INSMED INC
Form 10-Q
November 03, 2010

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, 2010

OR

[_] TRANSITION REPORT PURSUANT TO
SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

INSMED INCORPORATED
(Exact Name of Registrant as Specified in Its Charter)

Virginia
(State or Other Jurisdiction of Incorporation)

0-30739	54-1972729
(Commission File Number)	(IRS Employer Identification No.)
8720 Stony Point Parkway, Suite 200, Richmond, Virginia	23235
(Address of Principal Executive Offices)	(Zip Code)

(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	þ
Non-accelerated filer	o	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, 2010, the latest practicable date, there were [130,345,819] shares of Insmed Incorporated common stock outstanding.

INSMED INCORPORATED

FORM 10-Q
For the Quarterly Period Ended September 30, 2010

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

PART I
FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$9,687	$12,740
Short-term investments	114,605	109,441
Income tax receivable	59	2,023
Accounts receivable, net	178	245
Prepaid expenses	364	159
Total current assets	124,893	124,608
Long-term assets:		
Certificate of deposit	2,085	2,085
Deferred financing costs, net	-	2
Total long-term assets	2,085	2,087
Total assets	$126,978	$126,695
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$431	$312
Accrued project costs & other	1,150	1,150
Payroll liabilities	481	580
Interest payable	-	1
Deferred rent	132	132
Deferred revenue	98	398
Convertible debt	-	231
Debt discount	-	(23)
Net convertible debt	-	208
Total liabilities	2,292	2,781
Stockholders' equity:		
Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 130,345,819 in 2010 and 130,208,099 in 2009	1,303	1,302
Additional paid-in capital	350,458	350,243

Accumulated deficit	(228,666)	(228,076)
Accumulated other comprehensive income:		
Unrealized gain on investment	1,591	445
Net stockholders' equity	124,686	123,914
Total liabilities and stockholders' equity	$126,978	$126,695

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Royalties	$1	$21	$3	$79
Grant revenue	-	-	-	544
Other expanded access program income, net	1,806	2,454	5,597	7,262
Total revenues	1,807	2,475	5,600	7,885
Operating expenses:				
Research and development	769	1,143	2,304	8,483
Selling, general and administrative	1,636	2,096	5,058	8,419
Total expenses	2,405	3,239	7,362	16,902
Operating loss	(598)	(764)	(1,762)	(9,017)
Investment income	345	682	1,280	817
Interest expense	-	(68)	(28)	(730)
Gain on sale of asset, net	-	-	-	127,768
Income (loss) before taxes	(253)	(150)	(510)	118,838
Income tax expense	77	-	80	2,794
Net (loss) income	$(330)	$(150)	$(590)	$116,044
Basic net (loss) income per share	$(0.00)	$(0.00)	$(0.00)	$0.92
Shares used in computing basic net (loss) income per share	130,301	129,442	130,253	126,072
Diluted net (loss) income per share	$(0.00)	$(0.00)	$(0.00)	$0.92
Shares used in computing diluted net (loss) income per share	130,301	129,442	130,253	126,256

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

INSMED INCORPORATED
Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2010	2009
Operating activities		
Net income	$(590)	$116,044
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	25	661
Stock based compensation expense	215	2,425
Gain on sale of asset, net	-	(127,768)
Change in trading securities	-	(498)
Realized loss on investments	-	-
Changes in operating assets and liabilities:		
Accounts receivable	67	(197)
Income tax receivable	1,964	-
Prepaid expenses	(205)	(162)
Accounts payable	119	(696)
Accrued project costs & other	-	288
Payroll liabilities	(99)	(32)
Income tax liability	-	625
Deferred rent	-	(65)
Deferred revenue	(300)	(71)
Restricted stock unit liability	-	(113)
Asset retirement obligation	-	(2,217)
Interest payable	(1)	(11)
Net cash provided by (used in) operating activities	1,195	(11,787)
Investing activities		
Cash received from asset sale	-	127,768
Sales of short-term investments	90,739	-
Purchases of short-term investments	(94,757)	(94,646)
Net cash provided by (used in) investing activities	(4,018)	33,122
Financing activities		
Proceeds from issuance of common stock	-	580
Repayment of convertible notes	(231)	(1,016)
Certificate of deposits	-	10
Warrants converted into shares	-	3,493
Other	1	39
Net cash provided by (used in) financing activities	(230)	3,106
Increase (decrease) in cash and cash equivalents	(3,053)	24,441
Cash and cash equivalents at beginning of period	12,740	2,397

Cash and cash equivalents at end of period	$9,687	$26,838
Supplemental information		
Cash paid for interest	$-	$10
Cash paid for taxes	139	-

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

Insmed Incorporated
Notes to Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation, Current Development and Liquidity

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, 2009. 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.

