INSMED INC
Form 10-Q
August 09, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2006

OR

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

Commission File Number 0-30739

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia	**54-1972729**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4851 Lake Brook Drive	**(804) 565-3000**

Glen Allen, Virginia 23060
(Address of principal executive offices) **(Registrant s telephone number, including area code)**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes: x No ¨

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

As of July 31, 2006, the latest practicable date, there were 100,228,903 shares of Insmed Incorporated common stock outstanding.

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INSMED INCORPORATED

FORM 10-Q

For the Quarterly Period Ended June 30, 2006

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PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	June 30, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	**$ 48,356**	$ 18,835
Restricted cash	**285**	285
Accounts receivable	**105**	
Inventories	**1,797**	
Other current assets	**190**	83
Total current assets	**50,733**	19,203
Long-term assets:		
Restricted cash - long term	**2,830**	3,118
Deferred financing costs, net	**262**	532
Property and equipment, net	**3,029**	17
Total long-term assets	**6,121**	3,667
Total assets	**$ 56,854**	$ 22,870
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 2,884**	$ 968
Accrued project costs & other	**1,353**	1,990
Payroll liabilities	**1,690**	1,574
Interest payable	**28**	52
Restructuring reserve	**121**	286
Total current liabilities	**6,076**	4,870
Long-term liabilities:		
Convertible debt	**6,013**	11,438
Debt discount	**(2,466)**	(5,001)
Net convertible debt	**3,547**	6,437
Asset retirement obligation	**1,330**	1,034
Total liabilities	**10,953**	12,341
Stockholders equity:		

Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 100,228,903 in 2006 and 66,525,792 in 2005	**1,002**	665
Additional paid-in capital	**321,895**	264,522
Accumulated deficit	**(276,996)**	(254,658)
Net stockholders equity	**45,901**	10,529
Total liabilities and stockholders equity	**$ 56,854**	$ 22,870

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

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INSMED INCORPORATED

Condensed Consolidated Statements of Operations

(in thousands, except per share data - unaudited)

	Three Months Ended June 30		Six Months Ended June 30	
	2006	**2005**	**2006**	**2005**
Sales	**$ 180**	$	**$ 180**	$
Royalties	**30**	28	**83**	85
Total revenues	**210**	28	**263**	85
Operating expenses:				
Cost of goods sold	**23**		**23**	
Research and development	**4,348**	5,339	**11,522**	9,626
Selling, general and administrative	**5,163**	1,640	**8,963**	2,933
Total expenses	**9,534**	6,979	**20,508**	12,559
Operating loss	(9,324)	(6,951)	(20,245)	(12,474)
Interest income	**577**	252	**889**	316
Interest expense	**(164)**	(1,825)	**(2,983)**	(2,130)
Net loss	**$ (8,911)**	$ (8,524)	**$ (22,339)**	$ (14,288)
Basic and diluted net loss per share	**$ (0.09)**	$ (0.19)	**$ (0.25)**	$ (0.32)
Shares used in computing basic and diluted net loss per share	**100,152**	44,998	**90,125**	44,992

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

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INSMED INCORPORATED

Condensed Consolidated Statements of Cash Flows

(in thousands - unaudited)

	Six Months Ended June 30	
	2006	**2005**
Operating activities		
Net loss	**$ (22,339)**	$ (14,288)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	**2,809**	1,573
Non-cash stock acceleration		14
Stock based compensation expense	**481**	
Stock options issued for services	**40**	
Changes in operating assets and liabilities:		
Accounts receivable	**(105)**	
Inventory	**(1,797)**	
Other assets	**(107)**	(16)
Accounts payable	**1,916**	(690)
Accrued project costs	**(636)**	(586)
Payroll liabilities	**116**	(149)
Restructuring reserve	**(165)**	(158)
Asset retirement obligation	**296**	296
Interest payable	**(24)**	315
Net cash used in operating activities	**(19,515)**	(13,689)
Investing activities		
Purchase of property, plant and equipment	**(3,016)**	
Net cash used in investing activities	**(3,016)**	
Financing activities		
Proceeds from issuance of convertible debt with detachable stock warrants		35,000
Proceeds from issuance of common stock		165
Public offering - issuance of 23 million shares	**43,240**	
Issuance costs	**(421)**	
Warrants converted into shares	**8,810**	
Other	**135**	
Total proceeds from issuance of common stock	**51,764**	165
Costs incurred in conjunction with issuance of debt		(2,428)
Cash restricted to restricted letters of credit	**288**	185
Net cash provided by financing activities	**52,052**	32,922
Increase in cash and cash equivalents	**29,521**	19,233
Cash and cash equivalents at beginning of period	**18,835**	9,222
Cash and cash equivalents at end of period	**$ 48,356**	$ 28,455

Supplemental information		
Cash paid for interest	**$ 165**	$ 411

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

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Insmed Incorporated

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission regulations for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. It is presumed that users of this interim financial information have read or have access to the audited financial statements contained in the Annual Report on Form 10-K of Insmed Incorporated (Insmed or the Company), as amended, for the fiscal year ended December 31, 2005. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation have been included. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the full year.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

We record revenue from product sales when the goods are shipped and received and title passes to the customer. At the time of sale estimates for sales deductions, including rebates to government agencies are recorded. These provisions are provided for in the same period the related product sales are recorded. We began generating revenue from the sale of IPLEX , in May 2006. On May 23, 2006, we announced the IPLEX Utilization Program which informed the payer universe that the annual charge for therapy is limited to actual milligrams prescribed and used. The utilization program assures that there is no charge for unused product remaining after the prescribed dose is extracted. Any remaining product discarded as waste is accounted for when all the vials in a 30 vial pack are used, and any wastage is replaced by us at no charge to the payer or patient, to assure that the payer or patient pays only for the amount dosed and administered.

Inventories

Inventories are stated at the lower of cost or market and consist primarily of manufacturing costs for the production of IPLEX that were incurred subsequent to the approval for marketing by the U.S. Food and Drug Administration. Cost is determined using average costing. The valuation of inventory requires us to estimate the value of inventory that may become obsolete prior to use or that may fail to be released. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies or new information that suggests that the inventory will not be releasable. The components of inventories are as follows:

(in thousands)	June 30, 2006
Finished goods	$ 400
Work-in-process	997
Raw materials and supplies	400
	$ 1,797

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Property, Plant and Equipment

Included in property, plant and equipment is construction in progress which consists solely of the upgrade costs at our manufacturing facility in Boulder, Colorado. This asset is recorded at original cost and capitalized at the end of each quarter. We will depreciate the cost evenly over the remaining life of the lease when the project is fully commissioned.

Research and Development Costs

Research and development costs consist primarily of compensation and other expenses related to research and development personnel, costs associated with pre-clinical testing and clinical trials of our product candidates, including the costs of manufacturing the product candidates and facilities expenses. Research and development costs are expensed as incurred. We do not have separate accounting policies for internal or external research and development and does not conduct any research and development for others.

Litigation costs as they relate to our patents were recorded as research and development expenditures through the first quarter of 2006. However, now that we have shifted from research and development operations to commercial operations, litigation costs are recorded as a selling, general and administrative activity.

Stock-Based Compensation

We recognize expense for stock-based compensation in accordance with Statement of Financial Accounting Standards (SFAS) 123R, *Share-Based Payment*.

