ZYMOGENETICS INC
Form 10-Q
November 05, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(MARK ONE)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2009

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number: 0-33489

ZYMOGENETICS, INC.

(exact name of registrant as specified in its charter)

Washington	91-1144498
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1201 Eastlake Avenue East, Seattle, Washington 98102

(Address of principal executive offices) (Zip Code)

(206) 442-6600

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

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Common stock outstanding at October 30, 2009: 69,281,121 shares.

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ZYMOGENETICS, INC.

Quarterly Report on Form 10-Q

For the quarterly period ended September 30, 2009

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PART I FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

ZYMOGENETICS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

	September 30, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$ 91,331	$ 50,088
Short-term investments	12,035	39,799
Receivables	7,050	11,249
Inventory	57,081	28,241
Prepaid expenses	5,039	3,579
Total current assets	172,536	132,956
Property and equipment, net	59,651	63,676
Deferred financing costs, net	5,541	6,726
Long-term investment	2,049	1,547
Other assets	3,614	5,141
Total assets	$ 243,391	$ 210,046
Liabilities and Shareholders (Deficit) Equity		
Current liabilities		
Accounts payable	$ 7,885	$ 8,834
Accrued liabilities	14,482	13,099
Lease obligations	739	563
Deferred revenue	34,854	34,472
Collaboration obligation	55,178	
Total current liabilities	113,138	56,968
Lease obligations	66,918	67,366
Debt obligation	25,000	25,000
Deferred revenue	29,799	33,374
Collaboration obligation	26,900	
Other long-term liabilities	3,397	3,979
Commitments and contingencies		
Shareholders (deficit) equity		
Preferred stock, no par value, 30,000 shares authorized, no shares issued and outstanding		
	797,623	786,736

Common stock, no par value, 150,000 shares authorized, 69,141 and 68,736 issued and outstanding at September 30, 2009 and December 31, 2008, respectively		
Non-voting common stock, no par value, 30,000 shares authorized, no shares issued and outstanding		
Accumulated deficit	(818,754)	(762,203)
Accumulated other comprehensive loss	(630)	(1,174)
Total shareholders (deficit) equity	(21,761)	23,359
Total liabilities and shareholders (deficit) equity	$ 243,391	$ 210,046

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

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ZYMOGENETICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues				
Product sales, net	$ 8,492	$ 1,758	$ 18,999	$ 4,129
Royalties	420	1,598	1,036	4,832
Collaborations and licenses	18,544	8,520	54,838	29,009
Total revenues	27,456	11,876	74,873	37,970
Costs and expenses				
Costs of product sales	1,722	695	4,101	994
Research and development	21,349	30,216	75,223	102,524
Selling, general and administrative	13,658	15,038	45,398	45,620
Total costs and expenses	36,729	45,949	124,722	149,138
Loss from operations	(9,273)	(34,073)	(49,849)	(111,168)
Other income (expense)				
Investment income	251	490	1,141	3,120
Interest expense	(2,767)	(2,252)	(8,210)	(6,074)
Gain (loss) on sale of fixed assets	(18)	7,045	5	7,057
Total other income (expense)	(2,534)	5,283	(7,064)	4,103
Loss before income tax benefit	(11,807)	(28,790)	(56,913)	(107,065)
Income tax benefit	363		363	
Net loss	$ (11,444)	$ (28,790)	$ (56,550)	$ (107,065)
Basic and diluted net loss per share	$ (0.17)	$ (0.42)	$ (0.82)	$ (1.56)
Weighted-average number of shares used in computing net loss per share	69,073	68,724	68,993	68,632

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

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ZYMOGENETICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2009	**2008**
Operating activities		
Net loss	$ (56,550)	$ (107,065)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	5,323	5,328
Amortization of debt issuance costs	1,174	340
Net gain on disposition of property and equipment	(5)	(7,057)
Stock-based compensation	10,118	15,982
Net realized (gain) loss on sale of short-term investments	(3)	231
Impairment loss on short-term investments		400
Net amortization of premium on short-term investments	15	183
Changes in operating assets and liabilities		
Receivables	4,199	(10,023)
Inventory	(28,840)	(27,316)
Prepaid expenses	(1,460)	758
Other assets	1,527	917
Accounts payable	(949)	(2,442)
Accrued liabilities	1,383	876
Lease obligations	(272)	825
Deferred revenue	(3,193)	34,339
Collaboration obligation	82,078	
Other long-term liabilities	(582)	(917)
Net cash provided by (used in) operating activities	13,963	(94,641)
Investing activities		
Purchases of property and equipment	(1,306)	(3,707)
Purchases of short-term investments		(63,397)
Proceeds from sale of property and equipment	13	11,690
Proceeds from sale and maturity of short-term investments	27,793	153,348
Net cash provided by investing activities	26,500	97,934
Financing activities		
Debt financing cost		(1,299)
Proceeds from exercise of stock options	780	513
Net cash provided by (used in) financing activities	780	(786)
Net increase in cash and cash equivalents	41,243	2,507
Cash and cash equivalents at beginning of period	50,088	29,237

Cash and cash equivalents at end of period	$ 91,331	$ 31,744
Supplemental disclosures		
Cash paid for interest	$ 5,892	$ 3,794

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

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Basis of presentation

The accompanying unaudited consolidated financial statements of ZymoGenetics, Inc. (the Company) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the instructions to Form 10-Q. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. In the opinion of management, the financial statements reflect all normal recurring adjustments necessary to present fairly the Company s financial position and results of operations as of and for the periods indicated. Operating results for such periods are not necessarily indicative of the results that may be expected for the full year or for any future period.

These unaudited interim financial statements should be read in conjunction with the audited financial statements and related footnotes included in the Company s Annual Report filed on Form 10-K for the year ended December 31, 2008.

The preparation of financial statements in conformity with generally accepted accounting principles 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 that affect the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

The Company expects to fund its future operations using its existing cash resources, revenues from RECOTHROM sales, and cash generated from existing and newly established collaborations and licenses and public and private financing, including debt or equity financings. In particular, the co-development/co-promotion and license agreement with Bristol-Myers Squibb, executed in January 2009 (see Note 6), provided the Company with $105.0 million in March 2009. The Company also met milestones under the agreement in June 2009 of $25.0 million, which was received in July 2009, and in October 2009 of $70.0 million. The $70.0 million milestone payment is due to be received by the Company in November 2009. In addition, the Company has $75.0 million contractually available under a financing arrangement with Deerfield Management that can be drawn at any time until January 26, 2010 (see Note 5). The Company restructured its operations in April 2009 and reduced its workforce by 32% or approximately 160 employees. The Company believes that it has sufficient cash resources to fund its operations for at least the next two years; however, this outlook is dependent upon future events, including the sales performance of RECOTHROM, progress in the development activities for PEG-Interferon lambda and potential borrowings from Deerfield.

Effective January 1, 2009, the Financial Accounting Standards Board (FASB) requires companies to disclose the nature and purpose of their collaborative arrangements in their annual financial statements, their rights and obligations under the collaborative arrangements, the stage of the underlying endeavors life cycle, the company s accounting policies for the arrangements and the income statement classification and amount of significant financial statement amounts related to the collaborative arrangements. The Company has disclosed the nature of its collaboration agreements entered into prior to the adoption of this FASB release in its 2008 Form 10-K and its license and collaboration with Bristol-Myers Squibb in Note 6.

2. Loss per share

Basic and diluted net loss per share have been computed based on net loss and the weighted-average number of common shares outstanding during the applicable period. The Company has excluded certain options to purchase common stock, restricted stock units and warrants to purchase common stock, as such potential shares are antidilutive. The following table presents the securities not included in the net loss per share calculations for the periods ended September 30 (in thousands):

	2009	2008
Options to purchase common stock	15,322	13,959
Restricted stock units	281	593
Warrants to purchase common stock	1,500	

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

3. Available-for-sale securities

Short-term investments

Short-term investments consisted of the following at September 30, 2009 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Type of security:				
Asset-backed securities	$ 13,714	$ 7	$ (1,686)	$ 12,035
Contractual maturity date:				
Due in 1-5 years	$ 4,433			$ 4,436
Due in 5-10 years				
Due in 10 years or more	9,281			7,599
	$ 13,714			$ 12,035

The Company has evaluated its debt securities that have an estimated fair value below their carrying value and concluded that it does not intend to sell those securities and it is not more likely than not the Company will be required to sell those securities before the anticipated recovery of its amortized cost. In addition, the Company determined whether credit losses existed for any of its debt securities by calculating the present value of the future cash flows and concluded that a credit loss of $400,000 existed. This credit loss was recorded as an other-than-temporary impairment in the third quarter of 2008. As of September 30, 2009, the weighted average expected maturity dates for all securities did not exceed three years.

Long-term investment

Included in other assets is a long-term investment in common shares of BioMimetic Therapeutics, Inc. (BMTI), a company that licensed certain technologies from the Company and made certain payments in shares of common stock. These shares are publicly traded and are adjusted to fair value, with the unrealized gain reported as a separate component of shareholders equity. For the three months ended September 30, 2009, the unrealized gain on the investment increased by $498,000 and for the nine months ended September 30, 2009, the unrealized gain on the investment increased by $502,000. As of September 30, 2009, the unrealized gain on the investment was $1.1 million.

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

Fair value measurements

The Company records its short-term and long-term investments at fair value. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price) and establishes a fair value hierarchy based on the inputs used to measure fair value. The three levels of the fair value hierarchy are as follows:

Level 1 Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities (for example exchange quoted prices);

Level 2 Observable inputs, other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not sufficiently active to qualify as Level 1, other observable inputs, or inputs that can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3 Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels. The Company s assets and liabilities accounted for at fair value as of September 30, 2009 are summarized below (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 39,366	$	$	$ 39,366
Short-term investments:				
Asset-backed securities	$	$ 12,035	$	$ 12,035
Long-term investment:				
BMTI common stock	$ 2,049	$	$	$ 2,049

4. Inventory

Inventory is stated at the lower of cost or market. Cost includes amounts related to materials, labor and overhead, and is determined on a specific identification basis in a manner which approximates the first-in, first-out (FIFO) method. Inventory balances reflect the cost of post-approval manufacturing activities for RECOTHROM. The manufacturing of RECOTHROM requires multiple steps which are performed by a series of single-source third-party contractors based upon the Company s specifications. As protection against product shortages, the Company maintains safety stocks of inventory at each stage in the manufacturing process and has entered into manufacturing contracts, some of which contain annual minimum purchase commitments. The Company reduces inventory to its estimated net realizable value by reserving for excess and obsolete inventories based on forecasted demand. Inventory consisted of the following (in thousands):

	September 30, 2009	December 31, 2008
Raw materials	$ 2,256	$ 1,664
Work in process	52,865	25,751
Finished goods	1,960	826
Total	$ 57,081	$ 28,241

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

5. Debt financing

In June 2008, the Company entered into a financing arrangement with Deerfield Management (Deerfield), whereby the Company can borrow up to $100.0 million in four draws of $25.0 million each until January 26, 2010. Interest will accrue on amounts outstanding at a rate of 4.9% per annum, compounded quarterly, and will be due, along with outstanding principal, in June 2013. Each $25.0 million draw entitles Deerfield to a royalty equal to 2% of U.S. RECOTHROM net sales. The cumulative royalty will not exceed $45.0 million assuming the Company draws the entire $100.0 million and the cumulative royalties will be lower if the Company borrows less than $100.0 million. In addition, the Company agreed to issue Deerfield warrants to purchase 1.5 million shares of common stock at $10.34 per share at the earlier of the first draw or January 2010, and warrants to purchase 1.0 million shares each upon the second, third and fourth draws exercisable at a 25% premium to the average sale price of the Company s common stock for the 15 trading days prior to the draw. All warrants will have a six-year term and the Company is obligated to register with the Securities and Exchange Commission the common stock issuable under the warrants. The Company can repay borrowed amounts in whole or in part at any time, without penalty, and all associated interest and royalty obligations will cease.

In November 2008, the Company borrowed the first $25.0 million under the Deerfield financing arrangement and issued the related warrant to purchase 1.5 million shares. Deferred financing costs of $5.5 million are being amortized to interest expense through June 2013. Additionally, the Company accrues interest expense at a rate of 4.9% per annum, compounded quarterly and royalties equal to 2% of U.S. RECOTHROM net sales. During the three and nine-month periods ended September 30, 2009, $861,000 and $2.5 million, respectively, of related financing costs were recorded as interest expense.

6. Bristol-Myers Squibb agreement

In January 2009, the Company entered into a co-development/co-promotion and license agreement with Bristol-Myers Squibb for the type-3 interferon family, with PEG-Interferon lambda being the lead product candidate. The Company is primarily responsible for the completion of certain Phase 1 and Phase 2 clinical trials while Bristol-Myers Squibb is responsible for certain Phase 2 and the Phase 3 clinical trials, clinical and commercial manufacturing, the drug approval process and commercialization of any approved drugs. The Company is required to fund the first $100.0 million of joint development costs and additional development costs will be funded 80% by Bristol-Myers Squibb with the Company funding the remaining 20%. The Company is obligated to transfer all materials and manufacturing know-how to Bristol-Myers Squibb and will continue to exchange enabling technology through the commercialization period. The Company will also participate on Executive, Development and Commercialization steering committees. The Company has the right to cease contributing to all development and commercialization costs at any time, which would convert the agreement into a royalty arrangement. If the Company elects to convert to a royalty arrangement, the Company would still be required to fund the first $100.0 million of development costs and it would no longer participate on any of the steering committees.

The Company s substantive obligations under this agreement are expected to be satisfied in 2012, and it has the right to discontinue its funding obligations and active participation in the agreement at any time. The Company records revenue under the agreement as a single unit of accounting. As the Company is able to estimate its program costs through the performance period, revenue has been recognized using the proportional performance methodology. Of the $105.0 million of license fees received in March 2009, $100.0 million was recorded as a liability (the Collaboration Obligation) due to the Company s commitment to fund the initial $100.0 million of development costs incurred by both companies. The reimbursement of the Company s development costs from the Collaboration Obligation, together with the milestones earned and expected to be earned during the performance period, will be recognized as collaboration revenue by the Company based on the percentage of its total allowable program costs incurred to date compared to its total expected allowable program costs over the performance period.

