INSMED INC
Form 10-Q
November 09, 2007
Table of Contents

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.

Table of Contents

INSMED INCORPORATED

FORM 10-Q

For the Quarterly Period Ended September 30, 2007

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Income Taxes

Income taxes are accounted for in accordance with FASB Statement No. 109, *Accounting for Income Taxes* (FASB 109). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect a change in tax rates has on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

Net Loss Per Share

Basic net loss per share is computed based upon the weighted average number of common shares outstanding during the year. Our diluted net loss per share is the same as our basic net loss per share because all stock options, warrants, and other potentially dilutive securities are antidilutive and, therefore, excluded from the calculation of diluted net loss per share.

3. Recent Accounting Pronouncements

In June 2006, FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income*

Table of Contents

Taxes (FIN 48). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB 109. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on disclosure requirements, measurement and classification provisions, and transition requirements. We implemented FIN 48 on January 1, 2007 and due to the accumulated loss position of the Company, such implementation did not have a material impact on our financial statements.

In September 2006, FASB issued FASB Statement No. 157, *Fair Value Measurements* (FASB 157), which establishes a common definition for fair value under U.S. generally accepted accounting principles and creates a framework for measuring fair value. FASB believes that the new standard will make the measurement of fair value more consistent and comparable and improve disclosures about those measures. FASB 157 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the requirements and future impact of FASB 157 on our financial statements.

4. Equity Compensation Plan Information

As of September 30, 2007, we had two equity compensation plans under which we were granting stock options and shares of non-vested stock. We are currently granting stock-based awards from our Amended and Restated 2000 Stock Incentive Plan (the 2000 Plan) and our Amended and Restated 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 Board).

The 2000 Plan was originally adopted by the Board and approved by our shareholders in 2000. Its original ten-year term was extended to March 15, 2015 when the plan was last amended. Under the terms of the 2000 Plan, we are authorized to grant a variety of incentive awards based on our 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 ESPP was adopted by the Board on April 5, 2000 and approved by our shareholders on the same date. It was amended by the Board to increase the number of shares available for issuance, and such amendment was approved by our shareholders on May 11, 2005. The 2000 ESPP was subsequently amended and restated by action of the Board on October 4, 2006 and the amendment and restatement was approved by our shareholders on December 14, 2006. Under the terms of the 2000 ESPP, eligible employees have the opportunity to purchase our common stock through stock options granted to them. An option gives its holder the right to purchase shares of our common stock, up to a maximum value of $25,000 per year. The 2000 ESPP provides for the issuance of a maximum of 1,500,000 shares of our common stock to participating employees.

Table of Contents

The following table presents information as of September 30, 2007, with respect to the 2000 Plan and the 2000 ESPP.

	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)
Plan Category (1)			
Equity Compensation Plans Approved by Shareholders:			
Amended and Restated 2000 Stock Incentive Plan (3)	5,248,083	$ 2.32	3,176,261(2)
Amended and Restated 2000 Employee Stock Purchase Plan			794,501
Total:	5,248,083	$ 2.32	3,970,762(3)

(1) We do not have any equity compensation plans that have not been approved by our 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 2000 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 2000 Plan.

A summary of the status of our stock options as of September 30, 2007, and changes for the nine months then ended is presented below:

Description	2007	Average Exercise Price	Average Remaining Contractual Life in Years
Options outstanding at January 1, 2007	6,563,932	$ 3.04	
Granted	477,500	0.76	
Exercised	(18,000)	0.78	
Cancelled	(1,775,349)	2.50	
Options outstanding at September 30, 2007	5,248,083	2.32	3.68
Exercisable at September 30, 2007	3,511,225	$ 2.79	3.56

Table of Contents

The fair value of the options granted during the nine months ended September 30, 2007, and 2006, was estimated at the date of grant using a Black-Scholes-Merton option-pricing model with the weighted average assumptions described below:

	For the Nine Months Ended September 30,	
Assumptions	**2007**	**2006**
Volatility factors of expected market price of stock	**91%**	**113%**
Risk-free interest rate	**4.65%**	**4.4%**
Dividend yield	**0**	**0**
Expected option term (in years)	**3.47**	**2.59**
Forfeitures	**32%**	**27%**

5. Convertible Debt Financings

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to such investors certain 5.5% convertible notes in the aggregate principal amount of $35,000,000, which convert into a certain number of shares of our common stock (the 2005 Notes) as well as warrants to purchase, in the aggregate, approximately 14,864,883 shares of our common stock, at an exercise price of $1.36 per share (the 2005 Warrants).

At present, there remains $5,125,000 of the original $35,000,000 principal amount which has not been converted into shares. Should the remainder of the 2005 Notes remain unconverted, they will mature and be payable in nine quarterly installments of approximately $570,000 each quarter commencing on March 1, 2008. As of June 1, 2005, the holders of the 2005 Notes began to receive interest payments at a rate of 5.5% per annum, and such interest payments are payable quarterly until March 1, 2010. Any outstanding 2005 Notes must be repaid in cash or converted into shares of our common stock by March 1, 2010. Subject to the terms of the purchase agreements, the holders of the 2005 Notes may convert such notes into shares of 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 2005 Notes were initially convertible into, in the aggregate, 27,027,027 shares of our common stock. The holders of the 2005 Notes have the right to require us to repurchase such notes with cash payments upon the occurrence of specified events of default and repurchase events described in the 2005 Notes. The 2005 Warrants were initially exercisable in the aggregate for 14,864,883 shares of common stock at an exercise price of $1.36 per share. The 2005 Warrants will expire on March 15, 2010.

In connection with the issuance of the 2005 Notes and 2005 Warrants, we entered into registration rights agreements with the purchasers thereof pursuant to which we agreed to file a registration statement under the Securities Act of 1933, registering for resale the shares of our common stock issuable upon the conversion of the 2005 Notes or exercise of the 2005 Warrants. Between April 1, 2005 and September 30, 2007, we received notices from certain holders of the 2005 Notes electing to voluntarily convert approximately $29,875,000 principal amount of such notes into approximately 23,069,498 shares of common stock at the conversion rate of one share of common stock for each $1.295 in principal amount of the 2005 Notes. Following such conversions and as of September 30, 2007, $5,125,000 principal amount of the 2005 Notes remained outstanding.

Table of Contents

See Subsequent Events, Note 9 for additional conversions after September 30, 2007.

As of September 30, 2007, there were 21,116,587 shares reserved for issuance for all outstanding notes, warrants and options.