In accordance with SFAS No. 123R, the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation,* for all periods presented is as follows:

Stock Compensation Expense

(in $ thousands - except per share data)

	For the Three Months Ended June 30, 2005	For the Six Months Ended June 30, 2005
Net Loss	$ (8,524)	$ (14,288)
Net Loss Per Share (Basic and Diluted)	$ (0.19)	$ (0.32)
Pro-forma Fair value stock compensation expense	$ (617)	$ (1,177)
Pro-forma Net Loss	$ (9,141)	$ (15,465)
Pro-forma Net Loss Per Share (Basic and Diluted)	$ (0.20)	$ (0.34)

3. Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123R, which supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. We adopted SFAS 123R on January 1, 2006. We adopted the fair-value-based method of accounting for share-based payments effective January 1, 2006, using the modified prospective transition method

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described in SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.* Currently, we use the Black-Scholes-Merton Formula to estimate the value of stock options granted to employees and expects to continue to use this acceptable option valuation model. Under that transition method, compensation cost recognized during the three and six months ended June 30, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair valued estimated in accordance with the provisions of SFAS 123R. Prior to January 1, 2006, we applied APB Opinion No. 25 and related interpretations in accounting for our stock based compensation plans. Results for prior periods have not been restated. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro-forma net income and earnings per share in Note 2 to our condensed consolidated financial statements.

As a result of adopting SFAS 123R on January 1, 2006, our net loss for the three and six months ended June 30, 2006 is $211,000 and $481,000 higher, respectively, than if we had continued to account for share-based compensation under SFAS 123. Basic and diluted loss per share for the three and six months ended June 30, 2006 would have been $0.09 and $0.24 per share, respectively, if we had not adopted SFAS 123R, compared to reported basic and diluted earnings per share of $0.09 and $0.25 per share, respectively. Unamortized stock compensation expense as of June 30, 2006 is $3.0 million.

4. Equity Compensation Plan Information

As of June 30, 2006, we had two equity compensation plans under which we granted stock options and shares of non-vested stock. We are currently granting stock-based awards under the Insmed Incorporated Restated 2000 Stock Incentive Plan (the 2000 Plan) and the Insmed Incorporated 2000 Employee Stock Purchase Plan (the 2000 ESPP). Both the 2000 Plan and the 2000 ESPP are administered by the compensation committee of the board of directors and the board of directors.

The 2000 Plan was originally adopted by the board of directors and approved by our stockholders in 2000, and its original ten-year term was extended to March 15, 2015 when such 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, without limitation, 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 our common stock. These shares are reserved for awards to all participants in the 2000 Plan, including non-employee directors.

The 2000 ESPP was originally adopted by our board of directors and approved by our stockholders in 2000, and its original ten-year term was extended to May 11, 2015 when such, plan was last amended. The 2000 ESPP provides for the issuance of a maximum of 500,000 shares of our common stock to participating employees.

The following table presents information as of June 30, 2006, with respect to the 2000 Plan and the 2000 ESPP.

Plan Category (1)	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Stockholders:			
Amended and Restated 2000 Stock Incentive Plan, as amended	6,889,430	$ 3.03	1,564,913(2)
2000 Employee Stock Purchase Plan, as amended			105,479
Total:	6,889,430	$ 3.03	1,670,392(3)

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

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(2) Amounts exclude any securities to be issued upon exercise of outstanding options, warrants and rights.
(3) To the extent that stock options or stock appreciation rights granted under the 2000 Plan terminate, expire, or are canceled, forfeited, exchanged or surrendered without having been exercised, or if any shares of restricted stock or performance units are forfeited, the shares of common stock underlying such grants will again become available for purposes of such plan.

A summary of the status of our stock options as of June 30, 2006, and changes for the six months then ended is presented below:

Description	2006	Weighted average exercise price	Weighted average remaining contractual life in years
Options outstanding at January 1, 2006	5,924,930	$ 3.18	
Granted	1,029,250	2.08	
Exercised	(24,500)	0.53	
Cancelled	(40,250)	1.58	
Options outstanding at December 31, 2005	6,889,430	3.03	4.42
Exercisable at June 30, 2006	3,868,184	4.21	4.16

The fair value of the stock options granted during the six months ended June 30, 2006 and June 30, 2005, was estimated at the date of grant using a Black-Scholes-Merton option-pricing model with the weighted average assumptions described below:

Assumptions	For the Six Months Ended June 30, 2006	2005
Dividend yield	**0**	0
Volatility factors of expected market price of stock	**113%**	89%
Risk-free interest rate	**2.3%**	4.2%
Expected option term (in years)	**2.59**	5
Forfeitures	**27%**	0%

5. Operational Restructuring

In September 2002, we decided to discontinue our INS-1 development program. In connection therewith, we approved a restructuring plan to focus on our remaining drug candidates. In the third quarter of 2002, we recorded a restructuring charge of $2.5 million. At June 30, 2006, approximately $121,000 of these costs remains accrued in the current portion of the restructuring reserve. This balance is expected to closely approximate the remaining costs to be incurred by us for lease obligations. Lease termination costs are anticipated to extend through October 2006.

6. 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 and 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).

The principal of each 2005 Note will mature and be payable in nine quarterly installments of approximately $3,890,000 commencing on March 1, 2008. As of June 1, 2005, the holders of the 2005 Notes began to receive interest payments at a rate of 5.5% per annum, and such interest payments are payable quarterly until March 1, 2008. Any outstanding 2005 Notes must be repaid in cash or converted by March 1, 2010. The holders of the 2005 Notes may convert such notes into shares of common stock at a conversion price of $1.295 per share (as adjusted in accordance

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with certain adjustments for stock splits, dividends and the like) at any time prior to the close of business on March 1, 2010. The 2005 Notes were initially convertible into, in the aggregate, 27,027,027 shares of common stock. The holders of the 2005 Notes have the right to require us to repurchase such notes with cash payments upon the occurrence of specified events of default and repurchase events described in the 2005 Notes. The 2005 Warrants were initially exercisable for 14,864,883 shares of common stock at an exercise price of $1.36 per share. The 2005 Warrants will expire on March 15, 2010.

In connection with the issuance of the 2005 Notes and 2005 Warrants, we entered into registration rights agreements with the purchasers thereof pursuant to which we agreed to file a registration statement under the Securities Act of 1933, registering for resale the shares of common stock issuable upon the conversion of the 2005 Notes or exercise of the 2005 Warrants.

Between January 1, 2006 and June 30, 2006, we received notices from certain holders of the 2005 Notes electing to voluntarily convert approximately $5,425,000 principal amount of such notes into approximately 4,189,189 shares of common stock at the conversion rate of one share of common stock for each $1.295 in principal amount of the 2005 Notes. Following such conversions and as of June 30, 2006, approximately $6,013,000 in aggregate principal amount of the 2005 Notes remained outstanding. In addition, because certain of the 2005 Notes were converted prior to the March 1, 2006 quarterly interest payment, we issued an additional 29,800 shares of common stock for the forfeited cash interest payment at a conversion price of $1.295.

Between January 1, 2006 and June 30, 2006, we also received approximately $8,177,070 in proceeds from the exercise of certain of the 2005 Warrants that resulted in approximately 6,012,551 shares of common stock being issued at an exercise price of $1.36. Following such exercises and as of June 30, 2006, there were outstanding 2005 Warrants to purchase approximately 6,211,390 shares of common stock.

In addition to the warrant exercises from the March 2005 financing, we also received $633,332 from the exercise of certain warrants issued in November 2004 that resulted in 370,370 shares of common stock being issued at an exercise price of $1.71. Following such exercises and as of June 30, 2006, there were outstanding, warrants from November 2004 to purchase approximately 2,319,702 shares of common stock.