For the three and nine-month periods ended September 30, 2009, the Company recorded collaboration and license revenue of $13.6 million and $30.1 million, based on the proportional performance formula described above. In July 2009, the Company received a $25.0 million milestone payment, which was recorded as deferred revenue.

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

As of September 30, 2009, the remaining balance of the Collaboration Obligation was $82.1 million and deferred revenue was $17.6 million.

In October 2009, the Company initiated a Phase 2 clinical trial that triggered a $70.0 million milestone payment from Bristol-Myers Squibb. The Company expects to receive the associated milestone payment in November 2009 and it will be recorded as deferred revenue.

7. Stock compensation

The following table shows stock-based compensation expense by expense classification and type of award for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research and development expense				
Stock options	$ 1,213	$ 2,755	$ 5,249	$ 8,834
Restricted stock units	236	352	780	899
Unrestricted stock grants				519
	1,449	3,107	6,029	10,252
Selling, general and administrative expense				
Stock options	1,064	1,676	3,859	5,298
Restricted stock units	73	85	230	204
Unrestricted stock grants				228
	1,137	1,761	4,089	5,730
Total	$ 2,586	$ 4,868	$ 10,118	$ 15,982

No income tax benefit has been recorded for stock option exercises as the Company has a full valuation allowance and management has concluded it is more likely than not that the net deferred tax asset will not be realized.

8. Income tax benefit

In February 2008, the Economic Stimulus Act of 2008 (Act) was enacted which provided a tax incentive to encourage companies to purchase equipment in 2008. The Act also permitted companies that are in a tax loss position for 2008 to receive a tax refund for a portion of the cost of qualifying equipment purchased. The Company recorded an income tax benefit of $363,000 related to its qualified 2008 equipment purchases.

9. Comprehensive loss

For the three and nine months ended September 30, 2009, total comprehensive loss was $10.3 million and $56.0 million, respectively. For the three and nine months ended September 30, 2008, total comprehensive loss was $29.4 million and $109.7 million, respectively. Comprehensive loss is composed of net loss and unrealized gains and losses on short-term and long-term investments. The net change in accumulated other comprehensive loss for the nine months ended September 30, 2009 was a decrease of $544,000, reflecting a $42,000 decrease in net unrealized losses on short-term investments and an increase of $502,000 in unrealized gain on long-term investments.

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

10. Related party transactions

Novo Nordisk owned approximately 30% of the Company s outstanding common stock at September 30, 2009 and 2008.

Option and license agreement

In 2000, Novo Nordisk entered into an option and license agreement with the Company which, including extensions, expired in November 2006. Under the terms of the agreement, Novo Nordisk entered into individual license agreements for various proteins. Novo Nordisk is responsible for all development activities for the licensed proteins and is obligated to make payments upon the achievement of predefined development milestones and to pay royalties on sales of any resulting products.

Pursuant to these individual license agreements, the Company earned and recognized as revenue milestone payments of $3.5 million and $2.0 million for the nine-month periods ended September 30, 2009 and 2008, respectively.

Factor XIII

In 2004, the Company entered into a license agreement with Novo Nordisk with respect to recombinant Factor XIII (rFactor XIII). Novo Nordisk is independently developing and commercializing rFactor XIII on a worldwide basis and the Company has no significant continuing obligations under the license agreement. In February 2008 and May 2008, the Company received and recorded as revenue milestone payments of $2.5 million each related to Novo Nordisk s achievement of certain manufacturing targets for rFactor XIII.

11. Recent accounting pronouncements

In April 2009, the FASB issued authoritative guidance for estimating the fair value of a financial asset or liability when the volume and level of market activity for such asset or liability have decreased significantly and guidance on identifying circumstances that indicate when a transaction is not orderly. In situations where the volume and level of activity have decreased significantly or where transactions are deemed to be disorderly, quoted market prices may not be determinative of fair value. In such situations, the guidance calls for adjustments to quoted market prices in determining fair value. These adjustments may involve the use of other valuation techniques such as the present value of anticipated cash flows. This guidance is effective for interim and annual periods ending after June 15, 2009, and was to be applied prospectively. The Company s adoption of this guidance did not have a material impact on its results of operations, cash flows or financial condition.

In April 2009, the FASB issued authoritative guidance for debt securities and additional guidance regarding the credit and noncredit component of an other-than- temporary impairment (OTTI) event as it applies to debt securities, requiring that credit losses of an OTTI be included in the statement of operations. This was effective for interim and annual periods ending after June 15, 2009, and was to be applied prospectively. The Company s adoption of this guidance did not have a material impact on its results of operations, cash flows or financial condition.

In May 2009, the FASB issued authoritative guidance for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The guidance, which includes a new required disclosure of the date through which an entity has evaluated subsequent events, was effective for interim or annual periods ending after June 15, 2009. The Company s adoption of this guidance did not have a material impact on its results of operations, cash flows or financial condition.

In October 2009, the FASB issued authoritative guidance on revenue arrangements with multiple deliverables. Under the new guidance, when vendor specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, a best estimate of the selling price is required to separate deliverables and allocate arrangement consideration using the relative selling price method. The

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ZYMOGENETICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

new guidance includes new disclosure requirements on how the application of the relative selling price method affects the timing and amount of revenue recognition. This guidance is effective for fiscal years beginning after June 15, 2010. The Company believes the adoption of this new guidance will not have a material impact on its results of operations, cash flows or financial condition.

12. Subsequent events

In October 2009, the Company initiated a Phase 2 clinical trial that triggered a $70.0 million milestone payment from Bristol-Myers Squibb. The Company is entitled to receive the associated milestone payment in November 2009.

On November 2, 2009, King Pharmaceuticals, Inc., Monarch Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc., and GenTrac, Inc. (King) filed suit against the Company in the United States District Court for the Eastern District of Tennessee, naming the Company and fifty unnamed individuals as defendants. King alleges that the Company has engaged in unfair competition, false advertising, trademark infringement, and related claims under federal law and Tennessee state law. King seeks various forms of relief, including damages and injunctive relief precluding the Company from making certain representations regarding King s products and the Company s RECOTHROM product. King also filed motions with the District Court seeking temporary restraining orders and preliminary injunctive relief. On November 3, 2009, following a hearing in which the Company did not have an opportunity to participate, the District Court entered three Temporary Restraining Orders (TROs) temporarily prohibiting the Company from engaging in certain marketing or promotional conduct related to RECOTHROM. The Company is seeking immediate relief from the District Court to vacate the TROs, and it will seek an immediate hearing on this motion. A hearing on King s motions for preliminary injunctive relief is scheduled for November 16, 2009, and the Company will oppose King s request for preliminary injunctive relief at that hearing. In the interim, the Company is taking steps to comply with the TROs while they remain in effect. The Company disputes the allegations of wrongdoing in King s complaint and intends to vigorously defend itself in this matter, including opposing King s motions for preliminary injunctive relief. The Company is currently in the process of evaluating the potential financial impact of this suit and believes this litigation will not have a material impact on its results of operations, cash flows or financial condition.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

The following discussion and analysis should be read in conjunction with the financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2008. This Quarterly Report on Form 10-Q contains, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. This Act provides a safe harbor for forward-looking statements. All statements other than statements of historical fact made in this Quarterly Report on Form 10-Q are forward looking. When used in this Quarterly Report on Form 10-Q, the words may, will, should, could, would, estimate projects, believes, expects, anticipates, intends, plans and similar expressions, are intended to identify certain of these forward-looking statements. However, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: industry prospects and future results of operations or financial position, sales of and commercialization efforts related to RECOTHROM, achievement of milestones and payments under collaboration agreements, the progress of our research programs including clinical testing, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our future operating expenses, our future losses, our future expenditures for research and development, pending or threatened litigation and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission. The cautionary statements made in this Quarterly Report on Form 10-Q should be read as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report on Form 10-Q. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to revise any forward-looking statements whether as a result of new information, future events, or otherwise. Readers are urged to carefully review and consider the various disclosures made in this Quarterly Report on Form 10-Q and in our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks and other factors that may affect our business, prospects, results of operations and financial condition.

Business Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing therapeutic protein-based products for the treatment of human diseases. The process for taking one of our discoveries to the marketplace is long, complex and very costly. It is difficult to predict the time it will take to reach the market with any given product candidate, but it would not be unusual to span ten years or more and cost hundreds of millions of dollars. It is also a business of attrition; it is expected that, for the industry as a whole, less than 20% of the drug candidates entering human clinical trials will actually make it to the marketplace. For the products that do make it, particularly for those that address previously unmet medical needs, the markets can be significant, with a number of successful products selling in excess of $1 billion per year.

RECOTHROM®, recombinant thrombin, is a topical hemostatic agent used for the control of moderate bleeding during surgical procedures, which was approved by the Food and Drug Administration or FDA on January 17, 2008. We have retained the commercial rights to RECOTHROM in the U.S. We are marketing RECOTHROM in the U.S. using our own commercial infrastructure, which includes a dedicated field force of sales people and medical scientific liaisons. In June 2007, we entered into a license and collaboration agreement with Bayer Schering Pharma AG for development and commercialization of RECOTHROM outside of the U.S. Simultaneously, we entered into a co-promotion agreement with Bayer

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Healthcare LLC under which Bayer is assisting us with the promotion of RECOTHROM in the U.S. for up to four years, ending in March 2012. We have hired approximately 60 field personnel and additional headquarters-based personnel to support the commercial operations that are necessary for selling RECOTHROM. We are incurring substantial marketing costs to support the selling effort. We are also maintaining significant levels of inventory and have entered into long-term manufacturing agreements with contractual minimum purchase commitments to meet the expected demand for the product and minimize the risk of product shortages. These commercialization activities have and will continue to utilize substantial cash resources until such time as RECOTHROM sales reach a level, if ever, that will cover our related costs. While we anticipate higher revenue generation from RECOTHROM sales over time, we cannot be certain of the future rate of market penetration, if revenues will increase or when, if ever, our revenues will exceed our related costs.

An important element of our business strategy is that we intend to maintain a significant share of the commercial value for certain of our products under development. As a result, we will be required to pay a significant portion of the development and commercialization costs for these products. Even if we decide to license a product candidate to another company, we will generally be required to pay research and development costs up to the point of licensing. Another important element of our strategy is that we maintain research and development operations that enable us to discover new product candidates and advance them to the point where we can demonstrate clinical proof of concept. These operations are expensive to maintain and the level of output is uncertain. Substantial funding is required on an ongoing basis to maintain these operations.

Generating the funding necessary to operate our business is challenging. There are a number of potential sources of revenues and cash that we pursue in order to address our funding needs, including the following:

- sales of RECOTHROM, net of all related discounts and allowances;
- research, development and commercialization collaborations, such as the ones we have entered into with Bayer for RECOTHROM and Bristol-Myers Squibb for PEG-Interferon lambda, which provide the opportunity to earn revenues while also helping us to fund our ongoing research and development expenses;
- licensing of technologies or product candidates, such as atacicept and recombinant Factor XIII, to other companies, which typically provide license fees and potential milestone payments and royalties on sales;
- issuance of equity or equity-based securities;
- debt financing, such as the $100.0 million financing arrangement we entered into with Deerfield Management in June 2008; and
- investment income on our cash reserves.

We expect that it will be at least several years before we can generate enough product-related revenues to reach net income or cash flow breakeven, and we expect to continue to invest significant amounts of cash in developing our business. We intend to pursue additional collaboration and license transactions as a means of generating additional cash and reducing our ongoing expenses. These transactions may involve our product candidate IL-21, currently in Phase 2 clinical trials, and our earlier stage candidates that have not yet begun clinical testing. Additionally, as part of our corporate restructuring in April 2009, we reduced our work force by 32% or approximately 160 employees, as a means of further reducing operating costs, primarily in research and development. We believe this reduction will generate annual cost savings of approximately $30 million.

In addition, it is possible that we will look for opportunities to raise capital by issuing equity or equity-related securities to help fund our company over the next several years. These opportunities may arise at any time, depending on things such as overall market conditions, dynamics in the biotechnology sector of the market, investor appetite for certain types of investments, and fundamental characteristics of our business. At other times, it may be difficult to raise capital on terms favorable to our company, if at all, especially in light of the current global economic conditions. Accordingly, we may raise capital when it is available, whether or not there is an immediate need.

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Results of Operations

Revenues

Product sales. The FDA granted marketing approval of RECOTHROM on January 17, 2008 for the 5,000 IU vial configuration and on May 27, 2008 for the 20,000 IU vial configurations. Sales of RECOTHROM are recognized as revenue when the product is shipped and title and risk of loss have passed. Product sales are recorded net of provisions for estimated discounts, rebates, chargebacks and returns. Net product sales increased by $6.7 million to $8.5 million and by $14.9 million to $19.0 million for the three and nine-month periods ended September 30, 2009, respectively, as compared to the corresponding periods in 2008. The increase is due to overall market share increases as additional hospitals convert usage from bovine thrombin to RECOTHROM and existing customers increased their purchase volumes of RECOTHROM.

Royalties. We earn royalties on sales of certain products subject to license agreements with other companies. Royalties decreased by $1.2 million and $3.8 million for the three and nine-month periods ended September 30, 2009 as compared to the corresponding periods in 2008. The decreases were primarily due to the discontinuation of a minimum royalty obligation payable by BioMimetic Therapeutics, Inc. on its product GEM 21S and the expiration of royalty rights related to BeneFIX, a product of Wyeth Pharmaceuticals, Inc., in December 2008.

