INSMED INC
Form 10-Q
November 09, 2009

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, 2009

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 Richmond, Virginia 23235 (Address of principal executive offices)	(804) 565-3000 (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: þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes: o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer" "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	þ	Smaller reporting company	o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes: o No þ

As of November 1, 2009, the latest practicable date, there were 130,208,099 shares of Insmed Incorporated common stock outstanding.

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INSMED INCORPORATED

FORM 10-Q
For the Quarterly Period Ended September 30, 2009

PART I. FINANCIAL INFORMATION

PART I. FINANCIAL INFORMATION

PART I
FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED
Consolidated Balance Sheets
(in thousands, except share and per share data)

	(unaudited) September 30, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$26,838	$2,397
Short-term investments	95,144	
Accounts receivable, net	319	122
Prepaid expenses	236	74
Total current assets	122,537	2,593
Long-term assets:		
Certificate of deposit	2,085	-
Restricted cash, long-term	-	2,095
Deferred financing costs, net	7	70
Total long-term assets	2,092	2,165
Total assets	$124,629	$4,758
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$581	$1,277
Accrued project costs & other	1,224	936
Payroll liabilities	421	453
Income taxes payable	625	-
Restricted stock unit liability	-	113
Interest payable	2	13
Deferred rent	103	168
Deferred revenue	231	302
Convertible debt	461	2,211
Debt discount	(64)	(596)
Net convertible debt	397	1,615
Total current liabilities	3,584	4,877
Long-term liabilities:		
Convertible debt	-	553
Debt discount	-	(66)
Net long-term convertible debt	-	487

Asset retirement obligation	-	2,217
Total liabilities	3,584	7,581
Stockholders' equity (deficit):		
Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 130,208,099 in 2009 and 122,494,010 in 2008	1,302	1,225
Additional paid-in capital	350,125	342,378
Accumulated deficit	(230,382)	(346,426)
Net stockholders' equity (deficit)	121,045	(2,823)
Total liabilities and stockholders' equity (deficit)	$124,629	$4,758

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Royalties	$21	$29	$79	$83
Grant revenue	-	1,044	544	1,044
Other expanded access program income, net	2,454	2,998	7,262	7,713
Total revenues	2,475	4,071	7,885	8,840
Operating expenses:				
Research and development	1,143	4,997	8,483	15,774
Selling, general and administrative	2,096	960	8,419	3,739
Total expenses	3,239	5,957	16,902	19,513
Operating loss	(764)	(1,886)	(9,017)	(10,673)
Investment income	682	78	817	453
Realized loss on investments	-	(54)	-	(500)
Interest expense	(68)	(301)	(730)	(983)
Gain on sale of asset, net	-	-	127,768	-
Income (loss) before taxes	(150)	(2,163)	118,838	(11,703)
Income tax expense	-	-	2,794	-
Net income (loss)	$(150)	$(2,163)	$116,044	$(11,703)
Basic net income (loss) per share	$(0.00)	$(0.02)	$0.92	$(0.10)
Shares used in computing basic net profit (loss) per share	129,442	122,314	126,072	122,070
Diluted net income (loss) per share	$(0.00)	$(0.02)	$0.92	$(0.10)
Shares used in computing diluted net profit (loss) per share	129,442	122,314	126,256	122,070

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

INSMED INCORPORATED
Consolidated Statements of Cash Flows
(in thousands - unaudited)

	Nine Months Ended September 30,	
	2009	2008
Operating activities		
Net income (loss)	$116,044	$(11,703)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	661	813
Stock based compensation expense	2,425	505
Gain on sale of asset, net	(127,768)	-
Stock options issued for services	-	140
Change in trading securities	(498)	-
Realized loss on investments	-	500
Changes in operating assets and liabilities:		
Accounts receivable	(197)	178
Other assets	(162)	126
Accounts payable	(696)	213
Accrued project costs & other	288	176
Payroll liabilities	(32)	2
Income tax liability	625	-
Deferred rent	(65)	-
Deferred income	(71)	(54)
Restricted stock unit liability	(113)	-
Asset retirement obligation	(2,217)	-
Interest payable	(11)	(8)
Net cash used in operating activities	(11,787)	(9,112)
Investing activities		
Cash received from asset sale	127,768	-
Change in certificate of deposits	10	-
Purchases of short-term investments	(94,646)	9,428
Net cash provided by investing activities	33,132	9,428
Financing activities		
Proceeds from issuance of common stock	580	-
Repayment of convertible notes	(1,016)	(1,658)
Warrants converted into shares	3,493	-
Other	39	62
Net cash provided by (used in) financing activities	3,096	(1,596)
Increase (decrease) in cash and cash equivalents	24,441	(1,280)
Cash and cash equivalents at beginning of period	2,397	3,554
Cash and cash equivalents at end of period	$26,838	$2,274

Supplemental information		
Cash paid for interest	$10	$182

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

Insmed Incorporated
Notes to Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

These 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 GAAP for complete financial statements. It is presumed that users of this interim financial information have read or have access to the audited consolidated 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, 2008. In the opinion of c management, all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation have been included. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the full year.