7. Public Stock Offering

On March 15, 2006, we sold 23 million shares of common stock. The price to the public was $2.00 per share, and the underwriters purchased the shares from us pursuant to an underwriting agreement at a price of $1.88 per share. The offering was made pursuant to our effective shelf registration statement on Form S-3 (Registration No. 333-131535) previously filed with the Securities and Exchange Commission. Net proceeds from the offering were $42.8 million.

8. Legal Proceedings

Infringement Claims

We are currently defending several patent infringement claims brought against us.

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

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

On May 19, 2006, a hearing was held to determine claim construction and to address summary judgment motions. On June 30, 2006, the court issued its ruling on the meaning of the terms of the claims and on several summary judgment motions. The court adopted some claim interpretations proposed by Genentech and Tercica and others proposed by us. It also adopted some interpretations that were modifications of those proposed by the parties. The court likewise granted certain motions for summary judgment and denied others. The court s rulings did not fully resolve all of the pending issues regarding any of the three patents. The remaining issues will be resolved at trial, which is currently scheduled to commence on November 6, 2006.

With respect to the 414 patent, the court granted Genentech s and Tercica s motion that we infringes claims 1, 2, and 9 of the 414 patent. On July 7, 2006, we moved for leave to file a motion for reconsideration of this portion of the court s order. That motion is currently pending. The court found that due to disputes of material fact, our invalidity defenses will need to be resolved at trial and therefore denied our motion for summary judgment that the claims at issue are invalid.

With respect to the 151 patent, the court granted Genentech s and Tercica s motion for partial summary judgment that the patent was not invalidated by certain prior art. Because of the claim constructions it adopted and disputes of material fact, the court denied our motion for summary judgment on non-infringement of the 151 patent. The question of infringement will now need to be resolved at trial. Our defense that the 151 patent is unenforceable due to inequitable conduct will be resolved at trial.

With respect to the 287 patent, the court ruled on the scope of one disputed claim term. The issue of whether we infringe the 287 patent or whether the claims at issue are valid remain to be resolved at trial.

In a related matter, on May 27, 2005, Genentech and Tercica filed a motion for preliminary injunction seeking an order barring us, until trial, from making, using or selling IPLEX with respect to its allegations of infringement of the 414 and 151 patents, and requesting that we be required to share any Orphan Drug Exclusivity we obtain with Tercica. We filed an opposition to the motion for a preliminary injunction on June 10, 2005. On June 16, 2005, Genentech and Tercica withdrew their motion for a preliminary injunction, but reserved the right to refile such motion. We cannot predict whether Genentech and Tercica will seek a preliminary injunction at another time.

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Deceptive Promotional Statements and Unfair Business Practices Claims

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

On June 9, 2006, the court granted our motion to dismiss Tercica s complaint. In so dismissing such complaint, the court ruled, among other things, that Tercica had not met its burden of establishing that the alleged statements made by us constitute false advertising , or that the court had jurisdiction over us in this case and that the venue was proper. Further, by dismissing Tercica s complaint without leave to amend, the court recognized that the deficiencies in Tercica s lawsuit could not be cured by filing another lawsuit against us in the United States District Court for the Northern District of California. We previously notified Tercica that we would seek fees and costs related to Tercica s baseless lawsuit. Given the court s ruling, we intend to pursue a motion with the court seeking reimbursement of fees and costs related to this lawsuit.

On June 12, 2006, Tercica, filed a complaint in the U.S. District Court for the Eastern District of Virginia, Richmond division alleging that we violated the Lanham Act and related statutes relating to false advertising and unfair competition. Tercica s new filing added new allegations of false and misleading advertising that we disseminated specifically to pediatric endocrinologists, who, for purposes of the Lanham Act and related statutes, are among the relevant community of consumers affected. We filed a motion to dismiss this new complaint on July 27, 2006.

We cannot predict with certainty the outcome of the legal proceedings in which we are involved. We note, however, that an adverse ruling could materially and adversely impact our ability to make, use or sell our products.

9. Subsequent Events

On August 4, 2006, we entered into a material agreement for the lease of office space at 8720 Stony Point Parkway, Richmond, Virginia 23235. The agreement is for the lease of 18,551 square feet of office space for a term of 10 years commencing on November 1, 2006 and ending October 31, 2016. This new lease agreement represents savings of approximately $650,000 per annum as compared to the lease for our current office space in Glen Allen, VA, which is due to expire on October 31, 2006.

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

Forward Looking Statements

Statements contained herein, including without limitation, Management s Discussion and Analysis of Financial Condition and Results of Operation, contains 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, potential, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Forward-looking statements include, but are not limited to: our plans to develop and market new products and the timing of these development programs; our clinical development of product candidates, clinical trials and our ability to obtain and maintain regulatory approval for

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our product candidates; our estimates regarding our capital requirements and our needs for additional financing; our estimates of expenses and future revenues and profitability; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract collaborators with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate collaborations, license agreements and other collaborative efforts, including those relating to the development and commercialization of our product candidates; sources of revenues and anticipated revenues, including contributions from corporate collaborations, license agreements and other collaborative efforts for the development and commercialization of products; our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly; the rate and degree of market acceptance of our product candidates; the timing and amount of reimbursement for our product candidates; the success of other competing therapies that may become available; and the manufacturing capacity for our product candidates.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed in Part II. Item 1A Risk Factors and elsewhere in this report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in company 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 condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the condensed consolidated financial statements and related notes thereto in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2005.

Overview

We are a biopharmaceutical company focused on the development and commercialization of drug products for the treatment of metabolic diseases and endocrine disorders. Currently, our development activities principally focus on drugs that modulate IGF-I activity in the human body. We currently have three lead drug candidates: recombinant human insulin-like growth factor-I bound to recombinant human insulin-like growth factor binding protein-3 (rhIGF-I/rhIGFBP-3; also known as IPLEX and formerly called SomatoKine®), rhIGFBP-3 and INSM-18. IPLEX was approved by the FDA for the treatment of severe pediatric IGFD in December 2005. We are actively developing these drugs to treat indications in the metabolic and oncology fields.

We have not been profitable and have accumulated a deficit of approximately $277 million through June 30, 2006. We expect to incur significant additional losses for at least the next several years until such time as sufficient revenues are generated to offset expenses. In general, our expenditures will increase as development and commercialization of our product candidates progress. However, there will be fluctuations from period to period caused by differences in project-related expenditure requirements at each stage of development.

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Research and Development Activities

We are engaged in the research and development of proposed drug products for the treatment of metabolic diseases and endocrine disorders. All of our research and development expenditures, whether conducted by our own staff or by external scientists on our behalf and at our expense, are recorded as expenses as incurred. Research and development expenses consist primarily of salaries and related expenses, costs to develop and manufacture products and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

Our leading product, IPLEX , was approved in December 2005 for the treatment of Severe Primary Insulin-like Growth Factor Deficiency (Severe Primary IGFD). IPLEX has also been granted Orphan Drug Designation for the treatment of Severe Primary IGFD indication and other indications. Substantially all of our research and development expenditures for fiscal 2005 and 2006 have been related to IPLEX .