Collaborations and licenses. We enter into various collaborative agreements that may generate license, option or other upfront fees with subsequent milestone payments earned upon completion of development milestones. Where we have no continuing performance obligations under an arrangement, we recognize such payments as revenue when contractually due and payment is reasonably assured, as these payments represent the culmination of a separate earnings process. Where we have continuing performance obligations under an arrangement, revenue is recognized using one of two methods. Where we are able to estimate the total amount of services under the arrangement, revenue is recognized using a proportional performance model. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangement. Revenue recognized at any point in time is limited to cash received and amounts contractually due. Changes in estimates of total expected performance are accounted for prospectively as a change in estimate. Where we cannot estimate the total amount of service that is to be provided, a time-based method is used to recognize revenue. Under the time-based method, revenue is recognized over the arrangement s estimated performance period, starting with the contract s commencement, but not before the removal of any contingencies for each milestone. From period to period, license fees and milestone payments can fluctuate substantially based on the completion of new licensing or collaborative agreements and the achievement of development-related milestones.

In January 2009, we entered into a co-development/co-promotion and license agreement with Bristol-Myers Squibb for the type-3 interferon family, with PEG-Interferon lambda being the lead product candidate. We received $105.0 million in license fees in March 2009 and are entitled to receive milestone payments based on the achievement of certain objectives, including two additional milestone payments totaling $95.0 million related to the initiation of Phase 2 clinical trials. The first of these, in the amount of $25.0 million, was received in July 2009. The second milestone of $70.0 million was achieved in October 2009 and we are entitled to receive the payment in November 2009. We also received profit sharing and co-promotion rights in the U.S. and will receive royalties on sales outside of the United States. We are also eligible for sales bonuses based on world-wide sales of licensed products. We have granted a license to related technology and are obligated to fund the first $100.0 million of costs for development in the U.S. and Europe, after which we will be responsible for 20% of such costs. We are recognizing revenue using a proportional performance model. We are recording revenue related to the license fees and near-term milestone payments over approximately 42 months, which corresponds to the period over which we anticipate satisfying our performance obligations under the agreement.

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Collaboration and license revenues were $18.5 million and $54.8 million for the three and nine-month periods ended September 30, 2009, reflecting increases of $10.0 million and $25.8 million, respectively, as compared to the corresponding periods in 2008. The increases resulted primarily from the following:

- increases in collaboration revenue of $13.6 million and $30.1 million for the three and nine-month periods ended September 30, 2009, respectively, related to the Bristol-Myers Squibb agreement for PEG-Interferon lambda signed in January 2009; and

- increases in license revenue of $2.1 million and $8.5 million, for the three and nine-month periods ended September 30, 2009, respectively, due to the accelerated recognition of deferred revenue resulting from the August 2008 restructuring of our agreements with Merck Serono.

These increases were partially offset by the following:

- decreases in Bayer collaboration revenue of $4.4 million and $7.7 million for the three and nine-month periods ended September 30, 2009, respectively due to revisions to expected revenues during the remaining performance period, and

- decreases in milestone revenue related to licenses with Novo Nordisk for the nine-month period ended September 30, 2009, and a license with BioMimetic Therapeutics, Inc. for both the three and nine-month periods ended September 30, 2009.

For the three and nine months ended September 30, 2009, changes in deferred collaboration and license revenue were as follows:

	Three Months Ended September 30. 2009	Nine Months Ended September 30. 2009
Beginning balance	$ 74,745	$ 67,846
Cash received or receivable	30	30,530
Revenue recognized	(10,122)	(33,723)
Ending balance	$ 64,653	$ 64,653

As of September 30, 2009, the deferred revenue balances related to the Merck Serono agreements, the Bayer agreement, and the Bristol-Myers Squibb agreement were $629,000, $46.4 million and $17.6 million, respectively. As of September 30, 2009, the remaining Collaboration Obligation related to funding the first $100.0 million of development costs under the Bristol-Myers Squibb collaboration was $82.1 million.

Costs and expenses

Costs of product sales. Costs of product sales include the inventory and distribution costs associated with RECOTHROM product revenue. Prior to FDA approval of RECOTHROM in January 2008, all third-party manufacturing costs and an allocation of our labor and overhead associated with the manufacturing of RECOTHROM for commercial sale were expensed as research and development costs as incurred. Subsequent to approval, third-party manufacturing costs and labor and overhead associated with the commercial manufacturing of RECOTHROM are recorded as inventory. Accordingly, we expect that costs of product sales will be lower during the time we are selling product manufactured prior to approval.

Cost of product sales as a percentage of net product sales were 20.3% and 39.5% for the three months ended September 30, 2009 and 2008, respectively, and 21.6% and 24.1% for the nine months ended September 30, 2009 and 2008, respectively. The percentages were higher in 2008 compared to 2009 because of a $400,000 charge for obsolete inventory recorded in the three-month period ended September 30, 2008.

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Research and development. Research and development expense consists primarily of salaries and benefit expenses, costs of consumables, facility costs, contracted services and stock-based compensation. Research and development expense has been partially offset by cost reimbursements from collaborators for work performed on various co-development programs where each party shares costs and actively participates throughout the collaboration. A breakdown of research and development expenses is shown in the following table (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Salaries and benefits	$ 7,049	$ 11,453	$ 37,727	$ 41,695
Consumables	1,377	2,832	5,160	8,822
Facility costs	1,850	1,964	5,979	6,933
Contracted services	8,934	11,635	18,966	41,074
Depreciation and amortization	1,143	1,190	3,575	3,669
Stock-based compensation	1,449	3,106	6,029	10,252
Subtotal	21,802	32,180	77,436	112,445
Cost reimbursement from collaborators	(453)	(1,964)	(2,213)	(9,921)
Net research and development expense	$ 21,349	$ 30,216	$ 75,223	$ 102,524

Salaries and benefits, stock-based compensation and consumables generally track with changes in our employee base from year to year. In April 2009 and February 2008, we reduced our research and development headcount by 130 and 37 employees, respectively. Accordingly, we recorded related severance charges of $7.0 million in the second quarter of 2009 and $2.0 million in the first quarter of 2008. Excluding these severance-related amounts, salaries and benefits declined by 38.5% and 22.6% for the three and nine-month periods ended September 30, 2009, respectively, as compared to the same periods in 2008, reflecting the impact of the headcount reductions.

Contracted services include the cost of items such as contract research, contract manufacturing, clinical trials, non-clinical studies and payments to collaborators. These costs primarily relate to clinical development programs and can fluctuate substantially from period-to-period depending on the stage of our various programs. Generally, these external costs increase as a program advances toward commercialization, but there can be periods between major clinical trials or manufacturing campaigns during which costs decline. Our contracted services costs decreased by $2.7 million and $22.1 million for the three and nine-month periods ended September 30, 2009 as compared to the corresponding periods in 2008 primarily due to the discontinuation of our co-development and co-funding obligations under the atacicept Collaborative Development and Marketing Agreement with Merck Serono, which became effective in August 2008 with the restructuring of the agreement. These reductions were partially offset by increased costs related to our PEG-Interferon lambda collaboration with Bristol-Myers Squibb.

To date, our business needs have not required us to fully allocate all research and development costs among our various programs. However, we track direct labor, contracted services and certain consumable costs by program, which we monitor to assist us in appropriately utilizing our company resources. We also incur indirect costs that are not allocated to specific programs. These costs include indirect labor, certain consumable costs, facility costs, and depreciation and amortization, all of which benefit all of our research and development programs. The following table presents our research and development costs allocated to clinical development, pre-development and discovery research programs, together with the unallocated costs that benefit all programs for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Clinical development programs:				
Hemostasis	$ 1,715	$ 4,092	$ 8,105	$ 13,400
Autoimmunity and oncology	499	8,280	3,260	29,931
Antiviral	7,954	1,064	15,726	2,762
Preclinical and research programs	3,570	5,987	13,034	17,297
Unallocated indirect costs	7,611	10,793	35,098	39,134

Total	$ 21,349	$ 30,216	$ 75,223	$ 102,524

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The major trends in research and development program costs for the periods presented in the table were as follows:

Hemostasis program costs decreased for both the three and nine-month periods ended September 30, 2009, as compared to the same periods in 2008, reflecting the completion of certain rThrombin clinical trial programs. Additionally, for the nine-month comparison, a decrease resulted from internal and external RECOTHROM manufacturing costs that were charged to expense prior to FDA approval in January 17, 2008, and subsequent to approval were charged to inventory.

Autoimmunity and oncology clinical development program (atacicept and IL-21) costs decreased for both the three and nine-month periods ended September 30, 2009 as compared to the same periods in 2008 primarily due to the discontinuation of our co-development and co-funding obligations under the atacicept Collaborative Development and Marketing Agreement with Merck Serono.

Antiviral clinical development program costs increased for both the three and nine-month periods ended September 30, 2009 as compared to the same periods in 2008, primarily due to an increase in both internal and external costs related to PEG-Interferon lambda clinical trials.

Preclinical and research program costs decreased for both the three and nine-month periods ended September 30, 2009, as compared to the same periods in 2008, primarily due to the discontinuation of certain preclinical and research programs following our corporate restructuring in April 2009.

Unallocated indirect costs decreased for the three and nine-month periods ended September 30, 2009, as compared to the same periods in 2008, primarily reflecting the corporate restructuring that occurred in April 2009. The decrease in the nine-month period ended September 30, 2009 was partially offset by severance related costs associated with the April 2009 corporate restructuring.

Selling, general and administrative. Selling, general and administrative expense, which consists primarily of salaries and benefit expenses, professional fees and other corporate costs, decreased 9.2% for the three-month period ended September 30, 2009, as compared to the corresponding period in 2008 and remained constant for the nine-month period ended September 30, 2009 as compared to the same period in 2008. The decrease in the three-month period ended September 30, 2009 was primarily due to the reduction in administrative headcount of approximately 30 employees in April 2009 and decreases in stock-based compensation and legal expenses. These decreases were partially offset by an increase in commissions payable to Bayer related to RECOTHROM sales for both the three and nine-month periods ended September 30, 2009 and severance related costs associated with the employee terminations in April 2009 for the nine-month period ended September 30, 2009.

Stock-based compensation. Stock-based compensation expense decreased by $2.3 million and $5.9 million for the three and nine-month periods ended September 30, 2009, respectively, as compared to the corresponding periods in 2008. The decreases were primarily due to a lower underlying share price for stock options granted in 2008 and 2009, forfeiture of stock options related to the termination of

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approximately 160 employees in April 2009, and the unrestricted stock grants made to all employees in recognition of the FDA approval of RECOTHROM in January 2008. The following table shows stock-based compensation expense by expense classification and type of award for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research and development expense				
Stock options	$ 1,213	$ 2,755	$ 5,249	$ 8,834
Restricted stock units	236	352	780	899
Unrestricted stock grants				519
	1,449	3,107	6,029	10,252
Selling, general and administrative expense				
Stock options	1,064	1,676	3,859	5,298
Restricted stock units	73	85	230	204
Unrestricted stock grants				228
	1,137	1,761	4,089	5,730
Total	$ 2,586	$ 4,868	$ 10,118	$ 15,982

Other income (expense)

Investment income. Investment income is generated primarily from investment of our cash reserves in fixed-income securities. The primary factors affecting the amount of investment income that we report are: the amount of cash reserves invested, the effective interest rate, the amount of realized gains or losses on investments sold during the period and the amount of other-than-temporary impairment recorded in the period. The following table shows how each of these factors affected investment income for the periods presented (in thousands, except percentages):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Weighted average amount of cash reserves	$ 116,507	$ 92,955	$ 115,315	$ 129,645
Effective interest rate	0.21%	0.95%	0.99%	2.89%
Investment income before gains and losses	248	880	1,138	3,751
Net gain (loss) on sales of investments	3	10	3	(231)
Other-than-temporary impairment loss		(400)		(400)
Investment income, as reported	$ 251	$ 490	$ 1,141	$ 3,120

Interest expense. We have accounted for a sale-leaseback transaction completed in October 2002 as a financing transaction. Under this method of accounting, an amount equal to the net proceeds of the sale is considered a long-term interest-bearing liability. Rent payments under the leases are considered to be payments toward the liability and are allocated to principal and interest. We recorded related interest expense of $1.9 million and $5.7 million for the three and nine-month periods ended September 30, respectively, in both 2009 and 2008. In addition, we recorded interest expense of $861,000 and $2.5 million for the three and nine-month periods ended September 30, 2009, respectively, related to the Deerfield financing arrangement, which represents amortization of the deferred financing costs, including the assumed fair value of the warrants issued; 4.9% interest on the $25.0 million drawn in November 2008; and additional interest expense equal to 2% of RECOTHROM net sales in the U.S. beginning upon receipt of the $25.0 million draw.

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Liquidity and Capital Resources

As of September 30, 2009, we had cash, cash equivalents and short-term investments of $103.4 million, an increase of $13.5 million from December 31, 2008, primarily due to receipts from Bristol-Myers Squibb totaling $130.0 million in 2009 related to the PEG-Interferon lambda collaboration and license agreement offset by cash used to fund our net loss and to manufacture RECOTHROM. We intend to use these assets to fund our operations and capital expenditures. Our cash reserves have been held in a variety of fixed-income securities, including corporate bonds, commercial paper and money market instruments that were investment grade at the time of purchase. Subsequent to our purchase, some asset-backed securities have been downgraded by the major bond rating agencies. Together with the discretionary investment manager responsible for investing our portfolio, we monitor our investments closely and, based on market conditions and our expected working capital requirements, recorded other-than-temporary impairment loss of $400,000 on one security in the third quarter of 2008. We consider all other unrealized losses totaling $1.7 million to be temporary.