6. Public Stock Offering

On May 4, 2007, we sold 20,255,367 shares of our common stock and warrants to purchase up to 2,025,536 shares of our common stock. The price to the investors was $0.90 per unit, which was comprised of one share of our common stock and a warrant to purchase 0.1 shares of our common stock. The units were not issued or certificated and the shares of common stock and warrants were immediately separable and issued separately. The warrants may be exercised between November 3, 2007 and May 3, 2012 and have an exercise price of $1.10 per share. The offering was made pursuant to our effective shelf registration statement on Form S-3 (Registration No. 333-131535) previously filed with the Securities and Exchange Commission. Net proceeds from this offering were $17.0 million.

7. Legal Proceedings

In December 2004, Tercica and Genentech filed patent infringement suits against us in the United States District Court for the Northern District of California and in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court. In these cases, Tercica and Genentech alleged that production and use of IPLEX willfully infringed claims in certain United States and European Patents, owned by Genentech and Tercica, directed to methods of using rhIGF-I/rhIGFBP-3 and methods of producing rhIGF-1and IGFBP-3. In June 2006, Tercica also filed an unfair competition suit against us in the United States District Court for the Eastern District of Virginia, claiming that we disseminated misleading statements to the market in connection with our marketing of IPLEX.

On December 6, 2006, a jury in the United States District Court for the Northern District of California found that we infringed patents held by Tercica and Genentech and awarded damages of $7.5 million as an upfront payment and a royalty of 15% on sales of IPLEX below $100 million and 20% on sales above $100 million.

On March 6, 2007, we reached a settlement agreement ending all litigation with Tercica and Genentech. Pursuant to the settlement agreement, we agreed to cease sales and marketing of IPLEX in the United States and agreed to withdraw our European Marketing Authorization Application for IPLEX. We continue to provide IPLEX to named patients with Amyotrophic Lateral Sclerosis (ALS) in Italy under our Expanded Access Program. The settlement agreement also gives us the right, through a worldwide development partnership with Tercica and Genentech, to market IPLEX for conditions not related to short stature. These indications include severe insulin resistance, myotonic muscular dystrophy (MMD) and HIV-associated

Table of Contents

adipose redistribution syndrome (HARS), among others. The development partnership includes provisions that give us a 50% share of profits and reimbursement for 50% of development costs if either Tercica or Genentech exercises opt-in rights for marketing of IPLEX in any of these new indications that we develop. In addition, as part of the settlement agreement, Tercica and Genentech waived the damages awarded by the jury in the patent infringement suit from the District Court for the Northern District of California.

8. Restructuring Plan

On February 21, 2007, our Board committed to a business restructuring plan following our announcement of the Settlement Agreement with Tercica, Inc. and Genentech, Inc., which laid out the terms for settlement of all of the outstanding litigation between the parties and includes our agreement to withdraw IPLEX from the short stature market. The restructuring eliminated our commercial department and downsized our manufacturing facility located in Boulder, Colorado, resulting in an immediate reduction of approximately 34% of our previous workforce of 150. Employees who were affected by the restructuring were provided with severance payments.

As a result of the restructuring plan, we incurred a one-time restructuring charge in March 2007 of approximately $1.7 million for severance payments. The $1.7 million represented the total amount of restructuring charges that were incurred. These charges were recorded as research and development expenses and selling, general and administrative expenses in the income statement and the remaining payouts of approximately $78,000 are classified as payroll liabilities on the balance sheet.

9. Subsequent Events

On October 12, 2007 we received notices from holders of our 5.5% Convertible Notes due 2008 2010 electing to voluntarily convert $150,000 principal amount of the notes into 115,830 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, $4,975,000 principal amount of the Convertible Notes remained outstanding. In addition, because certain of the Convertible Notes were converted prior to the December 1, 2007 quarterly interest payment, we issued an additional 743 shares of common stock for the forfeited cash interest payment at a conversion price of $1.295.

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

Statements contained herein, including without limitation, Management s Discussion and Analysis of Financial Condition and Results of Operation, contain certain projections, estimates and other forward-looking statements. Forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995, are not historical facts and

Table of Contents

involve a number of risks and uncertainties. Words herein such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, projects, predicts, intends, potential, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Forward-looking statements include, but are not limited to: our plans to develop and market new products and the timing of these development programs; our clinical development of product candidates, clinical trials and our ability to obtain and maintain regulatory approval for our product candidates; our estimates regarding our capital requirements and our needs for additional financing; our estimates of expenses and future revenues and profitability; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract collaborators with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate collaborations, license agreements and other collaborative efforts, including those relating to the development and commercialization of our product candidates; sources of revenues and anticipated revenues, including contributions from corporate collaborations, license agreements and other collaborative efforts for the development and commercialization of products; our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly; the rate and degree of market acceptance of our product candidates; the timing and amount of reimbursement for our product candidates; the success of other competing therapies that may become available; and the manufacturing capacity for our product candidates.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed in Part II. Item 1A Risk Factors and elsewhere in this report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and related notes thereto in our Annual Report on Form 10-K, for the year ended December 31, 2006.

Overview

We are a biopharmaceutical company with unique protein process development and manufacturing experience, and a proprietary protein platform aimed at niche markets that have unmet medical needs. Our development activities involve drugs that modulate IGF-1 activity in the human body. In the past, we were focused on development and commercialization of IPLEX, our once-daily IGF-1 replacement therapy, for the treatment of short-stature disorders.

Table of Contents

IPLEX is a complex of recombinant human IGF-I and its binding protein IGFBP-3 (rhIGF-I/rhIGFBP-3). IPLEX was approved by the United States Food and Drug Administration (FDA) for the treatment of short stature disorders, in December 2005 and was commercially launched in the second quarter of 2006. As a result of our recent settlement agreement with Tercica and Genentech, as discussed below, we have withdrawn IPLEX from the short-stature market.

On March 6, 2007, we reached a settlement agreement which ended all ongoing litigation with Tercica and Genentech. Pursuant to the settlement agreement, we agreed to cease sales and marketing of IPLEX in the United States and agreed to withdraw our European Marketing Authorization Application for IPLEX. We will continue to provide IPLEX to named patients with ALS in Italy under our Expanded Access Program (EAP). The settlement agreement also gives us the right, through a worldwide development partnership with Tercica and Genentech, to market IPLEX for conditions not related to short stature. These indications include MMD, HARS and retinopathy of prematurity (ROP) among others. The development partnership includes provisions that give us a 50% share of profits and reimbursement for 50% of development costs if either Tercica or Genentech exercises opt-in rights for marketing of IPLEX in any of these new indications that we develop. In addition, as part of the settlement agreement, Tercica and Genentech waived the damages awarded by the jury in the patent infringement suit from the District Court for the Northern District of California.