On February 12, 2009, we announced that we had entered into a definitive agreement with Merck & Co., Inc. ("Merck") whereby Merck, through an affiliate, would purchase all assets related to our follow-on biologics platform. On March 31, 2009, we completed the sale of these assets for an aggregate purchase price of $130 million. After fees related to the transaction, we have received proceeds to date of $127.8 million as a result of this transaction. Income taxes due on the sale will be paid by installments during the balance of the year resulting in total expected net proceeds of approximately $125 million.

As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility and acquired ownership of all the equipment in the building. In addition, upon closing of the transaction, Merck offered positions to employees of the Boulder facility. We retain our Richmond, Virginia corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program.

On July 27, 2009 we announced that effective immediately we will cease the supply of IPLEX™ to any new patients. In addition, we will not initiate further clinical trials with IPLEX™ at this time. We have determined that our limited inventory on hand must be conserved for the treatment of existing patients. Following the transfer of our Boulder, Colorado manufacturing facility to Merck, we no longer have the capability to manufacture IPLEX™, an extremely complicated drug to produce. Moreover, any agreement with a third party to undertake the manufacture of IPLEX™, if it was economically feasible and could be arranged, would not result in production of additional quantities of IPLEX™ for at least 12 to 18 months.

At present there are approximately 60 patients who currently receive IPLEX(™), 12 in the U.S. and the remainder around the rest of the world. Most of the patients receive IPLEX™ pursuant to a court-ordered Expanded Access Program (EAP) for Amyotrophic Lateral Sclerosis (ALS) in Italy. The 12 U.S. patients are being treated for ALS under single patient Investigational New Drug applications approved by the U.S. Food and Drug Administration. We believe that we have sufficient IPLEX™ inventory to supply these patients through 2010.

We intend to analyze the on-going data collected for various indications, including myotonic muscular dystrophy Retinopathy of Prematurity (ROP) and ALS, and assess the overall IPLEX™ development program, including possible IPLEX™ manufacturing options with third parties and possible future clinical trials. Initiation of the Phase II clinical trial for ALS patients in the U.S. that had been discussed with FDA earlier this year has been postponed while we perform this assessment.

We have evaluated all subsequent events through November 9, 2009, the date the financial statements were issued – no material recognized or non-recognizable subsequent events were identified.

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, Incorporated, Insmed Pharmaceuticals, Incorporated and Celtrix Pharmaceuticals, Incorporated. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP 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.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current year presentation.

Cash and Cash Equivalents and short-term investments

We consider investments with maturities of three months or less when purchased to be cash equivalents. Short-term investments are classified as trading and consist primarily of mutual funds, short-term municipal bonds and treasury securities. The cost of the specific security sold is used to compute the gain or loss on the sale of short-term investments. For the three and nine months ended September 30, 2009 investment income includes $498,000 and $498,000 respectively, of gains on trading securities still held by us.

In September 2007, upon renewal of the lease for our former manufacturing facility located in Boulder, Colorado, we provided a Letter of Credit in the amount of $2.1 million to cover facility restoration expenses upon termination of the lease. This amount was classified as restricted cash on the balance sheet. The accrued restoration expenses as of December 31, 2008 were $2.2 million and were recorded in asset retirement obligations on the balance sheet. Subsequent to the transfer of this manufacturing facility to Merck on March 31, 2009, we were no longer responsible for the restoration expenses or required to maintain this letter of credit.

Revenue Recognition

Revenue from our Expanded Access Program in Italy is recognized when the drugs have been provided to program patients and collectibility is assured. Royalties previously paid to Tercica and Genentech are net against Expanded Access Program revenue. Grant revenue is recognized once payment has been received. Shipping and handling costs charged to customers are included in revenue.

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 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 first 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 are recorded as research and development expenditures.