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

On March 31, 2009, we completed the sale of our follow-on biologics ("FOB") platform to Merck & Co., Inc. ("Merck") for an aggregate purchase price of $130 million. As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility (which was also used to manufacture IPLEX™) and acquired ownership of all the equipment in the building. In addition, Merck offered positions to employees at the Boulder facility. After fees, taxes and other expenses related to the transaction, we received total net proceeds of approximately $127 million. In the fourth quarter of 2009 we recorded a $2 million tax refund receivable which increased the after tax proceeds on the sale from $125 million, as reported in the first quarter of 2009, to the $127 million reported in our full year results. The $2.0 million reduction in taxes results from the beneficial impact of revised tax laws, which came into effect in the fourth quarter of 2009, and allowed the Company to utilize more of its net operating losses ("NOLs") than previously able under former tax law to reduce the amount of taxes paid on the gain on sale of its FOB business to Merck in March 2009. The Company received the full tax refund in April 2010. We retained our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program.

Until the sale of our FOB 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. Following the sale of our FOB assets, we engaged the services of RBC Capital Markets to act as financial advisor in evaluating other options for use of these proceeds from the sale of our FOB business to Merck, which we refer to as our strategic review process. These options could include acquisitions of complementary 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. In parallel, we also intend to continue to focus on our proprietary protein platform and our product, the U.S. Food and Drug Administration ("FDA") approved IPLEX™, which is in various stages of development for a number of serious medical conditions. Based on a comprehensive market analysis, our current resource allocation strategy for IPLEX™ is focused on Amyotrophic Lateral Sclerosis ("ALS"), also known as Lou Gehrig's disease, and Retinopathy of Prematurity ("ROP"), the latter under a Material Transfer Agreement with Premacure AB, a Swedish corporation.

On June 15, 2009, we announced that Geoffrey Allan, Ph.D., resigned as our President, Chief Executive Officer and Chairman of the Board due to a health condition. Dr. Allan had held these positions since our Company was formed in 1999. Mel Sharoky, M.D., one of our directors, assumed the role of Chairman of the Board. Pending the completion of the strategic review process, we have decided not to hire a new President and Chief Executive Officer.

In June 2009, we announced results from our exploratory U.S. Phase II clinical trial evaluating IPLEX™ in patients with myotonic muscular dystrophy ("MMD"). The trial explored measures of endurance, muscle function and strength, cognitive function, gastrointestinal function, general health, pain, quality of life, insulin sensitivity, lipid metabolism, and safety and tolerability of IPLEX™. The results of the trial indicated that IPLEX™ did not exhibit a statistically significant improvement in the functional measure of endurance by the nine-minute walk test, muscle function, strength, cognitive function, general health, pain, or quality of life in any of the tests utilized in this study. IPLEX™ did, however, demonstrate improvements in standard measures of insulin sensitivity and reductions in fasting glucose, fasting insulin, cholesterol and triglycerides, which is consistent with the expected metabolic profile of insulin-like growth factor. Pending the completion of the strategic review process, we have decided not to conduct further clinical trials focused on MMD patients.

Following the transfer of our Boulder, Colorado manufacturing facility to Merck, we no longer have the capability to manufacture IPLEX™, which is an extremely complicated drug to produce. 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. We are not actively exploring any third party manufacturing arrangements for IPLEX™ at this time. Since we no longer have a facility to manufacture IPLEX™, we announced in July 2009 that we would conserve our limited inventory of IPLEX™ on hand for the treatment of existing patients, would cease the supply of IPLEX™ to any new patients, and would not initiate further clinical trials with IPLEX™ (including a Phase II clinical trial for ALS patients in the U.S. discussed with the FDA in early 2009). We plan, however, to continue to collect and analyze data for the ALS indication and to continue to monitor Premacure AB's collection and analysis of data for the ROP indication.

There are approximately 39 patients who currently receive IPLEX™, 8 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 ALS in Italy, pursuant to which we have received most of our operating revenues in the form of cost recovery charges. The 8 U.S. patients are being treated for ALS under single patient Investigational New Drug applications approved by the FDA. We believe that we have sufficient IPLEX™ inventory to supply these existing patients into approximately the second quarter of 2011, at which time our primary source of operating revenues will cease.