In June 2008, we completed a debt financing arrangement with Deerfield Management enabling us to draw up to $100.0 million in $25.0 million increments. In November 2008, we received our first draw of $25.0 million. Interest accrues on amounts outstanding at a rate of 4.9% per annum, compounded quarterly, and will be due, along with outstanding principal, in June 2013. Each $25.0 million draw entitles Deerfield Management to a royalty equal to 2% of RECOTHROM net sales in the U.S. The cumulative royalty will not exceed $45.0 million over the five-year term of the arrangement assuming we draw the entire $100.0 million. In addition, we issued a six-year warrant to purchase 1.5 million of our common shares upon receiving the initial draw in November 2008 and will issue an additional warrant to purchase 1.0 million of our common shares upon receipt of each additional draw. As of September 30, 2009, $75.0 million remains unused under the arrangement, and such amount can be accessed until January 26, 2010. At this time, we have no specific plans to draw the funds.

Cash flows from operating activities

The amount of cash used to fund our operating activities differs from our reported net losses due to the following items:

- noncash items, such as depreciation and amortization of fixed assets, amortization of deferred debt issue costs, gain or loss on sale or disposal of assets and stock-based compensation, which do not result in uses of cash;
- net realized gains and losses and accretion and amortization of discounts and premiums on short-term investments, which are reflected as sources of cash from investing activities upon maturity or sale of the respective investments;
- changes in receivables, which generally represent temporary timing differences between the recognition of certain revenues and the subsequent receipt of cash payments;
- additions to RECOTHROM inventory subsequent to the January 17, 2008 approval date, which reflect the use of cash but will not be expensed until the related product is sold;
- changes in deferred revenue, which reflect the difference in timing between the receipt of cash from option fees, license fees, other upfront payments and milestone payments, and the subsequent recognition of these amounts as revenue over the period we are contractually required to provide other rights or services that represent continuing obligations;
- the Collaboration Obligation under the Bristol-Myers Squibb agreement to fund the first $100.0 million of certain development costs, which is anticipated to be paid through early 2011; and
- changes in other assets and liabilities, which generally represent temporary timing differences between the recognition of certain expenses and their payment.

Most of these items do not cause material year-to-year fluctuations in the relationship between our net loss and the amount of net cash used in operating activities. Exceptions are noncash items, changes in deferred revenue and collaboration obligations, and RECOTHROM inventory increases. Substantial license or upfront fees may be received when we enter into new licensing or collaborative agreements and be recorded as deferred revenue, which is then recognized as revenue over a future period. For example, we have received milestone payments from Bayer related to the RECOTHROM collaboration totaling

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$77.0 million as of September 30, 2009, that have been recorded as deferred revenue and are being recognized as revenue through the first quarter of 2014. In addition, we received $130.0 million in upfront and milestone payments from Bristol-Myers Squibb in 2009, of which $100.0 million was recorded as a collaboration obligation reflecting our responsibility to fund the first $100.0 million of research and development costs incurred for the collaboration and expected to be paid through early 2011. The timing of additional collaboration transactions is expected to be irregular and, accordingly, has the potential to create additional future fluctuations in the relationship between our net loss and the amount of cash used in operating activities.

The supply chain for RECOTHROM involves single source suppliers in various countries. These suppliers often require annual minimum production levels, significant lead times and firm purchase commitments to ensure that manufacturing capacity is available. We have established safety stocks of inventory at each stage in the RECOTHROM manufacturing supply chain to ensure that sufficient product is available to meet anticipated demand. The purchase of inventory under these arrangements has resulted in a significant use of cash. Our current levels of inventory are higher than necessary to support our current volume of sales; however, both work in process and finished goods inventories have relatively lengthy shelf lives. We perform periodic reviews of inventory levels, including reviews of the product expiration dates and forecasted sales, and write-down the value of inventory to reflect any anticipated obsolescence. Such write-downs are reflected as a component of cost of product sales. For example, we recorded an obsolete inventory charge of $4.2 million in the fourth quarter of 2008. At September 30, 2009, we do not believe there exists the need to recognize any further inventory obsolescence.

Cash flows from investing activities

Our most significant use of cash in investing activities is for capital expenditures. We expend a certain amount each year on routine items to maintain the effectiveness of our business, such as to adopt newly developed technologies, expand into new functional areas, adapt our facilities to changing needs or replace obsolete assets. All of the $1.3 million and $3.7 million expended for purchases of property and equipment for the nine months ended September 30, 2009 and 2008, respectively, were of this nature. In the past, we used cash to purchase land and expand facilities. In August 2008, we sold land for $11.8 million that was purchased in 2001 and 2002. Cash flows from investing activities also reflect large amounts of cash used to purchase short-term investments and receipts from the sale and maturity of short-term investments. These amounts primarily relate to shifts between cash and cash equivalents and short-term investments. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these cash flows to be important to an understanding of our liquidity and capital resources.

Cash flows from financing activities

We paid $1.3 million in costs related to establishment of the $100.0 million Deerfield debt financing arrangement in the nine-month period ended September 30, 2008 and received $780,000 and $513,000 of proceeds from the exercise of stock options for the nine-month periods ended September 30, 2009 and 2008, respectively.

We expect to incur substantial additional losses in the coming years as we continue to build the market for RECOTHROM and advance our pipeline candidates, such as PEG-Interferon lambda. We are optimistic regarding the long-term commercial prospects for RECOTHROM; however, it might be some time, if ever, before our RECOTHROM revenues enable us to achieve positive operating cash flow. If at any time our prospects for funding our various initiatives decline, we may decide to look for ways to reduce our ongoing investment. For instance, we might consider discontinuing our funding under existing co-development arrangements, as we did with our atacicept collaboration with Merck Serono. Further, we may establish new co-development arrangements for other product candidates to provide additional funding sources, as we did in early 2009 with our PEG-Interferon lambda collaboration with Bristol-Myers Squibb. Also, we may out-license products, product candidates or certain rights related to products or product candidates that we might otherwise choose to develop and commercialize internally. Additionally, we could consider delaying or discontinuing development of product candidates to reduce the level of our related expenditures.

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In the first quarter of 2009, we received $105.0 million from our collaboration agreement with Bristol-Myers Squibb. In June 2009, we achieved a milestone of $25.0 million, which was received in July 2009. In October 2009, we initiated a Phase 2 clinical trial for PEG-Interferon lambda and earned a $70.0 million milestone which will be recorded in the fourth quarter of 2009. We are entitled to receive payment for this milestone in November 2009. Until January 26, 2010, we have the ability to draw $75.0 million of additional funding under our Deerfield Management funding arrangement, which is repayable in June 2013. We believe that we have sufficient cash resources to fund our operations for at least the next two years; however, this outlook depends on future events, including the sales performance of RECOTHROM, progress in the development activities for PEG-Interferon lambda and potential borrowings from Deerfield. We may also seek additional funding through new license and/or collaboration transactions or public or private financings, including debt or equity financings. If any of these sources of funds are not available as we currently believe they will be, we may need additional funding sooner than we expect.

Similarly, poor financial results, unanticipated expenses or unanticipated opportunities that require financial commitments could give rise to additional financing requirements. Financing may be unavailable when we need it or may not be available on acceptable terms, especially if the challenging economic climate continues. If we raise additional funds by issuing equity or equity-based securities (including convertible debt), the percentage ownership of our existing shareholders would be reduced, and these securities could have rights superior to those of our common stock. If we are unable to raise additional funds when we need them, we could be required to delay, scale back or eliminate expenditures for some of our development programs, or grant rights to third parties to develop and market product candidates that we would prefer to develop and market internally, with license terms that are not favorable to us.

Contractual Obligations

At September 30, 2009, we were contractually obligated to make payments as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Building lease obligations	$ 94,180	$ 8,364	$ 17,617	$ 18,872	$ 49,327
Operating leases	29,309	2,608	5,505	5,914	15,282
Collaboration Obligation	82,078	55,178	26,900		
Development contracts	269	269			
RECOTHROM manufacturing contracts	63,447	11,206	17,941	9,800	24,500
Total	$ 269,283	$ 77,625	$ 67,963	$ 34,586	$ 89,109

The building lease obligations resulted from our 2002 sale-leaseback financing transaction and run until May 2019. The operating leases relate to office space near our corporate headquarters buildings which expire in April 2019. We have certain renewal provisions at our option, which are not reflected in the above table, for the building leases and the operating leases. The Collaboration Obligation relates to the collaboration and license agreement we entered into with Bristol-Myers Squibb, which obligates us to fund the first $100.0 million of costs for development in the U.S. and Europe, after which we will be responsible for 20% of such costs unless we elect to convert to a royalty arrangement. RECOTHROM manufacturing contracts include the manufacture of rThrombin bulk drug and RECOTHROM finished product for commercial sale.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Until recently, our exposure to market risk has been primarily limited to interest income sensitivity, which is affected by changes in the general level of United States interest rates, particularly because the majority of our investments are in short-term debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our portfolio of cash, cash equivalents and short-term investments in a variety of interest-bearing instruments, which may include United States government and agency securities, high-grade United States corporate bonds, asset-backed securities, commercial paper and money market funds.

In 2008, due to deteriorating conditions in the debt markets, our exposure to market risk increased and our investment portfolio was impacted. Overall liquidity for many debt issues has declined substantially, meaning that we may realize losses if we are required to liquidate securities upon short notice. Additionally, the credit quality of certain issues has declined substantially, causing ratings downgrades and in some cases uncertainty regarding the ability of issuers to repay principal amounts. Also, with respect to asset backed securities, overall economic conditions have generated concerns about the value of underlying assets held as collateral and highlighted risks associated with insurance policies used to enhance the credit of the related debt issues. To date, we have not experienced defaults on any of our investment securities. We continue to monitor our investments closely and, based on market conditions, recorded an other-than-temporary impairment loss of $400,000 on one security in the third quarter of 2008. We have reviewed our investments as of September 30, 2009, and at this time do not believe that any additional other-than-temporary impairment loss is warranted.

We have no material foreign currency exposure, nor do we hold derivative financial instruments.

Item 4. Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, or Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that as of such date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. No change in our internal control over financial reporting occurred during the quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

On November 2, 2009, King Pharmaceuticals, Inc., Monarch Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc., and GenTrac, Inc., or, collectively, King, filed suit against us in the United States District Court for the Eastern District of Tennessee, naming as defendants ZymoGenetics, Inc. and fifty unnamed individuals. King alleges that we have engaged in unfair competition, false advertising, trademark infringement, and related claims under federal law and Tennessee state law. King seeks various forms of relief, including damages and injunctive relief precluding us from making certain representations regarding King s products and our RECOTHROM product. King also filed motions with the District Court seeking temporary restraining orders and preliminary injunctive relief. On November 3, 2009, following a hearing in which ZymoGenetics did not have an opportunity to participate, the District Court entered three Temporary Restraining Orders, or TROs, temporarily prohibiting us from engaging in certain marketing or promotional conduct related to RECOTHROM. We are seeking immediate relief from the District Court to vacate the TROs, and we will seek an immediate hearing on this motion. A hearing on King s motions for preliminary injunctive relief is scheduled for November 16, 2009, and we will oppose King s request for preliminary injunctive relief at that hearing. In the interim, we are taking steps to comply with the TROs while they remain in effect. We dispute the allegations of wrongdoing in King s complaint and intend to vigorously defend ourselves in this matter, including opposing King s motions for preliminary injunctive relief.

We currently believe that this litigation will not have a material adverse effect on our financial condition, our results of operation, or our cash flows. However, litigation is subject to inherent uncertainties and the actual cost and the distraction from the conduct of our business, as well as the ultimate outcome, will depend upon many unknown factors and our view of these may change in the future.

Item 1A. Risk Factors

You should carefully consider the risks described below together with the other information set forth in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2008, which could materially affect our business, financial condition or future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Risks Related to Our Business

If we fail to increase sales of RECOTHROM® recombinant thrombin or to successfully develop and commercialize product candidates in our pipeline, we will not meet our financial goals.

Our near-term success is highly dependent on our ability to increase revenue from the commercialization of RECOTHROM. The successful commercialization of RECOTHROM will depend on many factors, including the following:

- the effectiveness of our product differentiation, marketing, promotion, distribution, sales and pricing strategies and programs, and those of our competitors;
- regulatory constraints on our promotional materials and programs;
- product demand within the medical community;
- our ability to penetrate the existing thrombin market and develop complementary products;

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new data or adverse event information relating to RECOTHROM or any similar products and any resulting regulatory action;

clinical practice or other guidelines regarding topical hemostats published by professional organizations or specialty groups;

successfully maintaining a product supply chain to meet demand;

successfully maintaining a commercial infrastructure, including a sales force;

the ability to gain formulary acceptance and favorable formulary positioning in a timely fashion or at all;

approval and product demand in countries outside the U.S.; and

the strength and effectiveness of our co-development and co-promotion relationships with Bayer, both within and outside the U.S.

Part of our growth strategy involves developing and commercializing new products, such as PEG-Interferon lambda, IL-21 and other product candidates, at times through entry into strategic alliances and collaborations. This part of our growth strategy requires us or our collaborators to conduct clinical trials to support approval of these new products. The success of this component of our growth strategy will depend on the outcome of these clinical trials, the success of our collaborators, the content and timing of our submissions to regulatory authorities and whether and when those authorities determine to grant approvals. In addition, if we fail to significantly increase sales of RECOTHROM, our ability to maintain current levels of research, development and commercialization activities, and our ability to become profitable in the future, will be adversely affected.

If we fail to obtain or generate the capital we need to fund our operations, we will be unable to continue operations.