Income Taxes

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 on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The relevant accounting for income taxes also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. In evaluating the need for a valuation allowance, we take into account various factors, including the expected level of future taxable income and available tax planning strategies. If actual results differ from the assumptions made in the evaluation of our valuation allowance, we record a change in valuation allowance through income tax expense in the period such determination is made.

Net Income (Loss) Per Share

The following table sets forth the computation of basic and diluted (loss) earnings per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in thousands except per share data)			
Numerator:				
Net income (loss) for basic and diluted earnings per share	$(150)	$(2,163)	$116,044	$(11,703)
Denominator:				
Weighted average shares for basic earnings per share	129,442	122,314	126,072	122,070
Effect of dilutive securities:				
Convertible debt	-	-	-	-
Warrants	-	-	-	-
Stock options and restricted stock	-	-	184	-
Denominator for diluted earnings per share	129,442	122,314	126,256	122,070
Basic earnings (loss) per share	0.00	(0.02)	0.92	(0.10)
Diluted earnings (loss) per share	0.00	(0.02)	0.92	(0.10)

For the three month periods ended September 30, 2009 and 2008, and for the Nine month period ended September 30, 2008, our diluted net loss per share was the same as our basic net loss per share because all stock options, warrants, and other potentially dilutive securities were antidilutive and, therefore, excluded from the calculation of diluted net

loss per share. Also, our average stock price for the Nine month period ended September 30, 2009 was $1.04, therefore any warrant, option or convertible note that contained a strike price above this amount was excluded from diluted earnings per share.

Segment Information

We currently operate in one business segment, which is the development and commercialization of pharmaceutical products for the treatment of metabolic and endocrine diseases. We are managed and operated as one business. A single management team that reports to the Chairman of the Board comprehensively manages the entire business. We do not operate separate lines of business with respect to our products or product candidates. Accordingly, we do not have separately reportable segments.

3. Recent Accounting Pronouncements

In May 2009, the FASB issued a new standard pertaining to subsequent events which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The pronouncement provides, (a) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (b) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (c) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. We have reflected the recognition and disclosure requirements of this standard in this form 10Q.

In June 2009, the FASB issued new accounting guidance effective for financial statements issued for interim and annual periods after September 15, 2009 which identifies the FASB Accounting Standards Codification as the authoritative source of GAAP in the United States. Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative GAAP for SEC registrants. The adoption had no impact on our financial statements.

4. Equity Compensation Plan Information

As of September 30, 2009, we had two equity compensation plans under which we grant 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.

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 at the lesser of 85% of the fair market value of a share of common stock at the beginning of each offer period or 85% of the fair market value of a share of common stock on the date the purchase is made, 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.

The following table presents information as of September 30, 2009, with respect to the 2000 Plan and the 2000 ESPP.

Plan Category (1)	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Shareholders:			
Amended and Restated 2000 Stock Incentive Plan (2)	2,592,750	$ 2.30	1,957,089
Amended and Restated 2000 Employee Stock Purchase Plan	—	—	365,380
Total:	2,592,750	$ 2.30	2,322,469

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

(2) 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 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, 2009, and changes for the Nine months then ended is presented below:

Description	2009	Average Exercise Price	Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at January 1, 2009	4,282,249	$2.31		
Granted	-	-		
Exercised	(533,650)	1.09		
Cancelled	(1,155,849)	2.11		
Options outstanding at September 30, 2009	2,592,750	2.30	2.92	$67,170
Exercisable at September 30, 2009	2,367,000	$2.39	2.68	$53,710

The fair value of options granted is generally estimated at the date of grant using a Black-Scholes-Merton option-pricing model. No options were granted during the nine month period ended September 30, 2009. Stock-based compensation expense related to stock options was $78,969 and $207,475 for the three and nine months ended September 30, 2009, respectively.

Restricted Stock and Restricted Stock Units

In May 2008, under the 2000 Plan, we began granting Restricted Stock ("RS") and Restricted Stock Units ("RSU's") to eligible employees, including our executives. Each RS and RSU represents a right to receive one share of our common stock or an equivalent cash payment upon the completion of a specific period of continued service or our achievement of certain performance metrics. Shares of RS are valued at the market price of our common stock on the date of grant and RSU's are valued based on the market price on the date of settlement. RSU's are classified as liabilities, as they are settled with a cash payment for each unit vested, equal to the fair market value of our common stock on the vesting date. We recognize noncash compensation expense for the fair values of these RS and RSU's on a straight-line basis over the requisite vesting period of these awards.