The use of IPLEX™ in ROP is being conducted by Premacure AB in Sweden under a Phase 2 trial and we were recently informed by Premacure that the trial dosed its first patient in June 2010. We have supplied Premacure with sufficient IPLEX™ to complete the Phase 2 trial which Premacure is conducting and paying for.

Until the gain generated by the sale of our FOB platform to Merck, we had not been profitable. We accumulated deficits of approximately $230 million through December 31, 2009. Following the sale of our FOB assets to Merck, we operated on a cash neutral basis as a result of revenues on our Expanded Access Program and interest on the net proceeds of the sale of our FOB assets, offsetting our ongoing base operating costs. Moving forward, our major source of income will continue to be the cost recovery charges for our Expanded Access Program and our major expenses will be related to due diligence for the ongoing corporate strategic review process together with some research and development expenses. In general, our expenditures may increase if 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.

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.

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 available for sale and consist primarily of mutual funds, government agency 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.

Revenue Recognition

Revenue from our Expanded Access Program in Italy is recognized when the drugs have been provided to program patients and collectability is assured. Royalties previously paid to Tercica and Genentech are shown 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.

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 Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands except per share data)			
Numerator:				
Net income for basic and diluted earnings per share	$(330)	$(150)	$(590)	$116,044
Denominator:				
Weighted average shares for basic earnings per share	130,301	129,442	130,253	126,072
Effect of dilutive securities:				
Warrants	-	-	-	0
Stock options and restricted stock	0	0	0	184
Denominator for diluted earnings per share	130,301	129,442	130,253	126,256
Basic earnings per share	$(0.00)	$(0.00)	$(0.00)	$0.92
Diluted earnings per share	$(0.00)	$(0.00)	$(0.00)	$0.92

Basic net loss per share is computed based upon the weighted average number of common shares outstanding during the year. For the three months ended September 30, 2009 and 2010 and the nine months ended 2010, the Company's diluted net loss per share is the same as its basic net loss per share because all stock options, warrants, and other potentially dilutive securities are antidilutive and, therefore, excluded from the calculation of diluted net loss per share. Shares excluded from the calculation of diluted shares totaled 4 million for 2010 and 12 million for 2009 for the three months ended and 4 million for 2010 and 12 million for 2009 for the nine months ended because they were antidilutive.

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. Equity Compensation Plan Information

As of September 30, 2010, 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, 2010, 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)	2,395,454	$ 1.84	2,104,385
Amended and Restated 2000 Employee Stock Purchase Plan	—	—	365,380
Total:	2,395,454	$ 1.84	2,469,765

(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, 2010, and changes for the nine months then ended is presented below:

Description	2010	Average Exercise Price	Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at January 1, 2010	2,592,750	$2.30		

Granted	-	-		
Exercised	-	-		
Cancelled	(450,000)	4.50		
Options outstanding at September 30, 2010	2,142,750	1.84	2.25	$20,450
Exercisable at September 30, 2010	2,080,250	$1.88	2.11	$20,450

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, 2010. Stock-based compensation expense related to stock options was $43,824 and $207,475 for the nine months ended September 30, 2010 and 2009, respectively.

As of September 30, 2010, there were 3,970,991 shares reserved for issuance for all outstanding warrants, options and restricted stock.

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.

The weighted-average grant date fair value of RS and RSU's granted during the nine months ended September 30, 2010 was $0.88. As of September 30, 2010, there were 202,704 RS awards outstanding to our Board of Directors and 50,000 RS awards to our Chief Scientific Officer who was hired in March 2010; the remaining unrecognized stock-based compensation expense relating to these awards is $130,736 and will be recognized over the next twelve months in accordance with their vesting schedule.

Below is a table of RS and RSU activity for the nine months ended September 30, 2010.

	Number of Shares Restricted Stock
Outstanding at January 1, 2010	87,720
Granted	302,704
Vested	137,720
Outstanding at September 30, 2010	252,704

4. 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 June 1, 2005, the holders of the 2005 Notes began to receive interest payments at a rate of 5.5% per annum, and such interest payments were 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 were 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 March 1, 2010, 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. The final payment to our Convertible Note holders was made on March 1, 2010. As of September 30, 2010, we no longer had any outstanding debt related to these notes. The 2005 Warrants associated with these notes expired on March 15, 2010.