Our research and development efforts for other products are in the early stages and include primarily research and development regarding rhIGFBP-3 for the treatment of various cancers and INSM-18 for the treatment of various tumors. These products are either in preclinical stages or Phase I and II clinical trials. All of our research and development expenditures related to these early-stage products and our efforts associated with IPLEX are significantly interrelated to rhIGFBP-3 and INSM-18 as our efforts are all associated with drugs that modulate IGF-I activity in the human body. A significant finding in any one drug for a particular indication may provide benefits to our efforts across all of these products. All of these products also share a substantial amount of common fixed costs, such as salaries, facility costs, utilities and maintenance. Given the small portion of research and development expenses that are related to products other than IPLEX , we have determined that very limited benefits would be obtained from implementing cost tracking systems that would be necessary to allow for cost information on a product-by-product basis.

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

Our clinical trials with respect to IPLEX are subject to numerous risks and uncertainties that are outside of our control, including the possibility that necessary regulatory approvals may not be obtained. For example, the duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that is determined to be appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the product candidate.

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

Moreover, all of our product candidates and particularly those that are in the preclinical or early clinical trial stage must overcome significant regulatory, technological, manufacturing and marketing challenges before they can be successfully commercialized. Some of these projects may never reach the clinical trial stage of research and development. As preclinical studies and clinical trials progress, we may determine that collaborative relationships will be necessary to

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help us further develop or to commercialize our product candidates, but such relationships may be difficult or impossible to arrange. Our projects or intended projects may also be subject to change from time to time as we evaluate our research and development priorities and available resources.

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

Results of Operations

The second quarter of 2006 marked the initial period of sales for us as our US Food and Drug Administration (FDA) approved product, IPLEX , was launched on May 25, 2006.

Revenues reported for the three months ended June 30, 2006 were $210,000 as compared with $28,000 reported in the corresponding period of 2005. The $210,000 revenue figure for the second quarter of 2006 was made up of $172,000 in sales to patients in our named patient program, $8,000 in sales to commercial patients and $30,000 in royalties. Commercial sales of IPLEX , commenced on May 25, 2006 with the first month s supply being provided free to many of the children in order for them to begin treatment immediately rather than wait for IPLEX to be approved by the individuals payer plan. The $28,000 of revenue for the second quarter of 2005 reflects only royalties, as receipts from our named patient program for the second quarter of 2005, totaling $27,000, were classed as a reduction in expense, as we were reporting results on a research and development basis at the time.

Cost of goods sold (COGS) for the second quarter of 2006 was $23,000. The COGS figure for the current quarter was favorably impacted by the consumption of intermediates and raw materials which were manufactured and expensed in prior quarters when all costs were classed as research and development (R&D) expense.

The net loss for the second quarter ended June 30, 2006 was $8.9 million or $0.09 per share, as compared to a net loss of $8.5 million or $0.19 per share for the corresponding quarter of 2005.

The $0.4 million increase in the net loss for the second quarter of 2006 as compared to the second quarter of 2005 was due mainly to a $3.5 million increase in selling, general and administration (SG&A) expense, which was partially offset by a combination of a $1.7 million decrease in interest expense, a $1.0 million reduction in R&D expense and a $0.3 million increase in interest income.

The rise in SG&A expenses for the three months ended June 30, 2006 is mainly due to the hiring and ramping up of our commercial team and associated marketing expenses for the commercial launch of IPLEX , and patent litigation expenses are now recorded in the SG&A category as we commenced commercial operations in the second quarter. Previously patent litigation expenses were recorded in R&D. The decrease in interest expense is due to a $1.8 million reduction in non-cash amortization associated with the convertible debt discount of the 2005 notes, partially offset by a $0.1 million reduction in actual cash interest payments made with respect to those notes. The decrease in R&D expenses for the three months ended June 30, 2006 as compared to the corresponding period of 2005 was mainly due to the capitalization of inventory, and construction in progress at our production facility in Boulder, Colorado and the change in categorization of the previously mentioned patent litigation expenses from R&D into SG&A. The increase in interest income for the quarter resulted from the higher level of cash on hand for investment as a result of the completion of our public offering in March 2006.

Revenues reported for the six months ended June 30, 2006 were $263,000 as compared to $85,000 reported for the same period in 2005. The $263,000 of revenues reported for the half

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year were made up of $172,000 in sales to patients in our named patient program, $8,000 in sales to commercial patients and $83,000 from royalties. The $85,000 of revenue for the first half of 2005 reflects only royalties, as receipts from our named patient program for the first half of 2005, totaling $134,000, were classed as a reduction in expense at the time.

The net loss for the six months ended June 30, 2006 was $22.3 million, or $0.25 per share, compared to the net loss of $14.3 million, or $0.32 per share, reported for the corresponding period in 2005.

The $8.1 million increase in the net loss for the first half of 2006 as compared to the first half of 2005 was due mainly to a $6.0 million increase in SG&A expense, a $1.9 million increase in R&D expense and a $0.9 million rise in interest expense, partially offset by a $0.6 million increase in interest income.

The rise in SG&A expenses is primarily due to the build-up of our commercial team and associated marketing expenses as mentioned earlier, together with the recording of patent litigation expenses which were higher than corresponding quarters. The higher R&D expenses were mainly due to higher product and process development expenses at our manufacturing facility in Boulder, Colorado, as we added personnel and continued scale up and process improvements in support of current and future IPLEX production. These increases were partially offset by the change in categorization of patent litigation expenses from R&D into SG&A and the capitalization of inventory and construction in progress. The higher interest expense results from a $1.1 million increase in non-cash amortization of the March 2005 convertible debt discount, offset by a $0.2 million reduction in actual cash interest payments, as the conversion of the March 2005 notes and warrants, which were exercised during the first quarter of 2006, resulted in an acceleration of the debt discount and a reduction in interest paid. The increase in interest income for the quarter resulted from the higher level of cash on hand for investment.

As of June 30, 2006, we had total cash and cash equivalents of $48.4 million which represents an increase of $29.6 million from December 31, 2005. This net increase is due to the $52.1 million in net cash provided by financing activities during the first half of the year, which was partially offset by the $19.5 million in net cash used during the half in support of our business operations and $3.0 million of construction in progress at our Boulder manufacturing facility. The $52.1 million of cash from financing activities was generated from a combination of $42.8 million in net proceeds from the sale of common stock in March 2006, $8.8 million from the exercise of certain outstanding warrants and $0.4 million from a reduction in a restricted letter of credit and employee option exercises.

Liquidity and Capital Resources

At June 30, 2006, our cash and cash equivalents of $48.4 million were invested in investment grade, interest-bearing securities. Our business strategy contemplates selling additional equity and entering into agreements with corporate partners to fund research and development, and provide milestone payments, license fees and equity investments to fund operations. We will need to raise substantial additional funds to continue development and commercialization of our products. There can be no assurance that adequate funds will be available when we need them, or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we will be required to delay, restrict or eliminate some or all of our research or development programs, dispose of assets or technology or cease operations.