Our business does not currently generate the cash needed to finance our operations, and we do not expect it to do so in the near future. We anticipate that we will continue to expend substantial funds on our research and development programs, the amount of which may increase in the future. We expect to seek additional funding through public or private financings, including equity financings, or through other arrangements, including collaborative and licensing arrangements. Poor financial results, including sales of RECOTHROM being less than expected, unanticipated expenses or unanticipated opportunities that require financial commitments could give rise to additional financing requirements sooner than we expect. However, financing may be unavailable when we need it or may be unavailable on acceptable terms, especially in light of the current global economic conditions. If we raise additional funds by issuing equity or convertible debt securities, the percentage ownership of our existing shareholders will be diluted, and these securities may have rights superior to those of our common stock. If we are unable to raise additional funds when we need them, we may be required to delay, scale back or eliminate expenditures for some of our research and development or commercial programs. We may also be required to grant rights to third parties to develop and commercialize products and product candidates that we would prefer to develop and commercialize ourselves, and such rights may be granted on terms that are not favorable to us. If we were required to grant such rights, the ultimate value of these products or product candidates to us would be reduced. In addition, if our cash and cash equivalents drop below specified levels it may result in the loss of co-promotion rights under our agreement with Bristol-Myers Squibb relating to PEG-Interferon lambda and constitute an event of default under our June 28, 2008 Facility Agreement with Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P. and Deerfield ZG Corporation, which would result in the principal and accrued and unpaid interest on the loans made under the agreement to become immediately due and payable.

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Additionally, a substantial portion of our operating expenses are funded through our collaborative agreements with third parties. For example, as part of the license and collaboration agreement and a co-promotion agreement with Bayer, we received $70.0 million in milestone payments in 2007 and 2008 and as part of the co-development/co-promotion and license agreement with Bristol-Myers Squibb, we received $130.0 million through July 2009. The agreement with Bristol-Myers Squibb also provides for other potential milestone payments, including one for $70.0 million in connection with initiation of Phase 2 trials. To the extent that we lose collaborative partners for a program or a portion of a program that we do not fund internally, or to the extent that we do not receive the funding that we expect from our collaborative agreements, unless we are able to obtain alternative sources of funding, we would be delayed in or unable to continue developing product candidates under the affected program. In addition, to the extent that funding is provided by a collaborator for non-program-specific uses, the loss of significant amounts of collaborative funding could result in the delay, reduction or termination of additional research and development programs, a reduction in capital expenditures or business development and other operating activities, or any combination of these measures, which could seriously harm our business. Subject to the terms of the relevant agreement, each collaborator has the right to terminate its obligation to provide research funding.

We anticipate incurring additional losses and may not achieve profitability.

As of December 31, 2008, we had an accumulated deficit of $762 million. We expect to continue to incur significant losses over the next several years, and we may never become profitable. Although we began generating RECOTHROM sales revenue in 2008, it will be a number of years before we generate revenues from sales of other potential products, if ever. Our revenues from the sales of RECOTHROM and existing collaborative and licensing arrangements are currently insufficient to fund our operating expenses, and we may never generate revenues sufficient to fund these expenses. In addition, we will continue to incur substantial expenses relating to our research, development and commercialization efforts. The development and commercialization of our product candidates will require significant further research, development, testing, regulatory approvals and sales and marketing activities, including, in the immediate future, continuing to pursue the commercialization of RECOTHROM. We may be unable to complete this development or succeed in developing and commercializing products that will generate revenues that will justify the costs of development and commercialization. We may incur substantial operating losses for at least the near term as we continue to support the commercialization of RECOTHROM and as a result of our research and development activities for the other product candidates in our development pipeline. These losses have had and will have an adverse effect on our shareholders equity and working capital. Even if we become profitable in the future, we may not remain profitable.

Our success will depend on our and our collaborative partners ability to effectively develop, market and sell our products against those of our competitors.

The biotechnology and pharmaceutical field is extremely competitive. RECOTHROM faces substantial competition from alternative topical hemostats. In the U.S., stand-alone plasma-derived thrombin products on the market include Thrombin-JMI, a bovine plasma-derived thrombin sold by King Pharmaceuticals, Inc., and Evithrom, a pooled human plasma-derived thrombin sold by Ethicon, Inc., a division of Johnson & Johnson. In addition, Baxter International, Inc. markets the Gelfoam Plus Hemostasis Kit, which is Pfizer Inc. s Gelfoam sterile sponge co-packaged with human plasma-derived thrombin. Further, a number of companies, including Johnson & Johnson and Baxter International, Inc., currently market other hemostatic agents that may compete with RECOTHROM, including passive agents such as gelatin and collagen pads, as well as fibrin sealants and tissue glues. Many of these alternative hemostatic agents are inexpensive and have been widely used for many years. Consequently, physicians and medical decision-makers may be hesitant to adopt RECOTHROM.

For our product candidates in development, we face competition from other entities involved in the research and development of therapeutic proteins and antibody products, including Genentech, Inc., Human Genome Sciences, Inc., Medarex, Inc., Biogen Idec Inc., Amgen Inc., and AstraZeneca PLC, among others. A number of our largest competitors are pursuing the development or marketing of

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pharmaceuticals that address the same diseases that we are pursuing, and it is possible that the number of companies seeking to develop products and therapies for these diseases will increase. We also face competition from entities developing other types of products related to particular diseases or medical conditions, including other biotechnology and pharmaceutical companies.

Furthermore, our potential products, if approved and commercialized, may compete against well-established therapeutic protein-based products or well-established antibody products, many of which may be currently reimbursed by government health administration authorities, private health insurers and health maintenance organizations.

Many of our existing and potential competitors have substantially greater research, product development and commercial capabilities and financial, scientific, marketing and human resources than we do. As a result, these competitors may:

- succeed in identifying genes or proteins, or developing therapeutic protein-based products, earlier than we do;
- obtain approvals for products from the FDA or other regulatory agencies more rapidly than we do;
- obtain patents that block or otherwise inhibit our ability to develop and commercialize our product candidates;
- prevail in existing litigation or initiate additional litigation that seeks to, or petition regulatory authorities to, block, inhibit or otherwise alter our commercial and marketing activity with respect RECOTHROM or our product candidates;
- develop treatments or cures that are safer or more effective than those we propose to develop;
- devote greater resources to marketing or selling their products;
- introduce or adapt more quickly to new technologies or scientific advances, which could render RECOTHROM or our product candidates obsolete;
- introduce products that make the continued development of our potential products uneconomical;
- withstand price competition more successfully than we can;
- negotiate more favorable terms with third-party collaborators, licensees, group purchasing organizations and other large customers; and
- take advantage of acquisitions or other opportunities more readily than we can.

Because of these and other potential disadvantages, we may be unable to compete effectively with these competitors. All of our product candidates face competition and we expect that competition in our industry will continue to be intense.

RECOTHROM and our product candidates, even if approved by the FDA or foreign regulatory agencies, may not achieve market acceptance among hospitals, insurers or patients.

RECOTHROM and our product candidates, even if approved by the FDA or foreign regulatory agencies, may fail to achieve market acceptance or, if they achieve market acceptance, may not displace existing products, which would impair our ability to become profitable. We believe that market acceptance of RECOTHROM and our product candidates and subsequent market penetration will depend on:

our ability to continue to provide acceptable evidence of safety, efficacy and limited side effects;

our ability to provide these products at reasonable prices;

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- the availability of third-party reimbursement for these products;

- our ability to differentiate our products and compete effectively, including with products that are considered to be the standard of care; and

- the effectiveness of our sales and marketing capabilities.

We rely, and expect to continue to rely, on obtaining and maintaining third-party relationships to commercialize RECOTHROM and our product candidates.

We have entered into collaboration arrangements with partners to co-develop and co-commercialize products and expect to continue to pursue similar opportunities. To be successful, we must identify and attract partners whose competencies and priorities complement ours. We must enter into collaboration agreements on terms beneficial to us and integrate and coordinate their processes, resources and capabilities with our own on a continuing basis. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements or maintaining such relationships so as to benefit from them over time. Also, we may be unsuccessful in integrating the resources, processes, capabilities or priorities of these collaborators on a continuing basis. In addition, our collaborators may prove difficult to work with or less skilled than we originally expected. If we are unsuccessful in our collaborative efforts, our ability to develop and market our product candidates could be limited.

In June 2007, we entered into a license and collaboration agreement with Bayer, under which Bayer has agreed to develop and commercialize RECOTHROM outside of the U.S. Simultaneously, we entered into a co-promotion agreement with Bayer HealthCare LLC, under which Bayer has agreed to co-promote RECOTHROM in the U.S. for up to four years following the launch of RECOTHROM. Under these agreements, we have limited ability to direct or control Bayer s development and promotional efforts. Bayer may lack the experience or resources necessary to effectively develop and promote our products. Bayer may also fail to devote the necessary resources or staffing to the development and promotion of our products, or otherwise fail to perform under the agreements, and we may be unable to obtain any meaningful remedy for Bayer s failures. If Bayer fails to perform or fully honor its obligations under our agreements, our sales of RECOTHROM or other products could be harmed, which would negatively impact our business. In addition, under our license and collaboration agreement with Bayer, we would depend solely on Bayer to promote and market RECOTHROM in countries outside the U.S. where RECOTHROM may be approved, and Bayer has the right to terminate the license and collaboration agreement for its own convenience and upon its own election, even if we are in full compliance with our obligations under the agreement. If there were an early termination of our co-promotion agreement with Bayer, it would, in most cases, result in an obligation to pay Bayer $20.0 million.

In January 2009, we entered into a co-development/co-promotion and license agreement with Bristol-Myers Squibb, under which we and Bristol-Myers Squibb will co-develop PEG-Interferon lambda and Bristol-Myers Squibb will be solely responsible for commercializing PEG-Interferon lambda outside of the U.S. While we believe that we will be able to work effectively with our counterparts at Bristol-Myers Squibb, we have limited experience with them and are unable to accurately predict our ultimate ability to collaborate with them.

These and other collaborations will require close and frequent communications between several different teams within the respective companies, technology transfer, and in general a collaborative sharing of responsibilities for clinical studies and all other development activities. Difficulties in collaboration could result in lower than expected revenue, delays in development, loss of market opportunities, and significant deterioration in the value of the related product candidate and our company.

To the extent that we lose a collaborative partner who we rely on for specific services related to product commercialization, unless we are able to find an alternative collaborator who can provide such services on commercially similar terms or perform the services ourselves, our commercial operations would be harmed.

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Rigorous government regulations relating to the development, marketing approval and promotion of RECOTHROM and our product candidates may limit us in, or prevent us from, marketing or selling such products.

The FDA regulates, among other things, the collection, testing, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. If RECOTHROM and our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. Except for RECOTHROM in the U.S., none of our product candidates has been approved for sale in any country, and our experience in filing and pursuing applications necessary to gain regulatory approvals is limited and we may be unable to satisfy the rigorous government regulations relating to the development and marketing approval of our product candidates. The successful commercialization of PEG-Interferon Lambda, IL-21 or any of our other product candidates will depend on obtaining marketing approval from the applicable regulatory authorities in each market in which we or our collaborators or our licensees intend to market the product candidates. Any failure to receive the marketing approvals necessary to commercialize our product candidates could harm our business.

The regulatory review and approval process of governmental authorities, which includes nonclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain, and regulatory standards may change during the development of a particular product candidate. For example, securing FDA approval requires the submission of extensive nonclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate s safety and effectiveness, including significant information regarding the chemistry, manufacturing and controls for the product. The process typically takes many years to complete and may involve costly ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of the product candidate. In addition, we may not achieve governmental approval, including that of the FDA, of a product candidate even if we have met our internal safety and efficacy criteria and completed clinical trials. Also, any regulatory approval of any of our product candidates, once obtained, may be withdrawn. For example, later discovery of previously unknown problems with our products or their manufacture, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the products or manufacturing processes;
- withdrawal or suspension of the products from the market;
- prohibitions or significant delays in the marketing of potential products;
- recalls and discontinuation of the marketing of potential products;
- limitations of the indicated uses for which potential products may be marketed;
- product seizures; and
- injunctions or the imposition of civil or criminal penalties.

In addition, some of our product candidates may be approved for use in combination with other products that are not our own. Failure by any of these products to comply with the laws and regulations pertaining to their business, resulting in potential product restrictions or recalls, may materially harm our ability to successfully commercialize and generate revenues from our products used in combination regimens.

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The approved product labeling for RECOTHROM has a direct and significant impact on our marketing, promotional and sales programs and could adversely affect our ability to penetrate the market. The label does not state that RECOTHROM has demonstrated superior safety or efficacy to competing thrombin products. If medical decision-makers are not familiar with the labeling approved for competing products, unaware of side effects or other conditions associated with competitive products, or if they do not believe our product offers advantages over competing products, it may limit our ability to penetrate the market and result in lower product revenues and we may be restricted in our ability to raise awareness of these issues successfully. Our promotional materials or messages may not allow us to effectively differentiate and promote RECOTHROM. The FDA reviewed our core promotional materials in connection with the launch of RECOTHROM, and we must submit all additional promotional materials to the FDA at the time of their first use. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them, and in some cases we may be required to provide corrective information to healthcare practitioners. Accordingly, we may be unable to address all potential questions and concerns regarding our product or its label, or our competitors products, which could result in lower product demand and lower product sales.

If we or others identify previously unknown side effects of RECOTHROM our business could be harmed.

If we or others identify previously unknown side effects, or detect unexpected safety concerns, for RECOTHROM or any products perceived to be similar to RECOTHROM, then in any of these circumstances:

- sales of RECOTHROM may decrease significantly;
- regulatory approvals for RECOTHROM may be restricted or withdrawn;
- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;
- reformulation of the product, additional preclinical or clinical studies, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- our reputation in the marketplace may suffer; and
- government investigations and lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of RECOTHROM, increase our expenses and impair our ability to successfully commercialize RECOTHROM.

Furthermore, now that RECOTHROM is approved in the U.S., it is being used in a wider population and in a less rigorously controlled fashion than in clinical studies. It is expected that some patients exposed to RECOTHROM will become sick or die suddenly, that in some or even many of these cases there will not be sufficient information available to rule out RECOTHROM as a contributing factor or cause of sickness or mortality, and that safety reporting from physicians or from us to regulatory authorities may link RECOTHROM to death or other serious adverse effects. As a result, regulatory authorities, healthcare practitioners, third-party payers or patients may perceive or conclude that the use of RECOTHROM is associated with death or other serious adverse effects, any of which could mean that our ability to commercialize RECOTHROM could be adversely affected and our business could be impaired.