5. 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 September 30, 2010, the Company had net operating loss ("NOL") carryforwards for income tax purposes of approximately $172 million, expiring in various years beginning in 2010. The deferred tax assets of approximately $74 million at September 30, 2010, 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 2010, however presently all deferred tax assets have been fully offset by a valuation allowance. The Company has never been audited by the Internal Revenue Service.

6. 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. Financial instruments in Level 2 generally include government agency bonds listed in secondary markets.

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

Description	September 30, 2010	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)
Cash and Cash Equivalents	$9,687	$9,687	$-
Corporate bonds	10,279	10,279	-
U.S. Treasury securities	6,899	6,899	-
Mutual Funds	54,309	54,309	-
Government agency bonds	43,118	-	43,118
Certificate of deposit	2,085	2,085	
Total	$126,377	$83,259	$43,118

Description	December 31, 2009	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)
Cash and Cash Equivalents	$12,740	$12,740	$-
U.S. Treasury securities	16,473	16,473	-
Mutual Funds	52,827	52,827	-
Municipal bonds	40,141	-	40,141
Certificate of deposit	2,085	2,085	
Total	$124,266	$84,125	$40,141

At September 30, 2010, we held 5 securities which were in an unrealized loss position with a total estimated fair value of $9.1 million and gross unrealized losses of approximately $4,000. Of the 5 securities, none had been in a continuous unrealized loss position for greater than one year. At December 31, 2009, we held 23 securities which were in an unrealized loss position with a total estimated fair value of $40.1 million and gross unrealized losses of

approximately $88,557. Of the 23 securities, none had been in a continuous unrealized loss position for greater than one year. Below is a table which summarizes unrealized gains and losses for our investments. The net of our unrealized gains and losses, $1.6 million is reported in accumulated other comprehensive income in the stockholder's equity section of our Balance Sheet.

Gross unrealized gains and losses are summarized below (in thousands):

	September 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$6,886	$13	$-	$6,899
Corporate bonds	10,124	155	-	10,279
Mutual Funds	53,135	1,174	-	54,309
Government agency bonds	42,869	253	(4)	43,118
Total	$113,014	$1,595	$(4)	$114,605

	December 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$16,475	$-	$(2)	$16,473
Mutual Funds	52,293	534	-	52,827
Municipal bonds	40,228	-	(87)	40,141
Total	$108,996	$534	$(89)	$109,441

We review the status of each security quarterly to determine whether an other-than-temporary impairment has occurred. In making our determination, we consider a number of factors, including: (1) the significance of the decline, (2) whether the securities were rated below investment grade, (3) how long the securities have been in an unrealized loss position, and (4) our ability and intent to retain the investment for a sufficient period of time for it to recover. We have concluded that none of the available-for-sale securities with unrealized losses at September 30, 2010 has experienced an other-than-temporary impairment.

The maturity of our investments range from less than a month to approximately 5 years. The Company's sale of securities has not resulted in the reclassification of any gains or losses from accumulated other comprehensive income into earnings, for the nine months ended September 30, 2010 and 2009. We determine realized gains and losses on the sale of marketable securities on a specific identification method, and we reflect such gains and losses as a component of investment income in our accompanying Consolidated Statements of Income. Proceeds from the sale of our investments are immediately re-invested in similar securities.

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 success in identifying or reaching an agreement with acquisition or merger candidates; our estimates regarding our existing supply of IPLEX™; our estimates of expenses and future revenues and profitability; our plans to develop and market new products and the timing of these development programs; our clinical development of product candidates, clinical trials and our ability to obtain and maintain regulatory approval for our product candidates; our estimates regarding our capital requirements and our needs for additional financing; our estimates of 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, 2009.

Overview

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

On March 31, 2009, we completed the sale of our follow-on biologics ("FOB") platform to Merck & Co., Inc. ("Merck") for an aggregate purchase price of $130 million. As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility (which was also used to manufacture IPLEX™) and acquired ownership of all the equipment in the building. In addition, Merck offered positions to employees at the Boulder facility. After fees, taxes and other expenses related to the transaction, we received total net proceeds of approximately $127 million. In the fourth quarter of 2009, we recorded a $2 million tax refund receivable which increased the after tax proceeds on

the sale from $125 million, as reported in the first quarter of 2009, to the $127 million reported in our full year results. The $2.0 million reduction in taxes results from the beneficial impact of the revised tax laws, which came into effect in the fourth quarter of 2009, and allowed the Company to utilize more of its net operating losses ("NOLs") than previously able under former tax law to reduce the amount of taxes paid on the gain on sale of its FOB business to Merck in March 2009. The company received the full tax refund in April 2010. We retained our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program.