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Contractual Obligations

The following table provides a summary of certain of our significant contractual obligations as of June 30, 2006:

Contractual Obligations

(in thousands)

	Payments Due by Years				
	Total	2006	2007 - 2009	2010 - 2012	Beyond 2013
Long term debt (1)	$ 6,922	$ 165	$ 6,080	$ 677	$
Operating lease obligations	2,820	659	1,944	217	
	$ 9,742	$ 824	$ 8,024	$ 894	$

(1) Long-term debt obligations reflect the future interest and principal payments of the 2005 Notes outstanding as of June 30, 2006. The 2005 Notes become due in quarterly installments beginning on March 1, 2008 if not converted to shares of common stock at an earlier date.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at June 30, 2006, had $48.4 million invested in money market instruments and investment grade corporate debt. Such investments are subject to interest rate and credit risk. Our policy of investing in highly rated securities whose maturities at June 30, 2006 are all less than one year minimizes such risks. In addition, while a hypothetical decrease in market interest rates of 10% from June 30, 2006 levels would reduce interest income, it would not result in a loss of the principal and the decline in interest income would not be material.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. We carried out an evaluation, under the supervision and with the participation of certain members of our management team, including the Chairman of the Board and Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-14 under the Securities Exchange Act of 1934. Based upon that evaluation, our Chairman of the Board and Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to us (including our consolidated subsidiaries) required to be included in our periodic filings with the Securities and Exchange Commission.

Changes in Internal Controls over Financial Reporting. During the period covered by this report, there have been no changes in our internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

In addition to the foregoing, we are a defendant in various matters of litigation generally arising out of the normal course of business**.** Although it is difficult to predict the ultimate outcome of these cases, management believes that any ultimate outcome would not materially affect our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Certain Factors Which May Affect Future Results

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, as amended, for the fiscal year ended December 31, 2005, which was filed with the Securities and Exchange Commission on March 6, 2006, we describe risk factors related to the Company. For convenience, 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.

Since we have a limited operating history, 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 focused on the development and commercialization of drug candidates for the treatment of metabolic and endocrine disorders with unmet medical needs. We have incurred losses each year of operation and we expect to continue incurring operating losses for the foreseeable future. The process of developing and commercializing our products requires significant pre-clinical testing and clinical trials as well as regulatory approvals for commercialization and marketing before we were allowed to begin product sales. In addition, commercialization of our drug candidates requires us to establish a sales and marketing organization and contractual relationships to enable product manufacturing and other related activities. We expect that these activities, together with our general and administrative expenses, will result in substantial operating losses for the foreseeable future. As of June 30, 2006, our accumulated deficit was approximately $277 million. As of June 30, 2006, our consolidated net loss was $22.3 million.

We currently have three lead product candidates, rhIGF-I/rhIGFBP-3 (also known as IPLEX and formerly called SomatoKine®) and rhIGFBP-3 and INSM-18. IPLEX is currently approved for the treatment of Severe Pediatric IGFD and is in development for a number of metabolic and endocrine indications. Our second compound, rhIGFBP-3, is currently in pre-clinical development for a variety of cancers including breast, lung, colon and prostate. Our third compound INSM-18 is currently in a Phase I/II clinical trial in patients with refractory prostate cancer.

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IPLEX is our only product with respect to which we have completed the research and development stage. 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, pre-clinical and other research;
- submit for and receive regulatory approval to perform clinical studies;
- design and conduct appropriate clinical studies;
- select and recruit clinical investigators;
- select and recruit subjects for our studies;
- collect, analyze and correctly interpret the data from our studies;
- submit for and receive regulatory approvals for marketing; and
- manufacture the drug product candidates according to current good manufacturing practices.

The development program with respect to any given product will take many years and thus delay our ability to generate profit. In addition, 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;
- not effective;
- too difficult or expensive to 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 to pay for the development;

attract and retain appropriate personnel; and

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

Even if we are successful in developing our products, there are numerous developments that could prevent the successful commercialization of the products such as:

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

an event such as litigation drains our cash;

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

a 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; or

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

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

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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 either 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.

We are currently conducting an ongoing Phase III clinical trial of IPLEX in patients with Severe Pediatric IGFD. We have included the data from the trial in an Marketing Approval Application (MAA) which we recently submitted to the European Agency for the Evaluation of Medical Products (EMEA). We must receive approval of this application before we can market IPLEX in the respective European territories. We are also planning clinical trials with rhIGFBP-3.

The completion rate of clinical trials 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 trials for the same patient population.

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

We may be required to conduct broad, long-term clinical trials to address concerns that the long-term use of rhIGF-I/rhIGFBP-3 in broader chronic indications might increase the risk of diabetic retinopathy. This may materially adversely affect our business, financial condition and results of operations.

In previously published clinical trials of rhIGF-I, concerns were raised that long-term use of rhIGF-I might lead to an increased incidence and/or severity of retinopathy, a disease of new blood vessel growth in the eye which results in loss of vision. Because our product contains rhIGF-I, the FDA may require us to conduct broad, long-term clinical trials to address these concerns prior to receiving FDA approval for broad chronic

indications such as diabetes. These clinical trials would be expensive and could delay our commercialization of IPLEX for these broader chronic indications. Adverse results in these trials could prevent our commercialization of IPLEX for broad chronic indications or could jeopardize existing development and approvals in other indications.

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We cannot be certain that we will obtain any additional regulatory approvals in the United States and Europe. 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 drug 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 Europe includes evaluation of pre-clinical studies and clinical trials, as well as the evaluation of our manufacturing process and is complex, lengthy, expensive, resource intensive and uncertain. Securing regulatory approval to market our products also requires the submission of extensive pre-clinical 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 drug and/or 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 marketing of any drugs that our collaborative partners or we 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.

As part of our normal development we continue to increase our scale of production and refine our manufacturing process. Because of these changes we are required to perform various comparability analyses to demonstrate that the drug product used in our previous development studies is essentially the same as the new drug product produced. We have had several discussions with the FDA and other foreign regulatory agencies regarding our Phase III clinical study and this comparability analysis and believe we understand what is required to satisfy the FDA and EMEA. We plan to submit this data to the appropriate regulatory authorities as part of the regulatory process. If we are unable to produce comparable drug product or meet the regulatory requirements of comparability it will materially adversely affect our business, financial condition and results of operations.

The regulatory authorities have substantial discretion in the approval process and may either refuse to accept our applications, or may decide after review of our applications that our data is insufficient to allow approval of IPLEX. If the EMEA does not approve our application, it may require that we conduct additional clinical, pre-clinical or manufacturing studies and submit that data before it will reconsider our application. This could materially adversely affect our business, financial condition and results of operations.

Even though the FDA granted approval for IPLEX , such approval may limit the indicated uses for which we may market the drug, and limits the potential market for such drug. Furthermore, the marketing and manufacture of approved products remain subject to extensive regulatory requirements. Even though the FDA granted approval of IPLEX , such approval is subject to continual review, and later discovery of unknown problems could restrict the product s future use or cause its withdrawal from the market. Failure to comply with regulatory requirements could, among other things, result in fines, suspension of regulatory approvals, operating restrictions and criminal prosecution. In addition, many countries require regulatory agency approval of pricing and may also require approval for the marketing in such countries of any drug that our collaborative partners or we develop.

If our Phase III clinical trial of IPLEX is unsuccessful or if we cannot produce comparable drug product, have not correctly understood the regulatory requirements associated with comparability of drug products or for various other reasons cannot satisfy ongoing regulatory requirements, we may not receive MAA approval or such approval may be substantially delayed or withdrawn. Any of these events could materially adversely affect our business, financial condition and results of operations.

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We cannot be certain that we will obtain any regulatory approvals in foreign countries. The failure to obtain such approvals may 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 territories, our corporate partners and we must comply with numerous and varying regulatory requirements of other countries. The approval procedures vary among countries and can involve additional product testing and administrative review periods. The time required to obtain approval in these other territories might differ from that required to obtain FDA or 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 EMEA does not ensure approval by the regulatory authorities of other countries.