As a result of our settlement agreement with Tercica and Genentech, we decided to restructure our business and refocus our efforts. As part of our restructuring plan, our commercial operations unit was eliminated and production at our manufacturing facility in Boulder, Colorado, was scaled back, to reflect the reduced product requirement. In connection with this restructuring, our workforce was reduced by approximately 34%. As a result of taking IPLEX off the market, we incurred an impairment charge of $7.1 million in certain capital equipment and inventory which is reflected in our fiscal 2006 financial statements. The total cost of the severance awards granted pursuant to the restructuring plan was approximately $1.7 million, which was recorded in March 2007 and is reflected in our September 30, 2007 financial results.

We have refocused our business to pursue a dual strategy approach in order to minimize risk and, we believe, enhance our potential success in product development. Our dual strategy focuses on our continued clinical development of our FDA approved product, IPLEX as a development candidate for the treatment of metabolic and neuromuscular disorders and our follow-on biologics program. The follow-on biologics program aims to capitalize on our protein technology platform to develop generic or similar versions of an existing biologic which uses the same mechanism of action and treats the same clinical indications as the original innovator product.

We have not been profitable and have accumulated deficits of approximately $327 million through September 30, 2007. 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. Moving forward our major source of income is expected to be the cost recovery charges for our Expanded Access Program and our major expenses will be for research and development of our product candidates. In general, our expenditures may increase as development of our product candidates progresses. However, there will be fluctuations from period to period caused by differences in project costs incurred at each stage of development.

Table of Contents

Research and Development Activities

We are engaged in the research and development of potential drug products for the treatment of metabolic diseases and endocrine disorders. All of our research and development expenditures, whether conducted by our own staff or by external scientists on our behalf and at our expense, are recorded as expenses as incurred and have amounted to approximately $162 million for the time period since our inception, November 1999 through September 30, 2007. 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 research and development efforts for 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 our research and development expenditures related to these early-stage products and our 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 our efforts across all of these products. All of these products also share a substantial amount of our 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 track cost information on a product-by-product basis.

In the near term, we intend to focus substantially all of our research and development resources on the expansion of IPLEX into other indications. Our plans to expand IPLEX into additional indications are expected to represent our main research and development focus and expense in 2007. Our thrust to develop our other early-stage products will continue, but we expect those efforts to account for a much smaller portion of our research and development expenditures. These estimates are based on currently available information and we can provide no assurance that our research and development plans will not change in the future.

Our plans also include entering into arrangements, which can help us in developing our product candidates. Towards this end, on January 5, 2007, we entered into a license agreement with NAPO, whereby NAPO licensed from us the technology surrounding INSM-18, also known as Masoprocal. The license agreement gives NAPO the right to develop, manufacture and commercialize Masoprocal products for all indications relating specifically to diabetes, cardiac disease, vascular disease, metabolic disease and Syndrome X. The license agreement requires NAPO to make certain payments to us upon the achievement of certain milestones. Pursuant to the terms of the license agreement, on January 12, 2007, we received $500,000 from NAPO, which, as part of the license agreement, we immediately used to purchase 270,611 shares of NAPO common stock at the closing trading price of £0.94 ($1.85 in United States funds). Further, on April 16, 2007, we received $1,000,000 from NAPO for delivering certain clinical information to them in accordance with the terms of the license agreement. We recorded an unrealized loss on the NAPO stock as of September 30, 2007 in the amount of $101,030 due to the change in the closing trading price of £0.72 ($1.47 in United States funds).

Table of Contents

Our clinical trials with our product candidates are subject to numerous risks and uncertainties that are outside of our 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.

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

Moreover, all of our 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 product candidates 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 our product candidates, but such relationships may be difficult or impossible to arrange. Our projects or intended projects may also be subject to change from time to time as we evaluate our 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 our 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 our product candidates and the additional uncertainties related to our 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 is expected to become available.

Results of Operations

Revenues for the third quarter ended September 30, 2007 were $1.5 million, up from $226,000 for the corresponding period in 2006. The increase was mainly attributable to improvements in cost recovery from our Expanded Access Program (EAP) to treat patients with amyotrophic

Table of Contents

lateral sclerosis (ALS). This was partially offset by the revenues lost from our withdrawal of IPLEX from the short stature market pursuant to the terms of our settlement agreement with Genentech Inc. and Tercica Inc.

The net loss for the third quarter of 2007 was $3.9 million or $0.03 per share, compared with a net loss of $12.4 million or $0.12 per share in the third quarter of 2006. This improvement was attributable to a reduction in selling, general and administrative (SG&A) expenses, which fell to $1.0 million from $7.0 million, a drop in research and development (R&D) expenses to $4.6 million from $5.3 million, and the elimination of cost of goods sold.

The reduction in SG&A was due primarily to reduced litigation expenses and the elimination of commercial expenses associated with our business restructuring plan. The decrease in R&D expenses reflected a reduction in our clinical and commercial manufacturing activity and the elimination of the costs of goods sold resulted from our withdrawal of IPLEX from the short stature market.

Interest income in the third quarter of 2007 fell to $370,000 from $520,000 in the third quarter of 2006. This was due to the combination of a lower average cash balance on hand and lower interest rates during the most recent quarter. Interest expense quarter on quarter remained the same.

For the first nine months of 2007, revenues totalled $5.4 million, up from $489,000 in the first nine months of 2006. Thecorresponding period of 2006. This increase was due to improvements in the cost recovery from our EAP and the receipt of licensing income from our agreement with NAPO Pharmaceuticals, (NAPO), combined with increased sales of IPLEX during the first quarter of 2007.

The net loss for the first nine months of 2007 was $16.7 million or $0.15 per share, compared to $34.7 million or $0.37 per share for first nine months of 2006. R&D expenses dropped to $14.4 million from $16.8 million, reflecting lower litigation expenses included in R&D during the first quarter of 2006, and reduced clinical and commercial manufacturing activity. SG&A expenses fell to $7.5 million from $16.0 million, due to a combination of reduced litigation expenses and the elimination of commercial expenses which was partially offset by severance costs associated with our business restructuring plan.

Interest income for the first nine months of 2007 was $0.9 million, compared to $1.4 million for the first nine months of 2006. This decrease was mainly due to lower interest rates and a lower average cash balance for the first nine months of 2007 as compared to the same period in 2006. Interest expense for the first nine months of 2007 was $465,000, compared to $3.2 million for the first nine months of 2006. This decrease in interest expense resulted from lower amortization of the debt discount associated with our March 2005 financing, as an acceleration of the discount took place in the first quarter of 2006 due to the conversion of notes into shares of our common stock.