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Clinical trials may fail to demonstrate the safety and effectiveness of our product candidates, which could prevent or delay their regulatory approval.

Clinical trials involving PEG- Interferon lambda, IL-21 or any of our other product candidates may reveal that those candidates are ineffective, are insufficiently effective given their safety profile, have unacceptable toxicity or safety profiles or have other unacceptable side effects. In addition, data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Likewise, the results of preliminary studies do not predict clinical success, and larger and later-stage clinical trials may not produce the same results as earlier-stage trials. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. Similarly, clinical trial results may vary between different arms of a clinical trial for reasons that we cannot adequately explain. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials that have supported the approval of a product and may not be able to do so successfully. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

Guidelines, recommendations, codes and other literature published by various organizations, including competitors, may affect our ability to effectively promote and sell RECOTHROM.

Various professional societies, industry trade associations, practice management groups, private health/science foundations, and organizations periodically publish guidelines, codes, recommendations and other literature to the healthcare and patient communities. These organizations have in the past made recommendations about RECOTHROM or products that compete with RECOTHROM, such as the treatment guidelines of the Society of Thoracic Surgeons. Competitors may also conduct and publish the results of clinical trials aimed at diminishing concerns about their own products, or indicating advantages over RECOTHROM. We have no control over the content of many of these publications even those that we support financially. For example, from time to time, we make medical education grants to organizations. The content of these publications or independent medical education programs may negatively impact our ability to penetrate the market for RECOTHROM. In addition, organizations generating publications with our financial support may fail to comply with the relevant government regulations, which could lead to regulatory action that negatively impacts our business.

Our patents and patent applications, including those relating to RECOTHROM, may not result in meaningful protection against competitors, provide us with any competitive advantage, or provide adequate protection or rights for new discoveries, and our competitors may commercialize the discoveries we patent or attempt to patent.

While we hold patents to the manufacture of RECOTHROM, our composition of matter patent protection is limited to a key intermediate in the production of recombinant thrombin. Accordingly, we may be unable to prevent other parties from developing alternate methods of manufacturing recombinant thrombin or from selling recombinant thrombin. If a third party sold recombinant thrombin manufactured using an alternate method of manufacturing, it could impair our business. In addition, after FDA approval of RECOTHROM, we filed an application for patent term extension of our relevant U.S. patents, but thus far we have not received confirmation from the U.S. Patent and Trademark Office that the extension will be granted to the extent we requested, or at all. If we are unable to obtain the requested term extension of our RECOTHROM patents, it could limit our ability to stop competitors and could impair our business. Additionally, we are aware of certain U.S. and European patents and patent applications held by third parties relating to thrombin and to methods of manufacture of thrombin and other recombinant proteins. Based on our analyses of these patents, we believe that we do not and will not infringe these patents and that many of the claims of these patents are invalid or unenforceable; however, the patent holders, courts or other governmental or legal entities may conclude that our products, processes or actions in developing, manufacturing or selling RECOTHROM do infringe one or more patents. We may seek licenses to such patents if, in our judgment, such licenses are needed. If any licenses are required, we may be unable to obtain any such

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licenses on commercially favorable terms, if at all. If these licenses are not obtained, we might be prevented from selling RECOTHROM or from using certain of our technologies for the manufacture of RECOTHROM. Our failure to obtain a license to any technology that we may require may harm our business.

We own or hold exclusive rights to many issued U.S. and foreign patents and pending patent applications related to the development and commercialization of RECOTHROM and our product candidates. These patents and applications cover composition-of-matter for genes, proteins, and antibodies, medical indications, methods of use, methods of making, formulations, technologies and other inventions related to therapeutic proteins and antibodies. Our success will depend in part on our ability to obtain and maintain patent protection for our products and product candidates in the U.S. and other countries.

Although we diligently seek to identify and protect our important discoveries and inventions, we may fail to file timely patent applications. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Our pending and future patent applications covering products and product candidates may not meet the statutory requirements for patentability, meaning that our applications may not result in the issuance of any patents, and, if issued, such patents may not be valid or enforceable. Our rights under any patents may not provide us with sufficient protection against competitive products or otherwise cover commercially valuable products or processes. In addition, because patent applications in the U.S. are maintained in secrecy for eighteen months after the filing of the applications, and publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be sure that the inventors of subject matter covered by our patents and patent applications were the first to invent or the first to file patent applications for these inventions.

Our patents may not provide us with any competitive advantage. Although we have a number of issued patents, the discoveries or technologies covered by these patents may not have any value. These issued patents may not provide commercially meaningful protection against competitors, nor may they provide all rights necessary to commercialize our products or product candidates. In addition, we may not be able to or allowed to obtain patent term extension or restoration on patents covering our products in a manner that would provide commercially meaningful protection against competitors.

Other parties may have a dominating or blocking patent position covering a composition of matter, or methods of making or using our products or product candidates. In addition, other parties may be able to design around our issued patents or independently develop products having attributes or uses similar or identical to our patented product candidates. The business model of some companies is to design around patented marketed protein-based products by altering the amino acid sequence of the marketed product, thereby avoiding the patent, but maintaining functional equivalence. Similarly, it may be easier to develop equivalent versions of monoclonal antibodies and soluble receptors than to develop equivalent versions of the proteins with which they interact because there is often more than one antibody or receptor that can have the same therapeutic effect. Consequently, any of our existing or future patents that cover monoclonal antibodies or soluble receptors may not provide any meaningful protection against competitors. In addition, other parties may discover uses for genes or proteins that are different from the uses described in our patents, and these other uses may be separately patentable. If another party holds a patent on the use of a gene or protein, then even if we hold the patent covering the composition of matter of the gene or protein itself, that party might prevent us from promoting and selling any product directed to such use. Also, other parties may have patents covering the composition of matter of genes or proteins for which we have patents covering only methods of use or methods of manufacture. Furthermore, our patents on recombinant proteins or their precursors or methods of manufacturing such proteins, such as our patents covering the precursor to RECOTHROM and its method of manufacture, may not prevent competitors from developing other precursors or methods of manufacturing these proteins.

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We rely on third parties to manufacture commercial supplies of RECOTHROM and our product candidates and, therefore, we may be unable to effectively control production or obtain adequate supplies, particularly in situations where we rely on a sole source of supply, which could cause delays in product manufacturing, subject us to product shortages or reduce product sales.

We rely and expect to continue to rely on third-party manufacturers over whom we exercise little control and who may not always be motivated to do what is in our best interests. The manufacture and delivery of sufficient quantities of pharmaceutical products is a time-consuming and complex process. In order to successfully commercialize our products, including RECOTHROM, and continue to develop our product candidates, including line extensions for RECOTHROM, and PEG-Interferon lambda, we need to contract or otherwise arrange for the necessary manufacturing. For example, we have entered into an agreement with Abbott Laboratories for commercial-scale production of RECOTHROM bulk drug substance and an agreement with Patheon Italia S.p.A., Inc. for fill and finish of the dosage form of RECOTHROM. We have also entered into agreements with several suppliers of critical raw materials, manufacturing process intermediates and components for RECOTHROM, some of which are located outside the U.S. For our PEG-Interferon lambda product candidate, we will rely on our collaborative partner Bristol-Myers Squibb to manufacture supplies for late-stage clinical trials and, if approved, commercial sales.

Reliance on third-party manufacturers, other vendors and collaborators limits our control regarding many aspects of the manufacturing and delivery processes and therefore exposes us to a variety of significant risks relating to the following, particularly in situations where we rely on a sole-source manufacturer, vendor or other collaborator as with RECOTHROM:

- our ability to schedule production with third parties when needed to supply market demand or clinical trials;
- reliance on third parties for legal and regulatory compliance and quality assurance;
- third-party insistence on exclusivity, minimum and/or maximum levels of supply and related restrictions on our ability to increase or decrease supply, including provisions whereby we pay a penalty if we fail to order a minimum amount;
- breach of agreements by third-parties; and
- termination, price increases, or non-renewal of agreements by third-parties, based on other business priorities, at times that are costly or inconvenient for us.

Moreover, these third parties must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance, and the maintenance of records and documentation. One or more of these third parties may be unable to comply with these cGMP requirements and with other FDA, state, and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied of RECOTHROM or any other product we commercialize that is manufactured by a third party is compromised due to a manufacturer s failure to adhere to applicable laws or for other reasons, we may be unable to obtain regulatory approval for or successfully commercialize our products, which would seriously harm our business.

If any of the circumstances described in these risks occur, our product supply could be interrupted resulting in lost or delayed revenues, delayed clinical trials, and significant increase in production costs and cost of goods. While we seek to negotiate effective remedies in our agreements, we may not have an adequate remedy for all performance-related issues. In particular, terminating a manufacturing arrangement entails significant risks associated with identifying an alternative manufacturer, the length of time it takes for an alternative manufacturer to meet the regulatory requirements and the possibility of litigation arising from any alleged breach.

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In addition, if, for any reason, we are required to engage an additional, second-source or replacement manufacturer or other vendor, the investment of funds and management time could be significant. There are a limited number of manufacturers and other vendors that operate under the FDA s cGMP regulations capable of manufacturing for us, and we have not established backup manufacturers and suppliers for RECOTHROM or any of our product candidates. Accordingly, if we are unable to maintain third-party manufacturing on commercially reasonable terms, or if we lose a significant supplier used for RECOTHROM or for our other product candidates, we may be unable to market our products, meet certain contractual supply obligations or complete development of our product candidates on a timely basis, if at all. For example, under our agreements with Bayer, we are required to provide Bayer with RECOTHROM and may be in breach of the agreement if we cannot make the required deliveries on time.

In addition, some of the inventions and patents licensed to us were initially developed at universities or other not-for-profit institutions with funding support from an agency of the U.S. government. In accordance with federal law, our licensees or we may be required to manufacture in the U.S. products covered by those patents, unless we can obtain a waiver from the government on the basis that such domestic manufacture is not commercially feasible. We have not attempted to secure any such waivers from the government, and do not know if they will be sought or available if sought. If we are unable to obtain such waivers, if requested, on a timely basis, we might be forced to seek manufacturing arrangements at higher prices, or on otherwise less favorable terms, than might be available to us in the absence of this domestic manufacturing requirement.

We cannot predict whether any of the manufacturers and vendors that we may use will continue to meet our requirements for quality, quantity or timeliness for the manufacture of RECOTHROM, its intermediates or components or for our other product candidates.

We may be unable to generate any revenue from product candidates developed by collaborators or licensees.

We may be unable to derive any value from product candidates developed by collaborators or licensees, including Novo Nordisk, Merck Serono, Bayer Schering Pharma and Bristol-Myers Squibb. Our ability to generate revenues from existing or future collaborations and license arrangements is subject to numerous risks, including:

- the possibility that our collaborators or licensees lack sufficient financial, technical or other capabilities to develop these product candidates;
- the possibility that our collaborators or licensees choose to scale back or discontinue their development activities due to changes in their strategies, restructuring, mergers or acquisitions or because their view of the commercial market or regulatory landscape in their licensed territory has changed;
- the length of time that it takes for our collaborators or licensees to solve technical problems or achieve various clinical development and regulatory approval milestones;
- differences in opinion about development, clinical and regulatory strategies and timeframes;
- the inability of collaborators or licensees to successfully address any regulatory or technical challenges they may encounter; and

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the possibility that these product candidates may not be effective or may prove to have undesirable side effects, unacceptable toxicities or other characteristics that preclude regulatory approval or prevent or limit commercial use.

RECOTHROM has not been approved for sale outside of the United States and we currently depend on the efforts of Bayer Schering Pharma to seek approval for and market and promote RECOTHROM outside the U.S.

In the U.S., RECOTHROM was approved for marketing on the basis of clinical studies showing non-inferiority to bovine plasma-derived thrombin. The European Medicines Agency, Health Canada and other regulatory authorities may require other clinical trials having a different comparator or study design prior to, or after, approval, especially because bovine plasma-derived thrombin is not currently approved in Europe or Canada. In addition, the foreign regulatory authorities may not be satisfied with the safety and efficacy data submitted in support of the foreign applications, which could result in either non-approval or a requirement of additional clinical trials or further analysis of existing data. Furthermore, as an element of the foreign approval process, the applicable regulatory authority must be satisfied with the processes and facilities for all stages of the manufacture, packaging and distribution of RECOTHROM, which may include physical inspections of many or all relevant facilities. Any conclusion that there are shortcomings in the processes, facilities, quality control or oversight of contract manufacturers, or other quality assurance procedures related to manufacture, packaging and distribution of the drug could result in a significant delay in or failure to receive foreign approval.

Under a 2007 agreement, our ex-U.S. licensee, Bayer Schering Pharma AG, agreed to seek applicable government approvals for and develop and market RECOTHROM outside the U.S. During 2008, Bayer Schering Pharma filed applications in Europe and Canada; however, we and Bayer Schering Pharma do not know whether European or other foreign regulatory authorities will grant marketing approval of RECOTHROM. Additionally, we currently depend solely on Bayer Schering Pharma to promote and market RECOTHROM in countries outside the U.S. where RECOTHROM is approved, if any. We have limited ability to direct Bayer Schering Pharma in its regulatory strategies or its promotion of RECOTHROM in foreign countries. Bayer Schering Pharma may not have sufficient experience to promote topical hemostat products in foreign countries and may fail to devote appropriate resources to this task. No form of thrombin is currently sold in Europe or Canada and, therefore, Bayer Schering Pharma will have to create a new market for RECOTHROM, an endeavor in which it may fail. If Bayer Schering Pharma fails to effectively promote RECOTHROM in foreign countries, we may be unable to obtain any meaningful remedy against Bayer Schering Pharma. In addition, Bayer Schering Pharma has the right to terminate the license and collaboration agreement for its own convenience and upon its own election, even if we are in full compliance with our obligations under the agreement. If Bayer Schering Pharma were to fail to perform, or to terminate the agreement, sales of RECOTHROM in foreign countries may be harmed, which would negatively impact our business.