Until the sale of our FOB 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. Following the sale of our FOB assets, we engaged the services of RBC Capital Markets to act as financial advisor in evaluating other options for use of these proceeds from sale of our FOB business to Merck. These options could include acquisitions of complementary 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, which we refer to as our strategic review process. In parallel, we also intend to continue to focus on our proprietary protein platform and our product, the U.S. Food and Drug Administration ("FDA") approved IPLEX™, which is in various stages of development for a number of serious medical conditions. Based on a comprehensive market analysis, our current resource allocation strategy for IPLEX™ is focused on Amyotrophic Lateral Sclerosis ("ALS"), also known as Lou Gehrig's disease and Retinopathy of Prematurity ("ROP"), the latter under a Material Transfer Agreement with Premacure AB, a Swedish corporation.

On June 15, 2009, we announced that Geoffrey Allan, Ph.D., resigned as our President, Chief Executive Officer and Chairman of the Board due to a health condition. Dr. Allan had held these positions since our Company was formed in 1999. Mel Sharoky, M.D., one of our directors, assumed the role of Chairman of the Board. Pending the completion of the strategic review process, we have decided not to hire a new President and Chief Executive Officer.

In June 2009, we announced results from our exploratory U.S. Phase II clinical trial evaluating IPLEX™ in patients with myotonic muscular dystrophy ("MMD"). The trial explored measures of endurance, muscle function and strength, cognitive function, gastrointestinal function, general health, pain, quality of life, insulin sensitivity, lipid metabolism, and safety and tolerability of IPLEX™. The results of the trial indicated that IPLEX™ did not exhibit a statistically significant improvement in the functional measure of endurance by the nine-minute walk test, muscle function, strength, cognitive function, general health, pain, or quality of life in any of the tests utilized in this study. IPLEX™ did, however, demonstrate improvements in standard measures of insulin sensitivity and reductions in fasting glucose, fasting insulin, cholesterol and triglycerides, which is consistent with the expected metabolic profile of insulin-like growth factor. Pending the completion of the strategic review process, we have decided not to conduct further clinical trials focused on MMD patients.

Following the transfer of our Boulder, Colorado manufacturing facility to Merck, we no longer have the capability to manufacture IPLEX™, which is an extremely complicated drug to produce. 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. We are not actively exploring any third party manufacturing arrangements for IPLEX™ at this time. Since we no longer have a facility to manufacture IPLEX™, we announced in July 2009 that we would conserve our limited inventory of IPLEX™ on hand for the treatment of existing patients, would cease the supply of IPLEX™ to any new patients, and would not initiate further clinical trials with IPLEX™ (including a Phase II clinical trial for ALS patients in the U.S. discussed with the FDA in early 2009). We plan, however, to continue to collect and analyze data for the ROP and ALS indications.

There are approximately 39 patients who currently receive IPLEX™, 8 in the U.S. and the remainder around the rest of the world. Most of the patients receive IPLEX™ pursuant to a court-ordered EAP for ALS in Italy, pursuant to which we have received most of our operating revenues in the form of cost recovery charges. The 8 U.S. patients are being treated for ALS under single patient Investigational New Drug applications approved by the FDA. We believe that we

have sufficient IPLEX™ inventory to supply these existing patients into approximately the second quarter of 2011 at which time our primary source of operating revenues will cease.

The use of IPLEX™ in ROP is being conducted by Premacure AB in Sweden under a Phase 2 trial, and we were recently informed by Premacure that the trial dosed its first patient in September 2010. We have supplied Premacure with sufficient IPLEX™ to complete the Phase 2 trial for which Premacure is conducting and paying.

Until the gain generated by the sale of our FOB platform to Merck, we had not been profitable. We have accumulated deficits of approximately $230 million through December 31, 2009. Following the sale of our FOB assets to Merck, we operated on a cash neutral basis as a result of revenues on our Expanded Access Program and interest on the net proceeds of the sale of our FOB assets, offsetting our ongoing base costs. Moving forward, our major source of income will continue to be the cost recovery charges for our Expanded Access Program and our major expenses will be related to due diligence for the ongoing corporate strategic review process together with some research and development expenses. In general, our expenditures may increase as development of our product candidate's progresses. However, there will be fluctuations from period to period caused by differences in project costs incurred at each stage of development.