Effective on the closing of the Merck transaction on March 31, 2009, all RS and RSU awards were fully vested. Due to the acceleration of the vesting schedule, the Company recognized $1.4 million in stock-based compensation expense. The weighted-average grant date fair value of RS and RSU's granted during the three months ended September 30, 2009 was $1.00. As of September 30, 2009, there were 87,720 RS awards outstanding to our Board of Directors; the remaining unrecognized stock-based compensation expense relating to these awards is $95,835 and will be recognized over the next eight months in accordance with their vesting schedule.

Below is a table of RS and RSU activity for the nine months ended September 30, 2009.

	Number of Shares	
	Restricted Stock	Restricted Stock Units
Outstanding at January 1, 2009	3,155,534	1,846,605
Granted	1,492,043	368,234
Vested	4,559,857	2,214,839
Outstanding at September 30, 2009	87,720	-

Of the restricted stock vested, 3,253,136 were awarded as shares and 1,306,721 were withheld for taxes. Of the restricted stock units vested, 2,214,839 were awarded as cash.

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").

As of September 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. As of March 1, 2008, the 2005 Notes matured and beginning on March 1, 2008, the holders of the 2005 Notes were entitled to receive nine quarterly installments of $552,778 in the aggregate each quarter. 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 2005 Note 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. Between April 1, 2005 and September 30, 2009, we received notices from certain holders of the 2005 Notes electing to voluntarily convert approximately $31,312,000 principal amount of such notes into approximately 24,185,181 shares of our 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 principal repayment as of September 30, 2009, $461,111 principal amount of the 2005 Notes remained outstanding. The holders of the 2005 Notes could elect to convert such principal into an aggregate of approximately 356,070 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. In connection with our May 2007 public stock offering, the exercise price of the 2005 Warrants was reduced to $1.21 per share and the 2005 Warrants are currently exercisable into the aggregate of 3,615,320 shares of common stock. 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, as amended, registering for resale the shares of our common stock issuable upon the conversion of the 2005 Notes or exercise of the 2005 Warrants.

During the second quarter $1.3 million of convertible notes were converted into 1 million shares. During the same period the company also received $3.5 million and issued 2.9 million shares in conjunction with warrant exercises. There were no conversions or warrant exercises in the third quarter.

As of September 30, 2009, there were 11,042,712 shares reserved for issuance for all outstanding notes, warrants and options.

6. Income Taxes

The Company is subject to U.S. federal and state income taxes. Our loss carryforwards are subject to audit in any tax year in which those losses are carried and applied, notwithstanding the year of origin. The Company’s policy is to recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company has recorded no such expense.

At December 31, 2008, the Company had net operating loss (“NOL”) carryforwards for income tax purposes of approximately $288 million, expiring in various years beginning in 2009. The deferred tax assets of approximately $119 million at December 31, 2008, arise primarily due to NOL carryforwards for income tax purposes. The Company projects that it will be able to utilize a portion of these NOL carryforwards and deferred tax assets in 2009 and has projected income tax expense for the year of $2.8 million, consisting primarily of Alternative Minimum Taxes (“AMT”) to be paid. The Company has never been audited by the Internal Revenue Service.

7. Leases

The Company leases office space in Richmond, Virginia under an operating lease agreement expiring in October 2016. The lease provides for monthly rent of approximately $30,800 with a 3% escalation per year. Upon the close of the Merck transaction on March 31, 2009 the Company relinquished its leases of the manufacturing facility and warehouse in Boulder, Colorado. The Company also leases a vehicle and office equipment. Future minimum payments on all these leases at September 30, 2009 are presented in the table below.

	Payments Due by Years (in thousands)						
	Total	Remainder of 2009	2010	2011	2012	2013	2014 & Beyond
Operating lease obligations	$3,175	$115	$428	$424	$431	$445	$1,332

8. Fair Value Measurements

We categorize financial assets and liabilities measured and reported at fair value in the financial statements on a recurring basis based upon the level of judgments associated with the inputs used to measure their fair value. Hierarchical levels, which are directly related to the amount of subjectivity associated with the inputs used to determine the fair value of financial assets and liabilities are as follows:

- Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 – Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.
- Level 3 – Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Each major category of financial assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Financial instruments in Level 1 generally include U.S. treasuries and mutual funds listed in active markets.