As of September 30, 2007, we had total cash and cash equivalents of $18.9 million which represents a decrease of $5.2 million from December 31, 2006. This decrease is due to the $22.0

Table of Contents

million in net cash used in support of our business operations and $0.5 utilized for our investment in NAPO, which was mostly offset by the May 2007 offering of which we received net proceeds of $17.0 million and $0.3 million from a reduced letter of credit.

Liquidity and Capital Resources

At September 30, 2007, our cash and cash equivalents of $18.9 million were invested in investment grade, interest-bearing securities. On May 4, 2007, we sold 20,255,367 shares of our common stock. The price to the investors was $0.90 per share. Net proceeds from the offering were $17.0 million. 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 need to raise substantial additional funds to continue development and commercialization of our product candidates. 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.

Contractual Obligations

The following table provides a summary of certain of our significant contractual obligations as of September 30, 2007:

Contractual Obligations

(in thousands)

		Payments Due by Years					
	Total	2007	2008	2009	2010	2011	2012 & Beyond
Long term debt (1)	$ 5,548	$ 71	$ 2,513	$ 2,387	$ 577	$	$
Operating lease obligations (2)	9,297	257	996	1,011	1,008	809	5,216
	$ 14,845	$ 328	$ 3,509	$ 3,398	$ 1,585	$ 809	$ 5,216

(1) Long term debt obligations reflect the future interest and principal payments of the 2005 Notes outstanding as of September 30, 2007. The 2005 Notes become due in quarterly installments beginning on March 1, 2008 if not converted to shares of our common stock at an earlier date.

(2) On June 20, 2007 we notified the landlord of our intention to exercise our option to renew our lease at 2590 Central Avenue, Boulder Co. for an additional five year term through February 28, 2013, in accordance with section 3.4 of the original lease. The option to renew was accepted by the landlord on June 27, 2007.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at September 30, 2007, had $18.9 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 September 30, 2007 are all less than one year minimizes such risks. In addition, while a hypothetical decrease in market interest rates of 10% from September 30, 2007 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. We carried out an evaluation, under the supervision and with the participation of certain members of our management team, including the Chairman of our Board and Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934. Based upon that evaluation, the Chairman of our Board and Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting management to material information required to be included in our 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 our internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Table of Contents

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information presented in Section 8 of Item 1 (Legal Proceedings) of Part 1 of this Form 10-Q is incorporated herein by reference.

In addition to the foregoing, we are not currently a defendant in any matter of litigation; however, we could be involved in litigation in the future that could arise out of the normal course of business**.**

ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. Except for the historical information in this report, the matters contained in this report include forward-looking statements that involve risks and uncertainties. The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, results of operations and financial condition.

In Item 1A (Risk Factors) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006, which was filed with the Securities and Exchange Commission on March 16, 2007, we described risk factors related to our operations. Our updated risk factors are included below in this Item 1A.

You should consider carefully the following risk factors, together with all of the other information included in this quarterly report on Form 10 Q. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

RISK RELATED TO OUR BUSINESS

We will need additional funds in the future to continue our operations, but we face uncertainties with respect to our access to capital that could materially adversely impact our business, financial condition and results of operations.

We will require substantial future capital to implement our revised business plan with a renewed focus on research and development activities. As of September 30, 2007, we had $18.9 million of cash on hand. However, our future capital requirements will depend on many factors, including factors associated with:

research and development, including, among other items, preclinical testing and clinical studies;

process development;

Table of Contents

obtaining marketing, sales and distribution capabilities;

obtaining regulatory approvals;

retaining employees and consultants;

filing and prosecuting patent applications and enforcing patent claims;

establishing strategic alliances;

manufacturing; and

potential future litigation.

We may also need to spend more money than currently expected because we may further change our drug development plans, acquire additional drugs or product candidates or we may misjudge our costs. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. There can be no assurance that our cash reserves together with any subsequent funding will satisfy our capital requirements. The failure to satisfy our capital requirements will adversely affect our business, financial condition and results of operations. Our independent registered public accounting firm has expressed their view that there are material uncertainties which cast significant doubt upon our ability to continue as a going concern. The addition of this going concern disclosure may discourage investors from purchasing our stock.

We may seek additional funding through strategic alliances, private or public sales of our securities or licensing all or a portion of our technology. Such funding may significantly dilute existing shareholders or may limit our rights to our currently developing technology. There can be no assurance, however, that we can obtain additional funding on reasonable terms, or at all. If we cannot obtain adequate funds, we may need to significantly curtail our product development programs and relinquish rights to our technologies or product candidates. This may adversely affect our business, financial condition and results of operations.

We have not completed the research and development stage of any of our product candidates. If we are unable to successfully commercialize our products, it will materially adversely affect our business, financial condition and results of operations.

Our long-term viability and growth depend on the successful commercialization of products which lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. To succeed, among other things, we must be able to:

identify potential drug product candidates;

design and conduct appropriate laboratory, preclinical and other research;

submit for and receive regulatory approval to perform clinical studies;

design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices;

select and recruit clinical investigators;

select and recruit subjects for our studies;

collect, analyze and correctly interpret the data from our studies;

submit for and receive regulatory approvals for marketing; and

Table of Contents

manufacture the drug product candidates according to current good manufacturing practices.

The development program with respect to any given potential product will take many years and thus delay our ability to generate profits. In addition, potential products that appear promising at early stages of development may fail for a number of reasons, including the possibility that the products may require significant additional testing or turn out to be unsafe, ineffective, too difficult or expensive to develop or manufacture, too difficult to administer, or unstable.

In order to conduct the development programs for our products we must, among other things, be able to successfully:

raise sufficient money and pay for product development;

attract and retain appropriate personnel; and

develop relationships with other companies to perform various development activities that we are unable to perform.

Even if we are successful in developing and obtaining approval for our product candidates, there are numerous circumstances that could prevent the successful commercialization of the products such as:

the regulatory approvals of our products are delayed or we are required to conduct further research and development of our products prior to receiving regulatory approval;

we are unable to build a sales and marketing group to successfully launch and sell our products;

we are unable to raise the additional funds needed to successfully develop and commercialize our products or acquire additional products for growth;

we are required to allocate available funds to litigation matters;

we are unable to manufacture the quantity of product needed in accordance with current good manufacturing practices to meet market demand, or at all;

our product is determined to be ineffective or unsafe following approval and is removed from the market or we are required to perform additional research and development to further prove the safety and effectiveness of the product before re-entry into the market;

competition from other products or technologies prevents or reduces market acceptance of our products;

we do not have and cannot obtain the intellectual property rights needed to manufacture or market our products without infringing on another company s patents;

we are unsuccessful in defending against patent infringement claims being brought against us our products or technologies; or

we are unable to obtain reimbursement for our product or such reimbursement may be less than is necessary to produce a reasonable profit.