Overall, our agreement with Bayer Schering Pharma may:

limit the financial benefits we derive from products containing recombinant thrombin by precluding us from markets outside the U.S.;

limit the financial benefits we may derive from products containing recombinant thrombin by allowing Bayer Schering Pharma to license them in exchange for predetermined payments and royalties and with predetermined cost-sharing arrangements, which payments and royalty rates may be less than, and which cost-sharing arrangements may be less favorable to us than, terms we might otherwise obtain in collaborative or licensing arrangements with other parties;

result in a delay in developing one or more products containing recombinant thrombin due to Bayer Schering Pharma s internal decisions, procedures or development strategies; and

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prevent us from collaborating with or licensing a product candidate containing recombinant thrombin to another company that, by virtue of its particular skills and capabilities, may be a more desirable collaborator or licensing partner for that particular product candidate than Bayer Schering Pharma.

Lack of or limited marketing approval in a particular country could prevent or limit Bayer Schering Pharma from selling RECOTHROM in that country, which could harm our business.

The failure to attract or retain key management or other personnel could decrease our ability to discover, develop and commercialize potential products.

We depend on our senior executive officers as well as key scientific, management and other personnel. Only a small number of our key personnel are bound by employment agreements, and those with employment agreements are bound only for a limited period of time. Competition for scientists and other qualified employees is intense among pharmaceutical and biotechnology companies, particularly with the establishment or growth of other biotechnology research or development operations in Seattle, such as that of Novo Nordisk Inc.The loss of qualified employees, or an inability to attract, retain and motivate the highly skilled employees required for our activities, could hinder our ability to discover, develop and commercialize potential products.

Our restructuring may place additional strain on our resources, has adversely affected the morale of our personnel and may affect their performance.

Our restructuring in April 2009 resulted in a workforce reduction of approximately 160 employees. Following the workforce reduction, we had approximately 300 employees at our facility in Seattle, Washington. This workforce reduction has adversely affected employee morale and may have an adverse impact on the performance of our personnel. Our restructuring may yield unanticipated consequences such as attrition beyond our planned reduction in workforce. This workforce reduction could place significant strain on our administrative, operational and financial resources and result in increased responsibilities for certain personnel. As a result, our ability to respond to unexpected challenges may be impaired and we may be unable to take advantage of new opportunities. In addition, certain of the terminated employees possess specific knowledge or expertise, and that knowledge or expertise may prove to have been important to our operations. In that case, their absence may create significant difficulties. Furthermore, this headcount reduction, including the resulting increased strain on the remaining employees and lower morale, may subject us to the risk of litigation, which could result in substantial costs to us and could divert management s time and attention away from business operations. Any future restructuring or workforce reductions may further exacerbate these risks.

Failure to effectively manage the RECOTHROM supply chain could result in inventory shortages, supply interruptions or inventory obsolescence.

Our supply chain for RECOTHROM, its intermediates and components is particularly complex and involves a number of third parties on several continents. In addition to coordinating the efforts of these third-party contractors, we must navigate the laws and regulations of multiple jurisdictions, and our failure to do so effectively may negatively impact our business.

In addition, our contract manufacturers and other vendors have not produced RECOTHROM, its intermediates or components for commercial use for a sustained period of time. As such, unforeseeable risks may be encountered as we, together with our manufacturers and other vendors, continue to develop familiarity and experience with regard to manufacturing RECOTHROM, its intermediates and components. Failure to adequately manage our supply chain could result in inventory shortages or other supply interruptions that could negatively impact RECOTHROM sales and, consequently, negatively impact product revenue.

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We have limited expiration dating for RECOTHROM. Consequently, if we are unable to sell at forecasted levels we may have excess RECOTHROM inventory, resulting in inventory obsolescence, increased costs of product sales and ineffective use of our financial resources.

As a result of our progression from a primarily research and development company to a company involved in commercialization of products, we may encounter difficulties in adapting our operations.

We have only recently built a commercial organization to support the marketing and sale of RECOTHROM, and we continue to refine that organization. As we continue to advance product candidates through clinical trials and on to commercialization, we may need to adapt our development and commercial operations capabilities. If we are unable to provide these capabilities internally, we may need to rely on collaborative partners or other third parties to provide these services for us. These adapted operations would add significant complexity to our business and responsibilities to certain members of our management and key personnel. We may need to manage relationships with an increasing number of collaborative partners, suppliers and third-party contractors. If we are unable to successfully provide the required infrastructure, either internally or through third parties, and successfully manage an increasing number of relationships, we will have difficulty growing our business.

Because we will depend on third parties to conduct certain laboratory tests, clinical trials and other critical services, we have limited control and may encounter delays in our efforts to develop product candidates.

We commonly rely on third parties to conduct laboratory tests, clinical trials and other critical services for us, especially to the extent clinical trials include sites outside the U.S. If we are unable to obtain these services on acceptable terms, we may be unable to complete our product development efforts in a timely manner. Also, to the extent we will rely on third parties for laboratory tests and clinical trials, we will have limited control over these activities or may be unable to manage them appropriately, or may become too dependent on these parties. These third parties may not complete the tests or trials on our schedule, and the tests or trials may be methodologically flawed, may not comply with applicable laws or be otherwise defective. Delays or difficulties associated with third-party laboratory tests or clinical trials may delay, and increase the risks and costs of the development of, our product candidates.

We have shifted much of our discovery efforts to therapeutic antibodies with which we have limited experience and we may be unsuccessful discovering or commercializing such products.

We have shifted much of our discovery efforts to focus on developing therapeutic antibodies. We have limited experience developing antibodies and may be unsuccessful in these efforts. Moreover, we may be unsuccessful in obtaining adequate, if any, patent coverage for our discoveries and therapeutic antibody products. In addition, third parties may own key technology or target patents or dominating patents that may prevent us from developing, manufacturing or commercializing therapeutic antibodies.

For example, we are aware of broad patents owned by others relating to the discovery, development, manufacture, use and sale of recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies and other technologies. Many of our product candidates may use or include such technologies. While we have entered into agreements with certain third parties, including Dyax Corp. and Medarex, Inc., in order to gain access to their technology, often the technology is made available on a target-by-target basis upon submission of specific targets and payment of a fee. We have no assurance that a license to a particular target will be available until it is submitted as part of such a process. We are also aware that third parties own patents related to the target molecules with which our antibody products are designed to interact. Unlike Dyax Corp. and Medarex, Inc. and other companies with a technology platform, these third parties may not be willing to grant licenses to the technology. Consequently, even if we are successful at obtaining patent protection for our antibody

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product candidates, these antibody product candidates may infringe such third-party patents covering the targets. We may be unable to obtain necessary rights to such targets, or to key technologies needed for the discovery, development, production or commercialization of therapeutic antibodies through licensing agreements on terms attractive to us, if at all. If these licenses are not obtained, we might be prevented from developing antibodies aimed at such targets or from using certain of our technologies for the generation and development of our new discoveries. If we are unsuccessful in our efforts to obtain needed licenses, our ability to develop and commercialize antibody product candidates could be limited. Any patent infringement or other legal claims that might be brought against us may cause us to incur significant expenses, enjoin our development or commercialization of such products, divert the attention of our management and key personnel from other business concerns and, if successfully asserted against us, require us to pay substantial damages.

We may expand our business through the acquisition of companies or businesses or in-licensing products or product candidates that could disrupt our business and harm our financial condition.

We may in the future seek to expand our products and capabilities by acquiring one or more companies or businesses or in-licensing one or more product candidates. Acquisitions and in-licenses involve numerous risks, which may include:

- substantial cash expenditures;
- dilutive issuances of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- diverting our management s attention away from other business concerns;
- entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

Historically, we have not expanded our business through acquisition or in-licensing and, therefore, our experience in making acquisitions and in-licensing is limited. Any acquisition or in-license may not result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success could depend in part on our ability to manage the rapid growth associated with some of these acquisitions and in-licenses. We may be unable to make the combination of our business with that of acquired businesses or companies or in-licensed product candidates work or be successful. Furthermore, the development or expansion of our business or any acquired business or company or in-licensed product candidate may require a substantial capital investment by us. We may not have the necessary funds or they may be unavailable to us on acceptable terms, if at all. We may also seek to raise funds by selling shares of our stock, which could dilute our current shareholders ownership interest, or securities convertible into our stock, which could dilute current shareholders ownership interest upon conversion.

Third parties may infringe our patents and challenge the validity or enforceability of our patents.

Competitors and other third parties may infringe our patents, or use inventions described in our patent applications. It may be difficult or impossible for us to police third party activities and detect such infringement. For example, we may be unable to discover a competitor s manufacturing process to determine whether it infringes patent claims to a method of manufacture. Patent litigation is very expensive and time-consuming and is a distraction to management and personnel who are needed to

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supply evidence and support to litigation efforts. Enforcing our patents against third parties may require significant expenditures regardless of outcome. We may incur substantial expenditures in such patent litigation and the outcome of any lawsuit is uncertain.

Additionally, challenges raised in patent infringement litigation initiated by us or by third parties may result in determinations that our patents have not been infringed or that they are invalid, unenforceable or otherwise subject to limitations. Consequently, third parties, including licensees, may be able to use the discoveries or technologies claimed or described in our patents without paying licensing fees or royalties to us, which could diminish the value of our intellectual property.

Moreover, the issuance of a patent is not conclusive as to its scope, validity or enforceability. Third parties, including our competitors and licensees, may initiate proceedings to limit the scope, validity or enforceability of our patents, including but not limited to *inter-partes* re-examination proceedings in the U.S. Patent and Trademark Office, opposition proceedings in patent authorities outside of the U.S., declaratory judgment proceedings in U.S. courts, or in the event a third party independently makes an invention similar to ours, interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. Likewise, we may initiate *inter-partes* proceedings to challenge the scope, validity or enforceability of third-party patents. The outcome of any such proceeding is uncertain and could result in judicial determinations that our patents are invalid, limited in scope, not infringed, or unenforceable, which would impair our business. Participating in such proceedings or other challenges, whether initiated by us or by third parties may require significant expenditures and divert the attention of our management and key personnel from other business concerns, which may also impair our business.

Patent protection for protein-based therapeutic products and other biotechnology inventions is subject to a great deal of uncertainty, and if patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize products based on our discoveries.

Patent protection for protein-based therapeutic products is highly uncertain and involves complex legal and factual questions. In recent years, there have been significant changes in patent law, including the legal standards that govern the scope of protein and biotechnology patents. Standards for patentability of full-length and partial genes, and their corresponding proteins, are changing. Also, there is substantial uncertainty regarding the patentability of proteins without known function or specific correlation with diseases. Recent court decisions have made it more difficult to obtain patents, by making it more difficult to satisfy the requirement of non-obviousness, have decreased the availability of injunctions against infringers, have decreased the likelihood of proving willfulness, and have increased the likelihood of challenging the validity of a patent through a declaratory judgment action. Taken together, these decisions make it more difficult and costly for us to obtain, license and enforce our patents. In addition, in recent years, several members of the U.S. Congress have made numerous proposals to change the patent statute. These proposals include measures that, among other things, would expand the ability of third parties to oppose U.S. patents, introduce the first to file standard to the U.S. patent system, and limit damages an infringer is required to pay. If the patent statute is changed, the scope, validity and enforceability of our patents may be decreased.

There also have been, and continue to be, policy discussions concerning the scope of patent protection awarded to biotechnology inventions. Social and political opposition to patents on genes and proteins may lead to narrower patent protection, or narrower claim interpretation, for genes, their corresponding proteins and inventions related to their use, formulation and manufacture. Patent protection relating to biotechnology products is also subject to a great deal of uncertainty outside the U.S., and patent laws are evolving and undergoing revision in many countries. Changes in, or different interpretations of, patent laws worldwide may result in our inability to obtain or enforce patents, and may allow others to use our discoveries to develop and commercialize competitive products, which would impair our business.

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We may be subject to patent infringement claims, which could result in substantial costs and liability and prevent us from commercializing our products and product candidates.

Third parties may claim that our products or product candidates, or processes or related technologies infringe their patents. The risk of infringement claims filed against us is likely to increase as we commercialize products or move product candidates closer to commercialization. Furthermore, we may not have identified or analyzed all U.S. and foreign patents that pose a risk of our infringement.

Any patent infringement or other legal claims that might be brought against us may cause us to incur significant expenses, divert the attention of our management and key personnel from other business concerns and, if successfully asserted against us, require us to pay substantial damages. In addition, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing or selling products or product candidates that are claimed to infringe a third party s patent unless that party grants us rights to use its intellectual property. We may be unable to obtain these rights on terms acceptable to us, if at all. Even if we are able to obtain rights to a third party s patented intellectual property, these rights may be non-exclusive, which would allow our competitors to obtain access to the same intellectual property. Ultimately, we may be unable to commercialize our potential products or may have to cease some of our business operations, which could harm our business.

We may be unable to protect our unpatented proprietary technology and information.

In addition to our patented intellectual property, we also rely on trade secrets and confidential information. We may be unable to effectively protect our rights to such proprietary technology or information. Other parties may independently develop or gain access to equivalent technologies or information and disclose it for others to use. Disputes may arise about inventorship and corresponding rights to know-how and inventions resulting from the joint creation or use of intellectual property by us and our corporate partners, licensees, scientific and academic collaborators and consultants. In addition, confidentiality agreements and material transfer agreements we have entered into with these parties and with employees and advisors may not provide effective protection of our proprietary technology or information or, in the event of unauthorized use or disclosure, may not provide adequate remedies.

We may be required to defend lawsuits and pay damages in connection with alleged or actual harm caused by our products and product candidates or marketing and promotional activities.