Assets and liabilities measured at fair value are summarized below (in thousands):

		Fair Value Measurements at Reporting Date Using	
Description	September 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)
Cash and Cash Equivalents	$26,838	$26,838	$-
U.S. Treasury securities	23,248	23,248	-
Mutual Funds	52,377	52,377	-
U.S. Government bonds	19,519	-	19,519
Total	$121,982	$102,463	$19,519

We also hold an investment in NAPO Pharmaceuticals, Inc. ("NAPO") which is currently valued at $0. During the nine months ended September 30, 2008 we recorded an other than temporary impairment of this investment of $392,000. This amount is reported as a loss on investments in our statement of operations for 2008.

Relevant accounting literature requires the disclosure of the estimated fair value of financial instruments including those financial instruments for which the fair value option was not elected. The carrying amount reported in the balance sheets for convertible debt approximates its fair value due to the short-term maturity of these instruments.

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 Operations," 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 involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potenti 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 existing supply of IPLEX™; 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, 2008.

Overview

We are a biopharmaceutical company with expertise in recombinant protein drug development. Our corporate office is located in Richmond, Virginia.

On February 12, 2009 we announced that we had entered into a definitive agreement with Merck & Co., Inc. ("Merck") whereby Merck, through an affiliate, would purchase all assets related to our follow-on biologics ("FOB") platform. On March 31, 2009, we completed the sale of these assets for an aggregate purchase price of $130 million. After fees related to the transaction, we have received to date net proceeds of $127.8 million as a result of this transaction. Income taxes due on the sale will be paid by instalment during the balance of the year resulting in total expected net proceeds of approximately $125 million.

As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility and acquired ownership of all the equipment in the building. In addition, upon closing of the transaction, Merck offered positions to employees of the Boulder facility. We retain our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program.

On July 27, 2009 we announced that effective immediately we will cease the supply of IPLEX™ to any new patients. In addition, we will not initiate further clinical trials with IPLEX™ at this time. We have determined that our limited inventory on hand must be conserved for the treatment of existing patients. Following the tranfer of our Boulder, Colorado manufacturing facility to Merck, we no longer have the capability to manufacture IPLEX™, an extremely complicated drug to produce. Moreover, any agreement with a third party to undertake the manufacture of IPLEX™, if it was economically feasible and could be arranged, would not result in production of additional quantities of IPLEX™ for at least 12 to 18 months.

At present there are approximately 70 patients who currently receive IPLEX™, 12 in the U.S. and the remainder around the rest of the world. Most of the patients receive IPLEX™ pursuant to a court-ordered Expanded Access Program (EAP) for Amyotrophic Lateral Sclerosis (ALS) in Italy. The 12 U.S. patients are being treated for ALS under single patient Investigational New Drug applications approved by the U.S. Food and Drug Administration. We believe that we have sufficient IPLEX™ inventory to supply these patients through 2010.

We intend to analyze the on-going data collected for various indications, including myotonic muscular dystrophy, ROP and ALS, and assess the overall IPLEX™ development program, including possible IPLEX™ manufacturing options with third parties and possible future clinical trials. Initiation of the Phase II clinical trial for ALS patients in the U.S. that had been discussed with FDA earlier this year has been postponed while we perform this assessment.

Until the sale of our follow-on biologics platform, we pursued a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs.

We plan to use the net proceeds from the sale of our follow-on biologics platform to continue to support the development of IPLEX™ , which is in various stages of development for a number of serious medical conditions including MMD, ALS, also known as Lou Gehrig's disease, and Retinopathy of Prematurity ("ROP") and to support our proprietary protein platform. We have also engaged the services of RBC Capital Markets to act as financial advisor in evaluating other options for use of these proceeds which could include acquisitions of complimentary businesses or technologies, product licensing or mergers, and could also include share repurchase or the distribution of a portion of the proceeds to shareholders if we do not find attractive acquisition or licensing opportunities.

We have not been profitable and have accumulated deficits of approximately $230 million through September 30, 2009. While we expect that, following the sale of our FOB assets to Merck, for the balance of 2009 we will operate on a cash neutral basis as a result of anticipated revenues on our Expanded Access Program and interest on the net proceeds of the sale of our FOB assets offsetting our ongoing base costs, we expect to incur significant additional losses for at least the next several years until such time as sufficient commercial 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 related to research and development. 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.

Research and Development Activities

Since we began operations in late 1999, we have devoted substantially all of our resources to the research and development of a number of product candidates for metabolic and endocrine diseases. Until the sale of our FOB

assets on March 31, 2009, our research and development efforts were principally focused on pursuing a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. Our focus is now principally on our proprietary protein platform. Our lead proprietary protein product, the FDA-approved IPLEX™, is being studied as a treatment for several serious medical conditions including MMD, ROP and ALS. We conduct very little of our own preclinical laboratory research. We have outsourced several Phase II clinical studies with IPLEX™ and our other anti-cancer product candidates, INSM-18 and rhIGFBP-3, and are evaluating the conduction of additional clinical studies in the future.