Our growth strategy includes the commercialization of more than one product. We may not be able to identify and acquire complementary products, businesses or technologies and if acquired or licensed, they might not improve our business, financial condition or results of operations.

The failure to successfully acquire, develop and commercialize products will adversely affect our business, financial condition and results of operations.

Table of Contents

We have a history of operating losses and an expectation that we will generate operating losses for the foreseeable future, we may not achieve profitability for some time, if at all.

Our dual path strategy involves leveraging our unique protein process development and manufacturing experience to enter the generic biologics market, and to progress our proprietary protein platform for niche markets with unmet medical needs. We have incurred losses in each year we have been in operation and we expect to continue incurring operating losses for the foreseeable future. The process of developing and commercializing our products requires significant preclinical testing and clinical trials as well as regulatory approvals for commercialization and marketing before we were allowed to begin product sales. In addition, commercialization of our product candidates requires us to establish a sales and marketing organization and contractual relationships to enable product manufacturing and other related activities. We expect that these activities, together with our general and administrative expenses, will result in substantial operating losses for the foreseeable future. As of September 30, 2007, our accumulated deficit was $327 million and our consolidated net loss was $16.7 million through nine months ended September 30, 2007.

We currently have three lead product candidates, IPLEX, rhIGFBP-3 and INSM-18. IPLEX is currently in a Phase II clinical study for the treatment of MMD, a Phase II clinical trial for the treatment of HARS and a Phase I clinical trial for the treatment of ROP. Our second compound, rhIGFBP-3, is currently in a Phase I clinical study of breast cancer. A Phase I/II clinical trial of our third compound, INSM-18, in patients with refractory prostate cancer has recently been completed. Other clinical studies with these compounds are contemplated.

If our products fail in preclinical or clinical trials or if we cannot enroll enough patients to complete our clinical trials, such failures may adversely affect our business, financial condition and results of operations.

In order to sell our products, we must receive regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for use in each target indication. In addition, the results from preclinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. There can be no assurance that our clinical trials will demonstrate sufficient safety and effectiveness to obtain regulatory approvals for our products still in development. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late stage clinical trials even after promising results in early stage development. If our developmental products fail in preclinical or clinical trials, it will have an adverse effect on our business, financial condition and results of operations.

The completion rate of clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- investigator identification and recruitment;

Table of Contents

regulatory approvals to initiate study sites;

patient population size;

the nature of the protocol to be used in the trial;

patient proximity to clinical sites;

eligibility criteria for the study; and

competition from other companies clinical studies for the same patient population.

We believe our planned procedures for enrolling patients are appropriate; however, delays in patient enrollment would increase costs and delay ultimate commercialization and sales, if any, of our products. Such delays could materially adversely affect our business, financial condition and results of operations.

We may be required to conduct broad, long-term clinical trials to address concerns that the long-term use of one of our product candidates, IPLEX, in broader chronic indications might increase the risk of diabetic retinopathy. This may materially adversely affect our business, financial condition and results of operations.

In previously published clinical trials of rhIGF-I, concerns were raised that long-term use of rhIGF-I might lead to an increased incidence and/or severity of retinopathy, a disease of new blood vessel growth in the eye which results in loss of vision. Because IPLEX contains rhIGF-I, the FDA may require us to conduct broad, long-term clinical trials to address these concerns prior to receiving FDA approval for broad chronic indications such as diabetes. These clinical trials would be expensive and could delay our commercialization of IPLEX for these broader chronic indications. Adverse results in these trials could prevent our commercialization of IPLEX for broad chronic indications or could jeopardize existing development in other indications.

We cannot be certain that we will obtain regulatory approvals in the United States, European Union or other countries. The failure to obtain such approvals may materially adversely affect our business, financial condition and results of operations.

We are required to obtain various regulatory approvals prior to studying our products in humans and then again before we market and distribute our products. The regulatory review and approval process required to perform a clinical study in both the United States and European Union includes evaluation of preclinical studies and clinical studies, as well as the evaluation of our manufacturing process. This process is complex, lengthy, expensive, resource intensive and uncertain. Securing regulatory approval to market our products also requires the submission of extensive preclinical and clinical data, manufacturing information regarding the process and facility, scientific data characterizing our product and other supporting data to the regulatory authorities in order to establish its safety and effectiveness. This process is also complex, lengthy, expensive, resource intensive and uncertain. We have limited experience in filing and pursuing applications necessary to gain these regulatory approvals.

Table of Contents

Data submitted to the regulators is subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a product and the period required for review of any application for regulatory agency approval of a particular product. Delays in obtaining regulatory agency approvals could adversely affect the development and marketing of any drugs that we or our collaborative partners develop. Such delays could impose costly procedures on our collaborative partners or our activities, diminish any competitive advantages that our collaborative partners or we may attain and adversely affect our ability to receive royalties, any of which could materially adversely affect our business, financial condition and results of operations.

To market our products outside of the United States and European Union territories, we and our corporate partners must comply with numerous and varying regulatory requirements of other countries. The approval procedures vary among countries and can involve additional product testing and administrative review periods. The time required to obtain approval in these other territories might differ from that required to obtain FDA or European Agency for the Evaluation of Medicinal Products, or European Agency for the Evaluation of Medical Products (EMEA), approval. The regulatory approval process in these other territories includes at least all of the risks associated with obtaining FDA and EMEA approval detailed above. Approval by the FDA or the EMEA does not ensure approval by the regulatory authorities of other countries. The failure to obtain such approvals may materially adversely affect our business, financial condition and results of operations.

We may not be able to manufacture sufficient quantities of our products to meet our supply and clinical studies obligations, which may adversely affect our business, financial condition and results of operations.

We intend to manufacture IPLEX and rhIGFBP-3 bulk drug substance and perform the majority of analytical testing at our manufacturing facility in Boulder, Colorado and utilize contract manufacturers for sterile filtering, filling, finishing, labeling and some analytical testing. We intend to manufacture INSM-18 with contract manufacturers.

To meet our supply obligations and clinical demand for IPLEX and clinical demand for rhIGFBP-3, we plan to implement stepwise changes to our Boulder, Colorado manufacturing facility and manufacturing process this year. We must submit to the FDA information and data pertaining to these changes and the FDA must approve these changes before we will be allowed to use IPLEX or rhIGFBP-3 that is manufactured following implementation of these changes.

