3,417	5,125
Debt discount	(1,156)	(1,964)
Net long-term convertible debt	2,261	3,161

Asset retirement obligation	**2,069**	**1,626**
Total liabilities	**8,158**	**14,468**
Stockholders equity:		
Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 121,708,316 in 2007 and 101,328,118 in 2006	**1,217**	**1,013**
Additional paid-in capital	**340,773**	**323,664**
Accumulated deficit	**(327,465)**	**(310,797)**
Accumulated other comprehensive loss:		
Unrealized loss on investment	**(101)**	
Net stockholders equity	**14,424**	**13,880**
Total liabilities and stockholders equity	**$ 22,582**	**$ 28,348**

The accompanying notes are an integral part of these consolidated financial statements.

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INSMED INCORPORATED

Consolidated Statements of Operations

(in thousands, except per share data unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	**2006**	**2007**	**2006**
Sales, net	**$**	$ 202	**$ 423**	$ 210
Royalties	**28**	24	**80**	107
License income			**1,545**	
Other expanded access program income	**1,424**		**3,339**	172
Total revenues	**1,452**	226	**5,387**	489
Operating expenses:				
Cost of goods sold		631	**576**	654
Research and development	**4,602**	5,316	**14,398**	16,838
Selling, general and administrative	**973**	7,003	**7,508**	15,966
Total expenses	**5,575**	12,950	**22,482**	33,458
Operating loss	(4,123)	(12,724)	(17,095)	(32,969)
Interest income	**370**	520	**895**	1,409
Interest expense	**(159)**	(168)	**(465)**	(3,151)
Net loss	**$ (3,912)**	$ (12,372)	**$ (16,665)**	$ (34,711)
Basic and diluted net loss per share	**$ (0.03)**	$ (0.12)	**$ (0.15)**	$ (0.37)
Shares used in computing basic and diluted net loss per share	**121,708**	100,231	**112,279**	93,531

The accompanying notes are an integral part of these consolidated financial statements.

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INSMED INCORPORATED

Consolidated Statements of Cash Flows

(in thousands unaudited)

	Nine Months Ended September 30,	
	2007	**2006**
Operating activities		
Net loss	**$ (16,665)**	$ (34,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	**259**	2,897
Stock based compensation expense	**227**	681
Stock options issued for services	**39**	59
Changes in operating assets and liabilities:		
Accounts receivable	**216**	(250)
Inventory	**576**	(1,821)
Other assets	**(152)**	(56)
Accounts payable	**(6,454)**	2,816
Accrued project costs	**(514)**	(1,764)
Payroll liabilities	**(18)**	578
Deferred rent		(249)
Asset retirement obligation	**443**	444
Interest payable		(25)
Net cash used in operating activities	**(22,043)**	(31,401)
Investing activities		
Purchases of investments	**(500)**	
Purchases of property, plant and equipment		(4,503)
Net cash used in investing activities	**(500)**	(4,503)
Financing activities		
Proceeds from issuance of common stock		
Public offering	**18,230**	43,240
Issuance costs	**(1,266)**	(421)
Warrants converted into shares		8,810
Other	**83**	141
Total proceeds from issuance of common stock	**17,047**	51,770
Changes in cash restricted to restricted letters of credit	**297**	288
Net cash provided by financing activities	**17,344**	52,058
(Decrease) Increase in cash and cash equivalents	**(5,199)**	16,154
Cash and cash equivalents at beginning of period	**24,112**	18,835
Cash and cash equivalents at end of period	**$ 18,913**	$ 34,989
Supplemental information		
Cash paid for interest	**$ 211**	$ 248

The accompanying notes are an integral part of these consolidated financial statements.

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Insmed Incorporated

Notes to Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) and applicable Securities and Exchange Commission regulations for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly 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 (Insmed , the Company , us we or our), for the fiscal year ended December 31, 2006. In the opinion of our management, 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.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries, Insmed Therapeutic Proteins, Insmed Pharmaceuticals, Incorporated and Celtrix Pharmaceuticals, Incorporated (Celtrix). All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

We consider investments with maturities of three months or less when purchased to be cash equivalents.

On April 14, 2004, we announced that we had acquired a lease to operate a recombinant protein manufacturing facility located in Boulder, Colorado. We intended to use the facility for the commercial manufacture of our FDA approved product, IPLEX . We provided a Letter of Credit to the landlord of the manufacturing facility in the amount of $0.5 million for prepayment of the remaining outstanding lease term of approximately one year and a Letter of Credit to

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Baxter Healthcare Corporation for $2.2 million to cover facility restoration expenses upon termination of the lease. These amounts are classified as restricted cash on the balance sheet. The accrued restoration expenses as of September 30, 2007 were $2.1 million and are recorded as an asset retirement obligation on the balance sheet. Accretion expense for the three and nine months ended September 30, 2007 totaled $0.2 million and $0.4 million, respectively, and for 2006, totaled $0.2 million, and $0.4 million, respectively.

Fair Value of Financial Instruments

We consider the recorded cost of our financial assets and liabilities, which consist primarily of cash and cash equivalents, to approximate the fair value of the respective assets and liabilities at September 30, 2007 and December 31, 2006 due to the short-term maturities of these instruments. We also hold an investment in NAPO Pharmaceuticals, Inc. (NAPO), classified as an available-for-sale security and reported at fair value. The carrying value of the convertible debt is $5.1 million which approximates fair value. This is calculated using the intrinsic value of the conversion feature.

Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement 123(R), *Share-Based Payment* (Statement 123R), a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, which superseded APB Opinion No. 25, *Accounting for Stock Issued to Employees*. Statement 123(R) addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for equity instruments of the company or liabilities that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. This statement requires that share-based transactions be accounted for using a fair-value-based method to recognize non-cash compensation expense; this expense is recognized ratably over the requisite service period, which generally equals the vesting period of options, and is adjusted for expected forfeitures. We adopted this standard at the beginning of 2006 using the modified prospective method.

Revenue Recognition

We record revenue from product sales when the goods are delivered and title passes to the customer. At the time of sale, estimates for sales deductions, including rebates to government agencies, are recorded. These provisions are provided for in the same period the related product sales are recorded. Following our settlement agreement with Tercica and Genentech on March 6, 2007, we ceased to supply IPLEX to patients and discontinued sales of IPLEX as of March 7, 2007. Revenue from the expanded access program is recognized when the drugs have been provided to program patients and collectibility is assured. License income is recognized as revenue when the milestones are achieved and payments are due.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture drug

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candidates, patent protection costs, amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. We do not have separate accounting policies for internal or external research and development and we do not conduct any research and development for others. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with third party organizations that conduct and manage clinical trials on our behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

Litigation costs, as they relate to our patents, were recorded as research and development expenditures through March 31, 2006. From April 1, 2006 through March 6, 2007 we shifted from research and development operations to commercial operations and litigation costs were recorded as selling, general and administrative expenses. We are currently focused on research and development operations and, beginning March 7, 2007 our litigation expenses are expensed as research and development expenses.

Comprehensive Loss

Comprehensive loss is net loss plus certain other items that are recorded directly to stockholders equity. Total comprehensive loss for the three and nine months ended September 30, 2007 was $3.9 million and $16.7 million respectively.