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 amounted to approximately $197 million for the period since inception, in November 1999, through September 30, 2009. 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.

All of our research and development expenditures related to our proprietary protein platform are 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 be necessary to allow for cost information on a product-by-product basis.

External clinical research of IPLEX™ in the MMD indication together with the development cost of the proposed IPLEX™ trial for ALS patients in the US are expected to represent our main research and development focus for 2009.

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, 2009 were $2.5 million, as compared to $4.1 million for the corresponding period in 2008. The decrease was primarily attributable to $1.0 million of grant revenue related to the IPLEX™ myotonic muscular dystrophy ("MMD") clinical trial recorded in the third quarter of 2008 and a reduction of $0.5 million in cost recovery from our IPLEX™ Expanded Access Program ("EAP") for Amyotrophic Lateral Sclerosis ('ALS") in Europe. The reduction in cost recovery from the EAP is largely due to the determination made by Insmed in the third quarter that its limited IPLEX™ inventory on hand should be conserved for the treatment of existing ALS patients.

The net loss for the third quarter of 2009 was $150,000; break even on a dollar per share basis, compared with a net loss of $2.2 million, or $0.02 per share, in the third quarter of 2008. This $2.0 million decrease was primarily attributable to a $2.7 million decrease in total expenses, a $0.6 million improvement in investment income and a $0.2 million reduction in interest expense, which was partially offset by the $1.6 million reduction in total revenues.

The $2.7 million decrease in total expenses was due primarily to a $3.8 million decrease in research and development expenses ("R&D Expenses"), which was partially offset by a $1.1 million increase in selling, general and administrative expenses ("SG&A Expenses").

The lower R&D expenses reflected the elimination of manufacturing expenses following the sale of our follow-on biologics ("FOB") assets in March 2009, while the higher SG&A expenses were principally due to external finance, legal and consulting advisory services associated with the ongoing strategic review. The improvement in investment returns resulted from the increased amount of cash available for investment, and the lower interest expense was due to the reduction of the debt discount amortization associated with our 2005 convertible notes.

For the nine months ended September 30, 2009, revenues totaled $7.9 million as compared to $8.8 million in the first nine months of 2008. Consistent with third quarter results, the decrease was primarily attributable to a year-over-year decrease of $0.5 million in grant revenue related to the IPLEX™ MMD clinical trial, and a reduction of $0.5 million in cost recovery during the most recent period from our IPLEX™ EAP in Europe.

Net income for the nine months ended September 30, 2009 was $116.0 million, or $0.92 per share, compared to a net loss of $11.7 million, or $0.10 per share, for first nine months of 2008. This $127.7 million improvement was primarily due to the $127.8 million before tax gain on sale of our FOB assets to Merck, combined with a $2.6 million decrease in total expenses, a $0.4 million improvement in investment returns, a $0.3 million reduction in interest expense and the absence of a $0.5 million loss on investments, which was offset by $2.8 million of income tax expense on the gain on sale and a $1.0 million reduction in net revenue.

The $2.6 million decrease in total expenses was due to a $7.3 million reduction in R&D expenses, which was partially offset by a $4.7 million increase in SG&A expenses.

The $7.3 million reduction in R&D expenses was due primarily to a decrease in manufacturing expenses following the sale of our FOB assets in March 2009. The $4.7 million increase in SG&A expenses was due largely to a combination of the recognition of stock compensation expense for the restricted stock and restricted stock units that vested on

March 31, 2009, and the award of bonuses, together with the increased finance, legal and consulting fees related to the ongoing strategic review; as previously mentioned. The $0.5 million reduction in investment loss was due to the write off of the NAPO investment, which occurred in 2008.

Liquidity and Capital Resources

As of September 30, 2009, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling $124.1 million, consisting of $26.8 million in cash and cash equivalents, $95.1 million of short term investments and $2.1 million in a certificate of deposit, as compared to $2.4 million of cash on hand as of December 31, 2008. The $121.7 million increase in total cash was due to the $127.8 million in before tax proceeds from the sale of Insmed's FOB assets to Merck, $4.1 million from the conversion of warrants and options into common stock and the release of a $2.1 million previously restricted certificate of deposit and $0.5 million from securities, which was partially offset by $11.8 million utilized to fund operations and $1.0 million for the partial repayment of the Company's 2005 convertible notes.