The available capacity for the manufacture and testing of recombinant proteins that comprise our product candidates is limited. A shutdown or disruption at our manufacturing facility whether due to technical, regulatory, force majeure, or other problems, resulting in an interruption in supply of these materials, could delay our development activities and adversely impact our business, financial condition and results of operations.

Table of Contents

The number of contract manufacturers with the expertise and facilities to manufacture our products is extremely limited and it would take a significant amount of time and resources to arrange for alternative manufacturers. Even if we were to find alternative manufacturers, the prices they charge may not be commercially reasonable or they may only be able to provide our products in a quantity that is less than our needs. Furthermore, if we need to change to other contract manufacturers, we would also need to transfer to these new manufacturers and validate the processes and analytical methods necessary for the production and testing of our products. Any of these factors could lead to (1) the delay or suspension of our clinical studies, regulatory submissions and regulatory approvals, or (2) higher costs of production, or (3) our failure to effectively commercialize our products.

Our manufacturing facility and the facilities of contract manufacturers must undergo inspections by the FDA and the EMEA for compliance with current good manufacturing process (cGMP) regulations. In the event these facilities do not continue to receive satisfactory cGMP inspections for the manufacture and testing of our products, we may need to fund additional modifications to our manufacturing or testing processes, conduct additional validation studies, or find alternative manufacturing and testing facilities, any of which would result in significant cost to us as well as a significant delay of up to several years in the development of our products. In addition, our manufacturing facility and the facilities of any contract manufacturer we may utilize will be subject to ongoing periodic inspection by the FDA, the EMEA and other foreign agencies for compliance with cGMP regulations and similar foreign standards. We have limited control over contract manufacturers compliance with these regulations and standards, which could limit our production of our final drug product.

If our products fail to achieve market acceptance for any reason, such failure may materially adversely affect our business, financial condition and results of operations.

There can be no assurance that any of our product candidates if approved for marketing, will achieve market acceptance. If our product candidates, once approved, do not receive market acceptance for any reason, it will adversely affect our business, financial condition and results of operations. The degree of market acceptance of any drugs we develop will depend on a number of factors, including:

- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products;
- our products potential advantages over existing and future treatment methods;
- the price of our products; and
- reimbursement policies of government and third party payers, including hospitals and insurance companies.

For example, even after we obtain regulatory approval to sell our products, physicians and healthcare payers could conclude that our products are not safe and effective and physicians could choose not to use them to treat patients. Our competitors may also develop new technologies or products which are more effective or less costly, or that seem more cost-effective than our products.

Table of Contents

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us. While we cannot predict the likelihood of any legislative or regulatory proposals, if the government or an agency adopts such proposals, they could materially adversely affect our business, financial condition and results of operations.

We are dependent upon retaining and attracting key personnel and others, the loss of which could materially adversely affect our business, financial condition and results of operations.

We depend highly on the principal members of our scientific and management staff, the loss of whose services might significantly delay or prevent the achievement of research, development or business objectives and would materially adversely affect our business, financial condition and results of operations. Our success depends, in large part, on our ability to attract and retain qualified management, scientific and medical personnel, and on our ability to develop and maintain important relationships with commercial partners, leading research institutions and key distributors. We face intense competition for such personnel and relationships. We cannot assure that we will attract and retain such persons or maintain such relationships.

We expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, manufacturing, sales, marketing and distribution will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. The failure to attract and retain such personnel or to develop such expertise could materially adversely affect our business, financial condition and results of operations.

We rely on collaborative relationships for our success. If we are unable to form these relationships it could materially adversely impact our business, financial condition and results of operations.

We currently rely and may in the future rely on a number of significant collaborative relationships for intellectual property rights, research funding, manufacturing, analytical services, preclinical development, clinical development and sales and marketing. For example, almost all of our clinical trial work is done in collaboration with academic institutions and we have licensed intellectual property to permit the development, manufacture and commercialization of our product candidates. Reliance on collaborative relationships poses a number of risks, including the following:

- we may not be able to effectively control whether our corporate partners will devote sufficient resources to our programs or products;
- disputes may arise in the future with respect to the ownership of rights to technology developed with, licensed to or licensed from corporate partners;
- disagreements with corporate partners could result in loss of intellectual property rights, delay or terminate the research, development or commercialization of product candidates or result in litigation or arbitration;

Table of Contents

contracts with our corporate partners may fail to provide sufficient protection for our intellectual property;

we may have difficulty enforcing the contracts if one of these partners fails to perform;

corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue technologies or products either on their own or in collaboration with our competitors;

corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development.; and

conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and negatively influence our relationship with existing collaborators.

Certain of our collaborators could also be or become competitors. Our collaborators could harm our product development efforts by:

developing competing products;

precluding us from entering into collaborations with their competitors;

failing to obtain regulatory approvals;

terminating their agreements with us prematurely; or

failing to devote sufficient resources to the development and commercialization of products.

Given these risks, a great deal of uncertainty exists regarding the success of our current and future collaborative efforts. Failure of these efforts could delay, impair or prevent the development and commercialization of our products and adversely affect our business, financial condition and results of operations.

Our growth strategy includes acquiring complementary businesses or technologies that may not be available or, if available and purchased or licensed, might not improve our business, financial condition or results of operations.

As part of our business strategy, we expect to pursue acquisitions and in-license new products and technologies. Nonetheless, we cannot be certain that we will identify suitable acquisitions or products or that we can make such acquisitions or enter into such license agreements on acceptable terms. If we acquire businesses, those businesses may require substantial capital, and we cannot provide assurance that such capital will be available in sufficient amounts or that financing will be available in amounts and on terms that we deem acceptable. Furthermore, the integration of acquired businesses may result in unforeseen difficulties that require a disproportionate amount of management s attention and our other resources. Finally, we cannot provide assurance that we will achieve productive synergies and efficiencies from these acquisitions.

We may not accurately predict the protection afforded by our patents and proprietary technology and if our predictions are wrong, this may materially adversely affect our business, financial condition and results of operations.

Table of Contents

Our success will depend in part on our ability to obtain patent protection for our products, prevent third parties from infringing on our patents, and refrain from infringing on the patents of others, both domestically and internationally. Our patent positions are highly uncertain, and any future patents we receive for our potential products will be subject to this uncertainty, which may adversely affect our business, financial condition and results of operations.