Results of Operations

Total revenues for the third quarter ended September 30, 2010 were $1.8 million, as compared to $2.5 million for the corresponding period in 2009. The $0.7 million decline in revenue was entirely due to lower cost recovery in the most recent quarter from our IPLEX™ Expanded Access Program ("EAP") in Italy for the treatment of Amyotrophic Lateral Sclerosis ("ALS"). In 2009, the Company ceased patient enrollment in the EAP in order to preserve inventory for existing patients.

Net loss for the third quarter of 2010 was $0.3 million, break-even on a per share basis, compared with a net loss of $0.1 million, also break-even on a per share basis, reported in the third quarter of 2009. The $0.2 million change in net loss was primarily due to the $0.7 million decrease in revenues, noted above, and a $0.3 million decrease in investment income, which were largely offset by an overall reduction of $0.8 million in operating expenses.

The $0.8 million decrease in total expenses resulted from a $0.3 million reduction in research and development expenses ("R&D expenses") and a $0.5 million decline in selling, general and administrative expenses ("SG&A Expenses"). The lower R&D expenses resulted largely from the elimination of IPLEX™ fill-finish costs which we incurred in the third quarter of 2009, while the reduced SG&A expenses were principally due to lower external market research and consultancy fees associated with our ongoing strategic review process.

Investment income for the 2010 third quarter was $345,000, as compared to $682,000 for the same period in 2009; as overall market returns declined in the current quarter versus the corresponding period in 2009.

Total revenues for the nine-months ended September 30, 2010 were $5.6 million, as compared to $7.9 million for the corresponding period in 2009. The $2.3 million decline in revenue was due to a combination of a $1.7 million decline in EAP cost recovery, the receipt, during the first none months of 2009, of $0.5 million in grant revenue for our exploratory Phase 2 IPLEX™ trial in patients with myotonic muscular dystrophy and $0.1 million in lower income from an expired TGF-beta royalty.

Net loss for the first nine-months of 2010 was $0.6 million, break-even on a per share basis, compared with net income of $116.0 million, or $0.92 per share, reported in the same period of 2009. The $116.6 million change in net loss was primarily due to the $125.0 million after tax gain on sale of our follow on biologics ("FOB") assets to Merck in March 2009, together with the $2.3 million reduction in revenues noted above, which were partially offset by an overall reduction of $9.5 million in operating expenses, a $0.5 million improvement in investment income and a $0.7 million reduction in interest expense.

The $9.5 million decrease in total expenses resulted from a $6.2 million reduction in R&D expenses and a $3.3 million decline in SG&A expenses. The lower R&D expenses reflected the elimination of manufacturing expenses following the sale of our FOB assets in March 2009, while the reduced SG&A expenses were principally due to lower personnel costs also associated with the asset sale to Merck.

Investment income for the first nine-months of 2010 was $1.3 million. This was an increase of $0.5 million over the corresponding period of 2009, and was due to improved investment returns during the period and a significantly higher cash balance invested for the full nine-months of 2010. The reduction in interest expense for the first nine-months of 2010 as compared the same period in 2009 was entirely due to the elimination of the 2005 convertible notes, which were fully repaid in March 2010.

Liquidity and Capital Resources

As of September 30, 2010, the Company had total cash, cash equivalents and short-term investments on hand of $126.4 million, comprised of $114.6 million in short-term investments, $9.7 million in cash and cash equivalents and $2.1 million in a certificate of deposit. This compares to $124.3 million as of December 31, 2009. The $2.1 million increase in cash, cash equivalents and short-term investments was due primarily to the receipt of a $2.0 million income tax refund in 2010 and a $1.1 million improvement in unrealized gain on investments, which was partially offset by $0.8 million of net cash used in operating activities and the $0.2 million final payment on our 2005 convertible notes.

At September 30, 2010, our cash, cash equivalents and short-term investments of $126.4 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, we may in the future raise 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, 2010, had $126.4 million invested in money market instruments, treasury bills, mutual funds, government agency bonds and a certificate of deposit. Such investments are subject to interest rate and credit risk Our policy of investing in highly rated securities whose maturities at September 30, 2010 are all less than one year minimizes such risks. In addition, while a hypothetical decrease in market interest rates of 10% from September 30, 2010 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, 2010, 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

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (the "Plaintiff") in the United States District Court for the Northern District of New York (the "Court") seeking money damages and a court order requiring Insmed to support her compassionate use application to the FDA and if approved, to provide her with IPLEX™. Plaintiff was a participant in the phase II clinical trial of IPLEXTM sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy ("MMD"). The data from this trial did not suggest that IPLEX™ was effective to treat MMD. As a result, we decided not to proceed to a phase III trial.