At September 30, 2009, our cash, cash equivalents and short-term investments of $122 million were invested in investment grade, interest-bearing securities. Even though we currently have sufficient funds to meet our financial needs for the upcoming year, our business strategy also contemplates raising additional capital through debt or equity sales. We may enter into agreements with corporate partners in order to fund operations through milestone payments, license fees and equity investments.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at September 30, 2009, had $122 million invested in money market instruments, treasury bills, mutual funds and municipal bonds. Such investments are subject to interest rate and credit risk. Our policy of investing in highly rated securities whose maturities at September 30, 2009 are all less than one year minimizes such risks. In addition, while a hypothetical decrease in market interest rates of 10% from September 30, 2009 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

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 principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, as of September 30, 2009, our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

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.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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, 2008, which was filed with the Securities and Exchange Commission on March 31, 2009, 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.

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.

We are a biopharmaceutical company with expertise in protein recombinant drug development. We have incurred losses each year of operation and we expect to continue incurring operating losses for the foreseeable future. The process of developing and commercializing our products requires significant pre-clinical testing and clinical trials as well as regulatory approvals for commercialization and marketing before we are allowed to begin product sales. In addition, commercialization of our drug 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 December 31, 2008, our accumulated deficit was $346 million and for the year ended December 31, 2008 our consolidated net loss was $15.7 million.

The Italian Health Authority may refuse to pay for IPLEX™ used by patients in Italy under our Expanded Access Program, which could have a material adverse effect on our business, financial condition and results of operations.

At present the Italian Health Authority approves all drug payments for IPLEX™ used by Italian patients with ALS in Italy as part of our Expanded Access Program. Should the Italian Health Authority decide to stop approving IPLEX™ for ALS it would negatively affect our cash position and prevent us from being operationally cash neutral as we are at present.

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. In order 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
- manufacture the drug product candidates according to current good manufacturing processes ("cGMP").

The development program with respect to any given 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 the development of the products
- 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.

If we fail to meet the continued listing requirements of the NASDAQ Capital Market in the future, our common stock may be delisted from the NASDAQ Capital Market which may cause the value of an investment in our common stock to substantially decrease.

We may be unable to meet the continued listing requirements of the NASDAQ Capital Market in the future. To maintain the listing of our common stock on the NASDAQ Capital Market, we are required, among other things, to maintain a daily closing bid price per share of $1.00 (the "Minimum Bid Price Requirement"). By letter dated September 15, 2009, we were notified by the NASDAQ Listing Qualification Staff (the "Staff") that the bid price for our common stock had closed below $1.00 per share for the previous 30 consecutive business days and that in accordance with NASDAQ marketplace rules, we have been granted a 180-calendar day period, or through March 15, 2010, to regain compliance with the Minimum Bid Price Requirement. If we fail to meet the Minimum Bid Price Requirement by March 15, 2010, our common stock may be delisted from the NASDAQ Capital Market. If a delisting from the NASDAQ Capital Market were to occur, our Common Stock would be eligible, upon the application of a market maker, to trade on the OTC Bulletin Board or in the "pink sheets." These alternative markets are generally considered to be less efficient than, and not as broad as, the NASDAQ Capital Market or the NASDAQ Global Market. Therefore, delisting of our common stock from the NASDAQ Capital Market could adversely affect the trading price of our common stock and could limit the liquidity of our common stock and therefore could cause the value of an investment in our common stock to decrease. In addition, if we fail to meet the Minimum Bid Price Requirement by March 15, 2010 we may be required to implement a reverse stock split in order for our shares of common stock to remain listed on the NASDAQ Capital Market, which could have a material adverse affect on our stock price.

If our products fail in pre-clinical or clinical trials or if we cannot enroll enough patients to complete our clinical trials, such failure 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 pre-clinical studies and clinical trials that the product is safe and effective for use in each target indication. In addition, the results from pre-clinical 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 pre-clinical 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;
- 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 leading products, 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-1, concerns were raised that long-term use of rhIGF-1 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.

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.

In order to market our products outside of the United States and European Union, our corporate partners and we 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 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 have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations and our business, financial condition and results of operation may be adversely affected.