We intend to actively pursue patent protection for products resulting from our research and development activities that have significant potential commercial value. Nevertheless, it is possible that, in the patent application process, certain claims may be rejected or achieve such limited allowance that the value of the patents would be diminished. Further, there can be no assurance that any patents obtained will afford us adequate protection. In addition, any patents we procure may require cooperation with companies holding related patents. We may have difficulty forming a successful relationship with these other companies. Third parties may claim that we are infringing upon or have misappropriated their proprietary rights. Various third parties have obtained, and are attempting to obtain, patent protection relating to the production and use of our approved product and product candidates.

We can provide no assurance that any issued patents, or patents that may later issue to third parties, would not adversely affect our product candidates. We can provide no assurance that such patents can be avoided, invalidated or licensed. With respect to any infringement claim asserted by a third party, we can provide no assurance that we will be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. In the event of a successful claim against us for infringement or misappropriation of a third party s proprietary rights, we may be required to:

- pay damages, including up to treble damages, and the other party s attorneys fees, which may be substantial;
- cease the development, manufacture, marketing and sale of products or use of processes that infringe the proprietary rights of others;
- expend significant resources to redesign our products or our processes so that they do not infringe the proprietary rights of others, which may not be possible;
- redesign our products or processes to avoid third party proprietary rights, which may cause us to suffer significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and
- obtain one or more licenses arising out of a settlement of litigation or otherwise from third parties for the infringed proprietary rights, which may not be available to us on acceptable terms or at all.

Furthermore, litigation with any third party, even if the allegations are without merit, would likely be expensive and time-consuming and divert management s attention.

Any conclusions we may have reached regarding non-infringement and invalidity are based in part on a review of publicly available databases and other information. There may be information not available to us or otherwise not reviewed by us that might change our conclusions. Moreover, as described above, the scope and validity of patent claims are determined based on many facts and circumstances, and in a litigation, a court may reach a different conclusion on any given patent claim than the conclusions that we have reached.

Table of Contents

Moreover, we may have to undertake costly litigation to enforce any patents issued or licensed to us or to determine the scope and validity of another party s proprietary rights. We can provide no assurance that a court of competent jurisdiction would validate our issued or licensed patents. An adverse outcome in litigation or an interference or other proceeding in a court or patent office could materially adversely affect our business, financial condition and results of operations.

We operate in a highly competitive environment and if we are unable to adapt to our environment, we may be unable to compete successfully, which will materially adversely affect our business, financial condition and results of operations.

Biotechnology and related pharmaceutical technology have undergone and should continue to experience rapid and significant change. We expect that the technologies associated with biotechnology research and development will continue to develop rapidly. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any compounds, products or processes that we develop may become obsolete before we recover any expenses incurred in connection with their development. Rapid technological change could make our products obsolete, which could materially adversely affect our business, financial condition and results of operations.

We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. Specifically, we expect crucial factors will include the relative speed with which we can develop products, complete the clinical testing and regulatory approval processes and supply commercial quantities of the product to the market. We expect competition to increase as technological advances are made and commercial applications broaden. In each of our potential product areas, we face substantial competition from large pharmaceutical, biotechnology and other companies, universities and research institutions. Relative to us, most of these entities have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical studies and obtaining regulatory approvals, as well as in manufacturing and marketing pharmaceutical products. Many of our competitors may achieve product commercialization or patent protection earlier than us. Furthermore, we believe that our competitors have used, and may continue to use, litigation to gain a competitive advantage. Finally, our competitors may use different technologies or approaches to the development of products similar to the products we are seeking to develop.

Competitors could develop and gain FDA approval of products containing rhIGF-1, which could adversely affect our competitive position in all indications where we are currently developing IPLEX.

Table of Contents

rhIGF-1 manufactured by other parties may be approved for use in other indications in the United States in the future, including MMD, HARS and ROP. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by IPLEX, physicians may elect to prescribe a competitor s product containing rhIGF-1 to treat the indications for which IPLEX has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor s product containing rhIGF-1 to treat any diseases for which we have received FDA approval, even if it violates our patents and we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

If another party obtains orphan drug exclusivity for a product that is essentially the same as a product we are developing in a particular indication, we may be precluded or delayed from commercializing the product in that indication. This may materially adversely affect our business, financial condition and results of operations.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first marketing approval from the FDA for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Similar laws exist in European Union. If a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for our product for seven or more years, unless our product can be shown to be clinically superior. In addition, more than one drug may be approved by the FDA for the same orphan indication or disease as long as the drugs are different drugs. As a result, even if our product is approved and receives orphan drug exclusivity, as in the case of our drug IPLEX, the FDA can still approve different drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information. Disclosure of this information may materially adversely affect our business, financial condition and results of operations.

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information. Costly and time-consuming litigation may be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business, financial condition and results of operations.

Table of Contents

Our research, development and manufacturing activities involve the use of hazardous materials, which could expose us to damages that could materially adversely affect our business, financial condition and results of operations.

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including hazardous chemicals. We believe that our procedures for handling hazardous materials comply with federal and state regulations; however, there can be no assurance that accidental injury or contamination from these materials will not occur. We currently maintain a general liability insurance policy that has a $1.0 million per claim limit and also caps aggregate claims at $2.0 million. In addition, we have an umbrella insurance policy that covers up to $2.0 million of liability in excess of the general liability policy s $2.0 million limit. In the event of an accident, we could be held liable for damages, which would likely exceed our insurance coverage and other available financial resources. This liability would limit our ability to commercialize IPLEX and develop other products which would materially adversely affect our business, financial condition and results of operations.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. These laws and regulations may require us to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition and results of operations.

We may be subject to product liability claims if our products harm people, and we have only limited product liability insurance.

The manufacture and sale of human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. We currently have only limited product liability insurance for clinical studies and no commercial product liability insurance. We do not know if we will be able to maintain existing or obtain additional product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our products. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts. This could have a material adverse effect our business, financial condition and results of operations.

If our settlement agreement with Tercica and Genentech is terminated, the Consent order from the court would be reinstated, which would have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

As part of our March 2007 settlement agreement with Genentech and Tercica, we entered into a Consent Judgment and Permanent Injunction in the United States District Court for the Northern District of California. If our settlement agreement with Tercica and Genentech is terminated, the Consent Judgment and Permanent Injunction against us will survive termination, which would have a material adverse effect on our business, financial condition and results of operations, as we would no longer have a license to manufacture IPLEX using the present process without incurring significant penalties and royalties.

RISKS ASSOCIATED WITH OUR STOCK

Conversion of our outstanding notes and exercise of warrants and options issued by us will significantly dilute the ownership interest of existing shareholders.

As of September 30, 2007, the 2005 Notes, 2005 Warrants and the warrants we issued in May 2007, November 2004 and July 2003 were convertible into and exercisable for up to approximately 15.9 million shares of our common stock, representing approximately 13% of our then outstanding common stock.