We are currently conducting or planning to conduct several clinical studies in the United States, and countries in the European Union and other territories with our products. If we are unable to receive regulatory approval to conduct such studies, it may prevent or substantially delay our development programs which could materially adversely affect our business, financial condition and results of operations.

Although IPLEX was granted Orphan Drug Designation for multiple indications, another party may still obtain orphan drug or pediatric exclusivity for a product that is essentially the same as IPLEX for the treatment of growth disturbance due to Severe Pediatric IGFD. This will 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 Europe. Pediatric exclusivity can provide an additional six months of market exclusivity in the United States. Although IPLEX was granted Orphan Drug Designation for multiple indications, a competitor with a clinically superior product may be approved for the same indications as IPLEX . In addition, more than one product may be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, although IPLEX was approved and received orphan drug status for multiple indications, the FDA can still approve other drugs for use in treating the same indications covered by IPLEX , which could create a more competitive market for us.

Manufacturing capacity necessary to supply IPLEX and rhIGFBP-3 may not be available, which may adversely affect our business, financial condition and results of operations. If we are unable to find sufficient manufacturing capacity, it could materially adversely affect our business, financial condition and results of operations.

Failure to successfully manufacture our products could materially adversely affect our business, financial condition and results of operations. We are manufacturing IPLEX at out ITP facility in Boulder, Colorado and intend to enter into strategic alliances with other parties that have established commercial scale manufacturing capabilities. There can be no assurance that our ITP facility will have the capacity to produce the required products nor that we will enter into such strategic alliances on terms favorable to us or at all. If we are unable to increase production capacity at our ITP facility or establish and maintain relationships with third parties for manufacturing sufficient quantities of our product candidates and their components that meet our planned time and cost parameters, the development and timing of our pre-clinical and clinical trials may be adversely affected.

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In addition, there can be no assurance that an adverse regulatory inspection at our ITP facility or at our contract manufacturers facilities would not impede our commercial supply capability. If we choose to commercialize our products solely on our own, it would be time consuming, resource intensive and capital intensive. If our contract manufacturers facilities or our facilities can not produce our products according to current good manufacturing practices (cGMP) and pass a cGMP inspection or if our contract manufacturers or our facilities become unavailable, we may be unable to develop and commercialize our products. This will materially adversely affect our business, financial condition and results of operations.

The available capacity for the manufacture of recombinant proteins that comprise our products is limited. A shutdown or disruption at our ITP facility or in any of these third-party facilities due to technical, regulatory or other problems, resulting in an interruption in supply of these materials, could delay our development and commercialization activities and adversely impact our business, financial condition and results of operations.

We have manufactured IPLEX at our ITP facility and at Avecia s site at Billingham, England., IPLEX has never been manufactured by Avecia in quantities necessary for commercialization; If we are unable to manufacture sufficient quantities of IPLEX at ITP or such manufacture is delayed it could materially adversely affect our business, financial condition and results of operations.

Product for our clinical trials is currently made at our ITP facility and then sent to a third party contract manufacturer for sterile filtration and filling into vials. Should our ITP facility, or our contract sterile filtration and filling manufacturer become unavailable to us for any reason, including damage from any event, including fire, flood, earthquake or terrorism, we may be unable to complete manufacture of our products or validation of the manufacturing process for our products. This could delay our clinical trials and the approval of our MAA, which would delay or otherwise adversely affect revenues. If the damage to any of these facilities is extensive, or if the third-party manufacturer is unwilling or unable to operate in compliance with cGMP or perform under our agreements, we will need to find alternative facilities. The number of contract manufacturers with the expertise and facilities to manufacture our products bulk drug substance on a commercial scale in accordance with cGMP regulations is extremely limited, and it would take a significant amount of time and resources to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, we would need to transfer and validate the processes and analytical methods necessary for the production and testing of our products to these new manufacturers. Any of these factors could lead to the delay or suspension of our clinical trials, regulatory submissions, regulatory approvals or commercialization of our products, or higher costs of production and result in our failure to effectively commercialize our products.

Our ITP facility and the facilities used by our contract sterile filtration, filling and packaging manufacturers to produce finished rhIGF-I/rhIGFBP-3 may undergo an inspection by the FDA and/or EMEA for compliance with cGMP regulations, before rhIGF-I/rhIGFBP-3 can be approved. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a significant delay of up to several years in obtaining approval for rhIGF-I/rhIGFBP-3 in Europe. In addition, our contract manufacturers, and any alternative contract manufacturer we may utilize, are subject to ongoing periodic inspection by the FDA and EMEA and other foreign agencies for compliance with cGMP regulations and similar foreign standards. We do not have control over our contract manufacturers compliance with these regulations and standards.

Furthermore, if our ITP facility fails to deliver sufficient quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we are unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we will likely be unable to meet demand for our products and we would lose potential revenues.

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If we are unable to continue to build sales, marketing and distribution capabilities, it will materially adversely affect our business, financial condition and results of operations.

To market any of our products directly, we must continue to develop our marketing and sales force with technical expertise and with supporting distribution capability. There can be no assurance that we will successfully build on our established sales and distribution capabilities or gain market acceptance for our proprietary products. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third parties and there can be no assurance that our efforts will succeed. Failure to successfully sell, market or distribute our products once approved will materially adversely affect our business, financial condition and results of operations

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 IPLEX or any of our other products that may be approved for marketing will achieve market acceptance. If our products 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 products 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;

their potential advantage over existing and future treatment methods;

their price; and

reimbursement policies of government and third-party payers, including hospitals and insurance companies.

For example, even though we obtained FDA regulatory approval to sell IPLEX, physicians and healthcare payers could conclude that IPLEX is not safe and effective and physicians could choose not to use it 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 IPLEX or our other products.

Our commercial success will depend in part on third-party payers agreeing to reimburse patients for the costs of our products. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. Third-party payers frequently challenge the pricing of new drugs. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Therefore, third-party payers may not approve our products for reimbursement. If third-party payers do not approve our products for reimbursement, sales will suffer, as some patients will opt for a competing product that is approved for reimbursement. Even if third-party payers make reimbursement available, these payers reimbursement policies may adversely affect our corporate partners and our ability to sell such products on a profitable basis. Moreover, the trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after the FDA or other regulatory agencies approve any of our products for marketing. While we cannot predict the likelihood of any such 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.

If physicians, patients, third-party payers or the medical community in general do not accept and use the products we develop and commercialize, it will materially adversely affect our business, financial condition and results of operations.

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

We will require substantial future capital in order to execute our business plan. Our future capital requirements will depend on many factors, including factors associated with:

- manufacturing;
- process development;
- research and development, including, among other items, pre-clinical testing and clinical trials;
- obtaining regulatory approvals;
- obtaining marketing sales and distribution capabilities;
- launching products;
- retaining employees and consultants;
- filing and prosecuting patent applications and enforcing patent claims;
- establishing strategic alliances; and
- other activities required for product commercialization.

We may also need to spend more money than currently expected because we may change our product development plans, acquire additional products or product candidates or we may misjudge our costs. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. There can be no assurance that our cash reserves together with any subsequent funding will satisfy our capital requirements. The failure to satisfy our capital requirements will adversely affect our business, financial condition and results of operations. We believe that existing cash reserves will sufficiently fund our activities through the next nine months.

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/or relinquish rights to our technologies or product candidates. This may 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.