The transfer of the Boulder facility to Merck takes away our internal IPLEX™ production capability. We have announced that we will cease the supply of IPLEX™ to any new patients and not initiate further clinical trials with IPLEX™ at this time. We believe we have sufficient IPLEX™ inventory to supply existing patients through 2010, although this inventory may be used more quickly than expected. While we plan to assess possible IPLEX™ manufacturing options with third parties, we may decide not to pursue a third party manufacturing arrangement for IPLEX™. If we decide to pursue such a manufacturing arrangement, we may not find a manufacturer willing to produce IPLEX™ or may not be able to negotiate acceptable terms. Any agreement with a third party to undertake the manufacture of IPLEX™ would not result in production of additional quantities of IPLEX™ for at least 12 to 18 months and could take longer.

We also intend to manufacture rhIGFBP-3 clinical drug substance and INSM-18 with contract manufacturers. In addition, we intend to utilize contract manufacturers for sterile filtering, filling, finishing, labeling and analytical testing.

The number of contract manufacturers with the expertise and facilities to manufacture our products is 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 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.

The facilities of contract manufacturers must undergo inspections by the FDA and the EMEA for compliance with 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, 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 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.

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 products. 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;
    - contracts with our corporate partners may fail to provide sufficient protection of 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; and
    - 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.

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 assure you 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 intend to conduct proprietary development programs with collaborators, and any conflicts with them could harm our business, financial condition and results of operations. We intend to enter into collaborative relationships which will involve our collaborators conducting proprietary development programs. Any conflict with our collaborators could reduce our ability to obtain future collaboration agreements and negatively influence our relationship with existing collaborators, which could reduce our revenues and have an adverse effect on our business, financial condition and results of operations. Moreover, disagreements with our collaborators could develop over rights to our intellectual property.

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.

We may 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 may require additional future capital in order to acquire complementary businesses or technology or continue our research and development activities. On March 31, 2009, we completed the sale of our FOB assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $125 million as a result of this transaction. 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;
- 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 or alter drug development plans, acquire additional drugs or drug 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.

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 drug candidates. This may adversely affect our business, financial condition and results of operations.

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.

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 may 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 give no assurances as to whether any issued patents, or patents that may later issue to third parties, would affect commercialization of IPLEX™ or any other product. We can give no assurances that such patents can be avoided, invalidated or licensed. With respect to any infringement claim asserted by a third party, we can give no assurances 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, we may suffer significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; or
- 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.

In addition, 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 give no assurances 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™.

rhIGF-1 manufactured by other parties may be approved for use in other indications in the United States in the future, including MMD ROP and ALS. 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 EU. 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 could 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.

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

Our research, development and manufacturing activities at our former Boulder Facility involved the controlled use of hazardous materials, including hazardous chemicals and radioactive materials. Under the terms and conditions of our agreement with Merck for the sale of our FOB assets, we retained our obligations and liabilities under any environmental law relating to activities conducted before March 31, 2009 but which arise at any time during the two-year period beginning on March 31, 2009. If any such obligation or liability arises, we could be subject to an obligation to indemnify Merck for any losses incurred by Merck which could materially adversely affect our results of operations and financial condition.

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 our products. 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 was 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.

As part of our 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.

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, 2009, the convertible notes issued by us in March 2005 and the warrants issued by us in May 2007, March 2005 and November 2004 were convertible into and exercisable for up to approximately 8.1 million shares of our common stock, representing approximately seven percent of our then outstanding common stock.

As of September 30, 2009, our outstanding options and stock grants to our employees, officers, directors and consultants were exercisable for up to 2.6 million shares of our common stock, representing approximately an additional three 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 historically, we have never paid dividends on our common stock.

Our common stock is listed on the NASDAQ Capital 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 Capital 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;
- 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, unless these shares are held by "affiliates" of our company, as that term is defined in Rule 144 under the Securities Act.

Historically we have never paid dividends on our common stock and 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 from earnings in the foreseeable future. We are currently reviewing options for the use of the proceeds from the sale of our FOB assets to Merck. One of these options may include a special dividend to common shareholders.

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.

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

Not applicable.

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 of the Board or our Board.

ITEM 6. EXHIBITS

31.1 Rule 13a-14(a)/15d-14(a) Certification of Kevin P. Tully, C.G.A., Executive Vice President and Chief Financial Officer (principal executive officer and principal financial officer) of Insmed Incorporated.

32.1 Certification of Kevin P. Tully, C.G.A., Executive Vice President and Chief Financial Officer (principal executive officer and principal 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.*

* 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.

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, 2009

By:/s/ Kevin P. Tully
Kevin P. Tully, C.G.A.,
Executive Vice President and Chief Financial Officer (Duly Authorized Officer)