As of September 30, 2007, our outstanding options to our employees, officers, directors and consultants were exercisable for up to 5.2 million shares of our common stock, representing approximately an additional four percent of our then outstanding common stock.

The conversion or exercise of some or all of our convertible notes, warrants and options will significantly dilute the ownership interests of existing shareholders. Any sales in the public market of the common stock issuable upon such conversion or exercise could adversely affect prevailing market prices of our common stock.

The market price of our stock has been and may continue to be highly volatile, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Our common stock is listed on the Nasdaq Global Market under the ticker symbol INSM. The market price of our stock has been and may continue to be highly volatile, and announcements by us or by third parties may have a significant impact on our stock price. These announcements may include:

- our listing status on the Nasdaq Global Market;
- results of our clinical studies and preclinical studies, or those of our corporate partners or our competitors;
- our operating results;
- developments in our relationships with corporate partners;
- developments affecting our corporate partners;
- negative regulatory action or regulatory approval with respect to our announcement or our competitors announcements of new products;
- government regulation, reimbursement changes and governmental investigation or audits related to us or to our products;

Table of Contents

developments related to our patents or other proprietary rights or those of our competitors;

changes in the position of securities analysts with respect to our stock; and

operating results below the expectations of public market analysts and investors.

In addition, the stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and biopharmaceutical companies, and which have often been unrelated to their operating performance. These broad market fluctuations may adversely affect the market price of our common stock.

In the past, when the market price of a stock has been volatile, holders of that stock have often instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Future sales by existing shareholders may lower the price of our common stock, which could result in losses to our shareholders. Future sales of substantial amounts of common stock in the public market, or the possibility of such sales occurring, could adversely affect prevailing market prices for our common stock or our future ability to raise capital through an offering of equity securities. Substantially all of our common stock is freely tradable in the public market without restriction under the Securities Act of 1933, unless these shares are held by affiliates of our company, as that term is defined in Rule 144 under the Securities Act of 1933.

We have never paid dividends on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and, therefore, we do not anticipate paying any cash dividends in the foreseeable future.

Our common stock could be delisted from the Nasdaq Global Market if our stock price continues to trade below $1.00 per share.

On June 18, 2007, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market indicating that we are not in compliance with Nasdaq Marketplace Rule 4450(a)(5) (the Minimum Bid Price Rule) because the closing bid price per share for the our common stock had been below $1.00 per share for 30 consecutive business days. In accordance with Marketplace Rule 4450(e)(2), we were provided 180 calendar days, or until December 17, 2007, to regain compliance. This notification has no effect on the listing of our common stock at this time.

To regain compliance with the Minimum Bid Price Rule, the closing bid price of our common stock must remain at $1.00 per share or more for a minimum of ten consecutive business days. If we do not regain compliance with the Minimum Bid Price Rule by December 17, 2007, we can apply to list our common stock on the Nasdaq Capital Market and Nasdaq will determine whether we meet the Nasdaq Capital Market initial listing criteria as set forth in Nasdaq Marketplace Rule 4310(c), except for the bid price requirement. If we meet the initial listing criteria, Nasdaq will notify us that we have been granted an additional 180 calendar days to come into compliance with the Minimum Bid Price Rule. If we do not meet the initial listing criteria,

Table of Contents

Nasdaq will provide us with written notification that our common stock will be delisted. At that time we would be permitted to appeal Nasdaq s determination to delist our common stock to a Nasdaq Listings Qualifications Panel.

We will seek to regain compliance with the Minimum Bid Price Rule within the 180 day cure period and are considering alternatives to address compliance with the continued listing standards of the Nasdaq Global Market.

Delisting from the Nasdaq Global Market could have an adverse effect on our business and on the trading of our common stock. If a delisting of our common stock were to occur, our common stock would trade on the OTC Bulletin Board or on the pink sheets maintained by the National Quotation Bureau, Inc. Such alternatives are generally considered to be less efficient markets, and our stock price, as well as the liquidity of our common stock, may be adversely impacted as a result.

Certain provisions of Virginia law, our articles of incorporation and our amended and restated bylaws, and our Rights Plan make a hostile takeover by a third party difficult.

Certain provisions of Virginia law and our articles of incorporation and amended and restated bylaws could hamper a third party s acquisition of, or discourage a third party from attempting to acquire control of us. The conditions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. These provisions include:

a provision allowing us to issue preferred stock with rights senior to those of the common stock without any further vote or action by the holders of the common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of the common stock. In certain circumstances, such issuance could have the effect of decreasing the market price of the common stock;

the existence of a staggered board of directors in which there are three classes of directors serving staggered three-year terms, thus expanding the time required to change the composition of a majority of directors and perhaps discouraging someone from making an acquisition proposal for us;

the amended and restated bylaws requirement that shareholders provide advance notice when nominating our directors;

the inability of shareholders to convene a shareholders meeting without the chairman of the board, the president or a majority of the board of directors first calling the meeting; and

the application of Virginia law prohibiting us from entering into a business combination with the beneficial owner of 10% or more of our outstanding voting stock for a period of three years after the 10% or greater owner first reached that level of stock ownership, unless we meet certain criteria.

Table of Contents

In addition, in May 2001, our board of directors approved the adoption of a Rights Plan under which shareholders received rights to purchase new shares of preferred stock if a person or group acquires 15% or more of our common stock. These provisions are intended to discourage acquisitions of 15% or more of our common stock without negotiations with the board. The rights trade with our common stock, unless and until they are separated upon the occurrence of certain future events. Our board of directors may redeem the rights at a price of $0.01 per right prior to the time a person acquires 15% or more of our common stock.

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

We have not made any material changes to the procedures by which our stockholders may recommend director nominees to our Nominating Committee or our Board.

ITEM 6. EXHIBITS

**10.1	Settlement, license and development agreement, dated March 6, 2007, between Insmed Incorporated, Insmed Therapeutic Protiens, Inc., Celtrix Pharmaceuticals, Tercica Inc., and Genentech, Inc.
31.1	Rule 13a-14(a)/15d-14(a) Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmed Incorporated.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Kevin P. Tully, C.G.A., Executive Vice President and Chief Financial Officer of Insmed Incorporated.
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, C.G.A., Executive Vice President and Chief Financial 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.*

** Revised confidential treatment has been requested for certain portion of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

Table of Contents

* 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.

Table of Contents

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: November 9, 2007

By: /s/ Kevin P. Tully
Kevin P. Tully, C.G.A.,
EVP & Chief Financial Officer