In the complaint, Plaintiff alleges (i) the deprivation of constitutional due process and equal protection by depriving Plaintiff of continued access to IPLEXTM, (ii) fraudulent inducement to enter the phase II clinical trial with the false promise to support Plaintiff's compassionate use application to the FDA, (iii) negligent representation that we would support Plaintiff's compassionate use application, (iv) intentionally inflicted emotional distress by refusing to support Plaintiff's compassionate use application after providing IPLEXTM, (v) violation of an assumed duty of care to Plaintiff, (vi) breach of fiduciary duty to Plaintiff, (vii) negligence and (viii) unjust enrichment. Plaintiff seeks compensatory and punitive monetary damages.

On October 7, 2010, Plaintiff filed a motion for a preliminary injunction that would require us to provide a written statement supporting the "compassionate use" of IPLEXTM for Plaintiff and directing us to provide IPLEXTM to Plaintiff at cost in the event that the compassionate use application is granted by the FDA. On October 8, 2010, the Court issued an Order to Show Cause requiring us to respond to Plaintiff's motion. On October 13, 2010, we filed an opposition to Plaintiff's motion for the preliminary injunction and on October 15, 2010, an oral argument was held before the Court on the Plaintiff's motion.

On October 22, 2010, the Court denied Plaintiff's motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff has the option of immediately appealing the trial court's decision to the United States Court of Appeals for the Second Circuit. Plaintiff's claim for monetary damages still remains outstanding. We believe that the allegations contained in the complaint are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

In addition, we are subject to certain claims and litigation from time to time in the ordinary course of business. It is the opinion of management that the outcome of such matters is not expected to have a material adverse effect on our consolidated financial position, results of operations or cash flows.

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, 2009, which was filed with the Securities and Exchange Commission on March 16, 2010, 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 previous year of operation until 2009 with the sale of our manufacturing facility and other FOB assets to Merck. 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 would require us to establish a sales and marketing organization and contractual relationships to enable product manufacturing and other related activities. We expect that our activities, together with our general and administrative expenses, will continue to result in substantial operating losses for the foreseeable future. As of September 30, 2010, our accumulated deficit was $229 million. For the nine months ended September 30, 2010, our consolidated net loss was $590,000.

We may be unable to use our net operating losses.

We have substantial tax loss carryforwards for U.S. federal income tax purposes. Our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock upon exercise of outstanding warrants or in connection with a transaction that could result from our strategic review process, may further limit or eliminate our ability to use our net operating losses.

We may issue shares of our common stock and preferred stock to complete a business combination, which would reduce the equity interest of our stockholders and likely cause a change in control of our ownership.

Our amended and restated articles of incorporation authorize the issuance of up to 500 million shares of common stock and 200 million shares of preferred stock. We currently have 366 million authorized but unissued shares of our common stock available for issuance (after appropriate reservation for the issuance of shares upon full exercise of our outstanding warrants and options and issuance of restricted stock) and all of the 200 million shares of preferred stock available for issuance. Although we currently have no commitments to issue our securities, we will, in all likelihood, issue a substantial number of additional shares of our common stock or preferred stock, or a combination of common and preferred stock, to complete a business combination or other transaction in connection with our strategic review process, which could result in a change in control and also in the resignation or removal of some or all of our present officers and directors.

If we fail to meet the continued listing requirements of the NASDAQ Capital Market by December 15, 2010, 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 by December 15, 2010. 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

June 18, 2010, 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 were granted a 180-calendar day period, or through December 15, 2010, to regain compliance with the Minimum Bid Price Requirement. 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 order to regain compliance with the Minimum Bid Price Requirement of the NASDAQ Stock Market we may be required to implement a reverse stock split, which could have a material adverse effect on our stock price.

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. While such reverse stock split could bring us back into compliance, there can be no assurance that any increase in the market price for our common stock resulting from a reverse stock split, if approved and implemented, would be sustainable since there are numerous factors and contingencies that would effect such price, including the market conditions for our common stock at the time, our reported results of operations in future periods and general economic, geopolitical, stock market and industry conditions. Accordingly, the total market capitalization of our common stock after a reverse stock split may be lower than the total market capitalization before such reverse stock split and, in the future, the market price of our common stock may not exceed or remain higher than the market price prior to such reverse stock split. While a higher share price may help generate investor interest in our common stock, there can be no assurance that a reverse stock split would result in a per share market price that attracts institutional investors or investment funds, or that such price would satisfy the investing guidelines of institutional investors or investment funds.