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We need collaborative relationships to be successful. 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, pre-clinical development, clinical development and/or sales and marketing. Reliance on collaborative relationships poses a number of risks, including the following:

- we cannot 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 our corporate partners;
- disagreements with our 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;
- our 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
- our corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development.

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

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

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

We intend to conduct proprietary development programs with collaborators, and any conflicts with them could harm our business, financial condition and results of operations. We intend to enter into collaborative relationships which will involve our collaborator 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 timely regulatory approvals;

terminating their agreements with us prematurely; or

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

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We face uncertainties related to patents and proprietary technology that 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 arising from our research and development activities that have significant potential commercial value. Nevertheless, it is possible that, during 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.

We can give no assurance that a third party will not claim (with or without merit) that we have infringed or misappropriated its proprietary rights. A variety of third parties have obtained, and are attempting to obtain, patent protection relating to the production and use of rhIGF-I and/or rhIGFBP-3. We can give no assurances as to whether any issued patents, or patents that may later issue to third parties, would affect our commercialization of IPLEX or rhIGFBP-3. We can give no assurances that such patent(s) can be avoided, invalidated or licensed. If any third party were to assert a claim for infringement, we can give no assurances that we would 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. Furthermore, we may not be able to afford the expense of defending against such a claim.

Third parties, including Genentech and Chiron Corporation hold United States and/or foreign patents possibly directed to the composition, production and/or use of rhIGF-I, rhIGFBP-3, IPLEX and/or recombinant proteins in general. After examining these patents, we do not believe they present an obstacle to our commercialization of IPLEX and rhIGFBP-3. However, we can provide no assurance that any one of these third parties will not assert in the future a contrary position in the future, for instance in the context of an infringement action. Moreover, while we cannot predict with certainty the outcome of such a proceeding, an adverse ruling could impact our ability to make, use or sell our products.

In addition, Novartis AG and Chiron Corporation have rights to United States and foreign patents relating to the use of IGF-1 for the treatment of type 1 diabetes, and Novartis owns United States and foreign patents relating to the treatment of osteoporosis with IGF-1. Genentech owns U.S. and foreign patents directed to using IGF-I to increase the growth rate of certain patients with non-GH-deficient short stature and patients with partial growth hormone insensitivity syndrome. We do not expect that we will infringe these patents. We can give no assurances, however, that such patents can be avoided, invalidated or licensed. Thus, the patents could potentially have an adverse effect on our ability to make, use or sell IPLEX for certain indications.

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 subject us to significant liabilities to other parties, require us to license disputed rights from other parties or require us to cease using such technology, any of which could materially adversely affect our business, financial condition and results of operations.

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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 position.

Third-party claims that our products infringe on their proprietary rights may materially adversely affect our business, financial condition and results of operations.

We have entered into license agreements, and may enter into future license agreements, with various licensees to develop and market our products, and we can give no assurances that third parties will not claim that we and/or our licensees, by practicing our technology, are infringing on their proprietary rights. If other companies successfully bring legal actions against us or our licensees claiming patent or other intellectual property infringements, in addition to any potential liability for damages, a court could require us and/or our licensees to obtain a license in order to continue to use the affected processes or to manufacture or use the affected products, or alternatively, require us and/or our licensees to cease using such products or processes. Such a result may have an adverse effect on our business, financial condition and results of operations. Any such claim, with or without merit, could result in costly litigation or might require us and/or our licensees to enter into royalty or licensing agreements, all of which could delay or otherwise adversely impact the development of our potential products for commercial use. If a court requires us to obtain licenses, there can be no assurance that we and/or our licensees will be able to obtain them on commercially favorable terms, if at all. Without such licenses, we and/or our licensees may be unable to develop certain products. Our breach of an existing license or our failure to obtain, or our delay in obtaining, a license to any technology that we require to commercialize our products may materially adversely impact our business, financial condition and results of operations.

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

In addition, on December 23, 2004, Genentech and Tercica sued us for infringement of U.S. Patent Nos. 5,187,151, or the 151 patent, and 6,331,414, or the 414 patent, in the United States District Court for the Northern District of California. These patents are directed to certain methods of using rhIGF-1/rhIGFBP-3 and methods of producing rhIGF-1, respectively. On February 16, 2005, Tercica filed an amended complaint, adding an infringement allegation against us with respect to U.S. Patent No. 5,528,287, or the 287 patent. The claims of the 287 patent are directed to DNA encoding BP53 (i.e. IGFBP-3) and recombinant constructs, transformed host cells and methods for using the same. Genentech and Tercica claim that the production or use of IPLEX , a complex of rhIGF-1/rhIGFBP-3, will infringe these patents. We moved to dismiss the amended complaint for lack of jurisdiction and on other grounds. At a hearing on the motion on April 15, 2005, the court granted our motion and dismissed the case with leave for Genentech and Tercica to refile the complaint. A second amended complaint was filed on April 22, 2005 by Genentech and Tercica against us that, among other things, added Celtrix Pharmaceuticals, one of our wholly-owned subsidiaries, as a defendant. We moved to dismiss the portion of the second amended complaint that relates to the 287 patent. On June 29, 2005, the court denied our motion to dismiss. On July 14, 2005, we filed our answer and counterclaims, in which we denied infringement and sought a declaratory judgment that the

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asserted patents are not infringed, are invalid, and/or are unenforceable. The reply to the counterclaims by Genentech and Tercica was filed on August 5, 2005. On October 17, 2005, Tercica and Genentech filed a third amended complaint adding Insmed Therapeutic Proteins, one of our wholly-owned subsidiaries, as a defendant. The answer and counterclaims in response to the third amended complaint were filed by us on October 27, 2005. Discovery is complete except with respect to Genentech s and Tercica s allegations of willful infringement and a trial is currently scheduled for November 2006.

On May 19, 2006, a hearing was held to determine claim construction and to address summary judgment motions. On June 30, 2006, the court issued its ruling on the meaning of the terms of the claims and on several summary judgment motions. The court adopted some claim interpretations proposed by Genentech and Tercica and others proposed by us. It also adopted some interpretations that were modifications of those proposed by the parties. The court likewise granted certain motions for summary judgment and denied others. The court s rulings did not fully resolve all of the pending issues regarding any of the three patents. The remaining issues will be resolved at trial, which is currently scheduled to commence on November 6, 2006.

With respect to the 414 patent, the court granted Genentech s and Tercica s motion that we infringes claims 1, 2, and 9 of the 414 patent. On July 7, 2006, we moved for leave to file a motion for reconsideration of this portion of the court s order. That motion is currently pending. The court found that due to disputes of material fact, our invalidity defenses will need to be resolved at trial and therefore denied our motion for summary judgment that the claims at issue are invalid.

With respect to the 151 patent, the court granted Genentech s and Tercica s motion for partial summary judgment that the patent was not invalidated by certain prior art. Because of the claim constructions it adopted and disputes of material fact, the court denied our motion for summary judgment on non-infringement of the 151 patent. The question of infringement will now need to be resolved at trial. Our defense that the 151 patent is unenforceable due to inequitable conduct will be resolved at trial.

With respect to the 287 patent, the court ruled on the scope of one disputed claim term. The issue of whether we infringe the 287 patent or whether the claims at issue are valid remain to be resolved at trial.

In a related matter, on May 27, 2005, Genentech and Tercica filed a motion for preliminary injunction seeking an order barring us, until trial, from making, using or selling IPLEX with respect to its allegations of infringement of the 414 and 151 patents, and requesting that we be required to share any Orphan Drug Exclusivity we obtain with Tercica. We filed an opposition to the motion for a preliminary injunction on June 10, 2005. On June 16, 2005, Genentech and Tercica withdrew their motion for a preliminary injunction, but reserved the right to refile such motion. We cannot predict whether Genentech and Tercica will seek a preliminary injunction at another time.