We estimate that our supply of IPLEX™, our material source of operating revenues, will be exhausted in the second quarter of 2011, which could adversely affect our financial condition and results of operation.

Our supply of IPLEX™ is currently forecast to be exhausted in approximately the second quarter of 2011. At that time, our revenues from the EAP in Italy for cost recovery will end and, unless we execute an income generating transaction as a result of our strategic review process, we will have no material sources of operating revenue.

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 significantly impact our ongoing cash position.

We have not completed the research and development stage of any of our product candidates and are currently not spending material amounts on such research and development. 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 FDA 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.

Our ability to successfully commercialize our products will depend on a number of factors, any of which could delay or prevent commercialization, including:

- 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 that could be brought against us our products or technologies; or

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

To generate any growth, we would need to commercialize more than one product, which we currently have no plans to do. 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 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 procedures for enrolling patients have been 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 any commercialization of IPLEX™ for these broader chronic indications. Adverse results in these trials could prevent 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 collaborative 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 in connection with the sale of our FOB platform eliminated our internal IPLEX™ production capability. We believe, however, that we have sufficient inventory of IPLEX™ to support our

ongoing ALS EAP in the U.S. and Europe into approximately the second quarter of 2011. Any requirements for IPLEX™ beyond that or any significant increase in demand beyond our current commitments in the ALS fields will require that we identify a Contract Manufacturing Organization or CMO to produce the necessary IPLEX™ to meet the demand. We are not pursuing any third party manufacturing arrangement at this time, but if we chose to do so, we estimate that the technology transfer of our IPLEX™ production process could take 12 to 18 months once a CMO has been identified.

We could, but have no plans to, manufacture rhIGFBP-3 clinical drug substance and INSM-18 with contract manufacturers. In addition, we 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 clinical studies, regulatory submissions and regulatory approvals, (2) higher costs of production, or (3) inability to 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 do not currently have a President and Chief Executive Officer and are not currently searching for one as we are currently focusing on the strategic review process. This may hinder the organic growth of the Company in the short term.

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 any 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 depends on 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 could also 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 could conduct proprietary development programs with collaborators, and any conflicts with them could harm our business, financial condition and results of operations. We could enter into collaborative relationships which would 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. As of September 30, 2010, we had approximately $126.4 million of cash and investments on hand. That amount may not be sufficient to meet the capital requirements of any business activity that we may generate as a result of our strategic review process. 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 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 our potential 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; and
- obtain one or more licenses arising out of a settlement of litigation or otherwise from third parties for the infringed proprietary rights, which may not be available to us on acceptable terms or at all.

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

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

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.

Our agreement with Merck prohibits us from competing with Merck in the FOB arena.

In connection with the sale of our FOB platform to Merck in March 2009, we agreed not to compete, directly or indirectly, in the U.S. with Merck in the business of developing, marketing or manufacturing the FOB products or product candidates we sold to Merck for a period of five years beginning March 31, 2009.

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 have been developing IPLEX™.

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

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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first marketing approval from the FDA for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Similar laws exist in 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 on our business, financial condition and results of operations.

If our settlement agreement with Tercica and Genentech (now Ipsen and Roche) 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.

Exercise of warrants and options issued by us will dilute the ownership interest of existing shareholders.

As of September 30, 2010, the warrants issued by us in May 2007 were exercisable for up to approximately 1.6 million shares of our common stock, representing approximately one percent of our then outstanding common stock.

As of September 30, 2010, our outstanding restricted stock and stock options to our employees, officers, directors and consultants were exercisable for up to 2.5 million shares of our common stock, representing approximately an additional two percent of our then outstanding common stock.

The exercise of some or all of our warrants, restricted stock and options will 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;
- operating results below the expectations of public market analysts and investors; and
- the results of our strategic review process.

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 or any new shareholders receiving our shares in any transaction resulting from our strategic review process 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 our "affiliates", 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. (Removed and Reserved)

None.

ITEM 5. OTHER INFORMATION

None.

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, Principal Financial Officer and Principal Accounting Officer) of Insmed Incorporated.

32.1 Certification of Kevin P. Tully, C.G.A., Executive Vice President and Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting 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 3, 2010

By:/s/ Kevin P. Tully
Name: Kevin P. Tully, C.G.A.,
Title: Executive Vice President and Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)