Deceptive Promotional Statements and Unfair Business Practices Claims

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

On June 9, 2006, the court granted our motion to dismiss Tercica s complaint. In so dismissing such complaint, the court ruled, among other things, that Tercica had not met its burden of establishing that the alleged statements made by us constitute false advertising , or that the court had jurisdiction over us in this case and that the venue was proper. Further, by dismissing Tercica s complaint without leave to amend, the court recognized that the deficiencies in Tercica s lawsuit could not be cured by filing another lawsuit against us in the United States District Court for the Northern District of California. We previously notified Tercica that we would seek fees and costs related to Tercica s baseless lawsuit. Given the court s ruling, we intend to pursue a motion with the court seeking reimbursement of fees and costs related to this lawsuit.

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On June 12, 2006, Tercica, filed a complaint in the U.S. District Court for the Eastern District of Virginia, Richmond division alleging that we violated the Lanham Act and related statutes relating to false advertising and unfair competition. Tercica s new filing added new allegations of false and misleading advertising that we disseminated specifically to pediatric endocrinologists, who, for purposes of the Lanham Act and related statutes, are among the relevant community of consumers affected. We filed a motion to dismiss this new complaint on July 27, 2006.

We cannot predict with certainty the outcome of the legal proceedings in which we are involved. We note, however, that an adverse ruling could materially and adversely impact our ability to make, use or sell our products.

An inability to compete successfully will materially adversely affect our business, financial condition and results of operations.

We engage in a business characterized by extensive research efforts, rapid developments and intense competition. We cannot assure that our products will compete successfully or that research and development by others will not render our products obsolete or uneconomical. Our failure to compete effectively would 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, as well as 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 trials 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 we will. 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.

Since all of our products are under development, we cannot predict the relative competitive position of our products if they are approved for use. However, we expect that the following factors, among others, will determine our ability to compete effectively:

- safety and efficacy;
- product price;
- ease of administration; and
- marketing and sales capability.

Growth hormone may also be a competitive product for the treatment of some indications that we may pursue with IPLEX . The major suppliers of commercially available growth hormone are Genentech, Eli Lilly, Novo Nordisk, Pfizer and Serono. We believe that Novo Nordisk may be conducting clinical trials for the use of its growth hormone in pediatric IGF-I deficiency. We are also aware that Serono is conducting a Phase III trial with growth hormone for the treatment of HIV associated adipose redistribution syndrome.

In addition, we believe that Genentech, Merck, Novo Nordisk and Pfizer have previously conducted research and development of orally-available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We are not aware of any continued clinical development of these molecules by these companies. We believe that Rejuvenon Corporation may have licensed certain rights to Novo Nordisk s growth hormone secretagogues,

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which are in pre-clinical development. We are also aware that Theratechnologies is developing various peptides that stimulate the release of hormones that could be used in the treatment of some of the same indications we plan to pursue with IPLEX .

Many companies are seeking to develop products and therapies for the treatment of diabetes. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Our largest competitors include Amylin Pharmaceuticals, Bristol-Myers Squibb Company, Eli Lilly, GlaxoSmithKline, Merck, Novartis, Novo Nordisk and Takeda Chemical Industries. Various products are currently available to treat type 2 diabetes, such as insulin and oral hypoglycemic drugs.

In addition, several companies are developing various new approaches to improve the treatments of type 1 and type 2 diabetes. Specifically, Amylin Pharmaceuticals has conducted and is continuing to conduct clinical trials for two products, Symlin and Exenatide, for the treatment of type 2 diabetes. Tercica has indicated that it plans to pursue the development of rhIGF-I in the treatment of severe forms of diabetes.

Many companies are pursuing the development of products for the treatment of cancer. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Although we are unaware of any companies developing rhIGFBP-3 for cancer we are aware of companies who are developing products that are intended to target the same pathway as rhIGFBP-3.

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 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.

Our inability to compete in our industry could materially adversely affect our business, financial condition and results of operations.

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

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including hazardous chemicals and radioactive materials. We believe that our procedures for handling hazardous materials comply with federal and state regulations; however, there can be no assurance that accidental injury or contamination from these materials will not occur. In the event of an accident, we could be held liable for any damages, which could exceed our available financial resources, including our insurance coverage. This liability could materially adversely affect our business, financial condition and results of operations.

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

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

The manufacture and sale of human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. We currently have only limited product liability insurance for clinical trials and commercial sales We do not know if we will be able to maintain

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existing or obtain additional product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our products. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts. This could have a material adverse effect our business, financial condition and results of operations.

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

Our common stock is listed on the Nasdaq Stock Exchange 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 Stock Exchange;
- results of our clinical trials and pre-clinical studies, or those of our corporate partners or our competitors;
- our operating results;
- developments in our relationships with our corporate partners;
- developments affecting our corporate partners;
- negative regulatory action or regulatory approval with respect to our announcement or our competitors announcement of new products;
- government regulations, reimbursement changes and governmental investigations or audits related to us or to our products;
- developments related to our patents or other proprietary rights or those of our competitors;
- changes in the position of securities analysts with respect to our stock; and/or
- operating results below the expectations of public market analysts and investors.

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

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

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

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

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Certain provisions of Virginia law, our articles of incorporation and our amended and restated bylaws, and our Stockholder 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 Shareholder Rights Plan under which shareholders received rights to purchase new shares of preferred stock if a person or group acquires 15% or more of our common stock. These provisions are intended to discourage acquisitions of 15% or more of our common stock without negotiations with the board. The rights trade with our common stock, unless and until they are separated upon the occurrence of certain future events. Our board of directors may redeem the rights at a price of $0.01 per right prior to the time a person acquires 15% or more of our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At the Company s Annual Meeting of Stockholders held on May 10, 2006, the stockholders took the following actions:

The Company Stockholders elected three Class III directors as follows:

		Votes
Director	**Votes For**	**Withheld**
Dr. Geoffrey Allan	83,337,381	816,642
Dr. Melvin Sharoky	83,632,258	521,765
Dr. Randall W. Whitcomb	83,617,101	536,922

No other persons were nominated, nor received votes for election as a Director of the Company at the 2006 Annual Meeting of Stockholders. The other Directors of the Company whose terms continued after the 2006 Annual Meeting of Stockholders were Mr. Kenneth G. Condon, Dr. Steinar J. Engelsen and Dr. Graham K. Crooke.

The Company Stockholders ratified the selection of Ernst & Young LLP as auditors for the fiscal year ending December 31, 2006 as follows:

	Votes For	**Votes Against**	**Abstain**
Ratification of selection of Ernst & Young LLP	83,707,754	351,786	94,483

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

10.1 Office lease, dated August 4, 2006 by and between Highwoods Realty Partnership and Insmed Incorporated.

31.1 Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmed Incorporated, pursuant to Securities Exchange Act Rules 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.

31.2 Certification of Kevin P. Tully, C.G.A., Executive Vice President and Chief Financial Officer of Insmed Incorporated, pursuant to Securities Exchange Act Rules 13a-14(a) and amended-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.

32.1 Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.*

32.2 Certification of Kevin P. Tully, C.G.A., Executive Vice President and Chief Financial Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.*

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

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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: August 9, 2006

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

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