The design, testing, manufacture and sale of therapeutic products involve an inherent risk of product liability claims and associated adverse publicity, even if the claims arise from use of the product in a manner inconsistent with label or other instructions. In addition, RECOTHROM is and will be used on patients undergoing surgery, where there are significant risks to patients. Further, our marketing and promotional efforts for RECOTHROM have resulted in litigation, and could increase the risk of or result in additional litigation, based on claims by our competitors or others of unfair competition, unfair advertising or similar claims. For example, on November 2, 2009, King Pharmaceuticals, Inc., Monarch Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc., and GenTrac, Inc., or, collectively, King, filed suit against us in the United States District Court for the Eastern District of Tennessee, naming as defendants ZymoGenetics, Inc. and fifty unnamed individuals. King alleges that we have engaged in unfair competition, false advertising, trademark infringement, and related claims under federal law and Tennessee state law. King seeks various forms of relief, including damages and injunctive relief precluding us from making certain representations regarding King s products and our RECOTHROM product. King also filed motions with the District Court seeking temporary restraining orders and preliminary injunctive relief. On November 3, 2009, the District Court entered three Temporary Restraining Orders, or TROs, temporarily prohibiting us from engaging in certain marketing or promotional conduct related to RECOTHROM.

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If any of these actual or potential lawsuits against us were to be successful, we may incur significant costs and could be required to make significant modifications to our business, including our product marketing and commercialization strategies, which could have a material adverse effect on our business. Even if such lawsuits are without merit or otherwise unsuccessful, they could cause adverse publicity, divert management attention and be costly to respond to, and, therefore, could have a material adverse effect on our business. Although we maintain product liability and general insurance, our coverage may not be adequate to cover product liability or other claims. We do not know if we will be able to maintain existing or obtain additional product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may be unavailable on acceptable terms, if at all. 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 continue to develop or commercialize RECOTHROM or any other product candidates. Any product liability claims, whether or not ultimately successful, could have a material negative effect on our reputation, stock price, ability to penetrate the market and sell our products and our financial condition and results.

Environmental and health and safety laws may result in liabilities, expenses and restrictions on our operations.

State and federal laws and regulations and those of foreign jurisdictions regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. The use of hazardous substances in our operations exposes us to the risk of accidental releases. If our operations, including those of our third-party service providers and collaborators, result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations. In addition, the site where our principal headquarters and facilities are located has been listed as a contaminated property by the state of Washington due to its previous use by the city of Seattle as an electricity-generating plant. The city of Seattle has agreed to defend us against and indemnify us for any claims that arise from this pre-existing contamination, except to the extent that we caused the claim through our negligence or intentional fault, or to the extent that we contributed to the contamination that is the subject of the claim, caused an increase in the clean-up costs or failed to comply with our obligations under our agreement with the city of Seattle. This indemnity may be insufficient and we may be subject to environmental liabilities or be prohibited from using or occupying some or all of the property as a result of environmental claims.

If we use biological and hazardous materials in a manner that causes contamination or injury or violates laws, we may be liable for damages.

Our research and development activities and clinical trials involve the use of potentially harmful biological materials, as well as hazardous materials, chemicals, and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury from the distribution, use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our available financial resources. We do not maintain liability insurance coverage for our handling of biological or hazardous materials. We, our collaborative partners, the third parties that conduct clinical trials on our behalf, and our third-party manufacturers are subject to federal, state, local or foreign laws and regulations governing the use, storage, handling, and disposal of these materials and waste products. The cost of compliance with these laws and regulations could be significant. The failure to comply with any of these laws and regulations could result in significant fines and work stoppages and may harm our business.

We are exposed to financial risks related to foreign currency exchange rates.

Some of our costs and expenses are denominated in foreign currencies and, even if they are not as a matter of contract, vendors may seek concessions in the event that their anticipated economic return is impaired by exchange rate fluctuations. Most of our existing foreign expenses are associated with

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the manufacture of RECOTHROM, sharing of development costs with foreign partners or our global clinical studies. We are primarily exposed to changes in exchange rates with the Euro. When the U.S. dollar weakens against other currencies, the dollar value of the foreign-currency denominated expense increases, and when the dollar strengthens against other currencies, the dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the U.S. dollar, may adversely affect our operating results. We currently do not hedge against our foreign currency exposure.

Risks Related to Our Industry

If the healthcare system, reimbursement policies or any other healthcare-related regulations change, the prices of our products and product candidates may fall or our potential sales may decline.

In recent years, U.S. government officials have made numerous proposals to change the healthcare system in the U.S. These proposals include measures that would limit or prohibit payments for certain medical procedures and treatments or subject the pricing of pharmaceuticals to government control. Government and other third-party payers increasingly have attempted to control healthcare costs by limiting both coverage and the level of reimbursement of newly approved healthcare products. Increasingly, third-party payors have been challenging the prices charged for products. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted marketing approval. The government may adopt future legislative proposals, such as price controls on prescription drugs, and federal, state or private payors for healthcare goods and services may take further action to limit payments for healthcare products and services. In addition, in certain foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control with many of the same types of challenges as in the U.S. Any of these factors could limit our ability to successfully commercialize our potential products.

We may face increased competition from lower-priced products re-imported into the U.S. from Canada and other countries. The current law, enacted in December 2003, allows the importation of drugs from Canada, but only if the Secretary of Health and Human Services certifies that importation will pose no additional risk to the public s health and safety. To date, no such certifications have been given. Legislative proposals have been made to change the law to allow importation without any certification. If this or other new legislation or regulations were passed allowing the reimportation of drugs, it could adversely affect the prices of our potential products.

In addition, there has been much discussion regarding the creation of laws permitting follow-on or generic versions of biologics. While there is not currently an abbreviated approval pathway for biologics as there is with branded drugs, Congress and the FDA are studying the issue and legislation addressing this issue could be passed as a part of the healthcare reform initiative. An abbreviated pathway for follow-on biologics may permit the FDA to rely on clinical data submitted by innovator developers like ourselves when evaluating applications filed by sponsors of follow-on biologics and may not require full or any clinical trials, significantly lowering the risks and financial barriers to entry. The approval of follow-on biologics could result in new and increased competition, including competition prior to expiration of our patents covering our products, and related litigation. In addition, if follow-on or generic versions are permitted, data exclusivity, the period during which generic manufacturers may not cite the clinical trial results of the innovator, will become critical. Adoption of a relatively short data exclusivity period could result in products that, over the life of such product, are less profitable.

Negative public opinion and increased regulatory scrutiny of genetic and clinical research may limit our ability to conduct our business.

Ethical, social and legal concerns about genetic and clinical research could result in additional regulations restricting or prohibiting some of our activities or the activities of our suppliers and collaborators. In recent years, federal and state agencies, congressional committees and foreign

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governments have expressed interest in further regulating the biotechnology industry. More restrictive regulations could delay or complicate nonclinical studies or clinical trials, or prevent us from obtaining regulatory approvals or commercializing any products. In addition, animal rights activists may protest our use of animals in research and development and may attempt to disrupt our operations, which could cause us to incur significant expenses and distract management attention from other business concerns.

The marketing and sale of pharmaceutical products and biologics is subject to extensive regulation and aggressive government enforcement, and our corporate compliance program cannot guarantee that we are in compliance with all relevant laws and regulations.

Our activities relating to the sale and marketing of RECOTHROM and any other products we commercialize will be subject to extensive regulation under the U.S. Federal Food, Drug and Cosmetic Act and other federal statutes and associated regulations. These laws and regulations limit the types of marketing claims and other communications we can make regarding marketed products. We are also subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Anti-kickback laws prohibit payments of any kind intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services, including the selection of a particular prescription drug. These laws make certain business practices that are relatively common in other industries illegal in our industry. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent. The government has asserted very broad interpretations of these laws against pharmaceutical manufacturers, even though these manufacturers did not directly submit claims for reimbursement to government payors. In addition, regulation is not static and regulatory authorities, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our sales and marketing efforts. In addition, it is possible that action by federal or state regulatory authorities, such as the FDA, or private legal actions related to our sales and marketing efforts could result in additional investigations or legal actions by state attorneys general. Violations of the above laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs, including Medicare and Medicaid. Many pharmaceutical and biotechnology companies have in recent years been the target of lawsuits and investigations, by both federal and state governmental authorities, alleging violations of government regulation, including claims asserting violations of the federal False Claims Act, the federal anti-kickback statute, state consumer protection statutes and other violations in connection with off-label promotion of products, pricing, and government price reporting. While we will strive to comply with these complex requirements, the interpretation of these laws as applied to particular sales and marketing practices continues to evolve, and it is possible that our sales and marketing practices might be challenged. Further, although we have taken measures to prevent potential challenges, including through our corporate compliance program, we cannot guarantee that such measures will protect us from future challenges, lawsuits or investigations. Even if such challenges are without merit, they could cause adverse publicity, divert management attention and be costly to respond to, and thus could have a material adverse effect on our business, including impact on our stock price. In addition, our strategic partners and licensees are required to comply with comparably complex requirements in jurisdictions outside the U.S.

In order to sell RECOTHROM to federal institutions, such as military hospitals and the Veterans Administration, we must satisfy the requirements of listing on the Federal Supply Schedule and we are required to periodically report product pricing-related information. The calculations used to generate the pricing-related information are complex. If we fail to accurately and timely report product pricing-related information or to comply with any of these or any other laws or regulations, various negative consequences could result, including criminal and/or civil prosecution, substantial criminal and/or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs (including Medicare and Medicaid), costly litigation and restatement of our financial statements. In addition, our efforts to comply with this wide range of laws and regulations are, and will continue to be, time-consuming and expensive.

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Risks Related to Ownership of Our Stock

Our operating results are subject to fluctuations that may cause our stock price to decline.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenues have been unpredictable and could fluctuate due to slow or erratic uptake of RECOTHROM sales or the timing of licensing fees or the achievement of milestones under new or existing licensing and collaborative arrangements. In addition, our expenses may fluctuate from quarter to quarter due to the timing of expenses, particularly with respect to collaborative cost-sharing, contract manufacturing and clinical and nonclinical testing.

Accordingly, we believe that period-to-period comparisons of our past operating results are not good indicators of our future performance and should not be relied on to predict our future operating results. It is possible that in the future our operating results in a particular quarter or quarters will not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline, perhaps substantially.

Our stock price is volatile and subject to many factors beyond our control.

The market price of our common stock may fluctuate significantly in response to many factors beyond our control, including:

- changes in the recommendations of securities analysts or changes in their financial estimates of our operating results;
- recommendations or opinions of journalists, media personalities or market commentators;
- failures in meeting performance expectations of securities analysts or investors;
- acts or omissions of our licensees, collaborators and suppliers;
- changes in the political climate and changes in or uncertainties about federal and state legislation, policies, and programs affecting healthcare and pharmaceuticals;
- fluctuations in the valuations of companies perceived by securities analysts or investors to be comparable to us; and
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares.

Furthermore, the stock markets have experienced significant price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. In particular, there have been high levels of volatility in the market prices of securities of biotechnology companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock.

Certain of our shareholders have significant control of our management and affairs, which they could exercise against other shareholders best interests.

Novo Nordisk, together with Warburg Pincus Equity Partners, L.P., beneficially owned an aggregate of approximately 45.1% of our outstanding common stock as of September 30, 2009, with Novo Nordisk beneficially owning approximately 31.5% and Warburg beneficially owning approximately 13.6%. Four of the nine members of our board of directors are representatives or

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designees of these shareholders pursuant to a shareholders agreement. Novo Nordisk, acting independently or together with Warburg, has the ability to significantly influence our management and affairs and matters requiring shareholder approval, including the election of directors and approval of corporate strategy and significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, Novo Nordisk, acting independently or together with Warburg, may be able to cause a change in control, as well as delay or prevent a change in control. They may also discourage a potential acquirer from making a tender offer or otherwise attempting to effect a change in control, even if such a change in control would benefit our other shareholders.

Provisions in Washington law, our charter documents and executive employment agreements we have entered into may prevent, discourage or delay a change in control.

We are subject to the Washington laws regulating corporate takeovers, which, with limited exceptions, prohibit a target corporation from engaging in certain significant business transactions for a period of five years after the share acquisition by an acquiring person, unless (i) the prohibited transaction or the acquiring person s purchase of shares was approved by a majority of the members of the target corporation s board of directors prior to the acquiring person s share acquisition or (ii) the prohibited transaction was both approved by the majority of the members of the target corporation s board and authorized at a shareholder meeting by at least two-thirds of the outstanding voting shares (excluding the acquiring person s shares) at or subsequent to the acquiring person s share acquisition. An acquiring person is defined as a person or group of persons that beneficially owns 10% or more of the voting securities of the target corporation. Such prohibited transactions include, among other things:

- certain mergers or consolidations with, dispositions of assets to, or issuances of stock to or redemptions of stock from, the acquiring person;
- termination of 5% or more of the employees of the target corporation as a result of the acquiring person s acquisition of 10% or more of the shares;
- allowing the acquiring person to receive any disproportionate benefit as a shareholder; and
- liquidating or dissolving the target corporation.

After the five-year period, certain significant business transactions are permitted, as long as they comply with certain fair price provisions of the Washington statute or are approved by a majority of the outstanding shares other than those of which the acquiring person has beneficial ownership. A corporation may not opt out of this statute.

As such, these laws could prohibit or delay mergers or a change in control and may discourage attempts by other companies to acquire us.

In addition, our articles of incorporation and bylaws contain provisions, such as undesignated preferred stock and prohibitions on cumulative voting in the election of directors that could make it more difficult for a third party to acquire us without the consent of our board of directors. Also, our articles of incorporation provide for a staggered board, removal of directors generally only for cause and certain requirements for calling special shareholder meetings. Further, our bylaws require advance notice of shareholder proposals and nominations and impose restrictions on the persons who may call special shareholder meetings. These provisions may have the effect of preventing or hindering any attempts by our shareholders to replace our current board of directors or management.

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Item 6. Exhibits

Exhibit Number	
10.1	Employment Agreement, dated as of September 28, 2009, by and between ZymoGenetics, Inc. and Dennis M. Miller, Ph.D.
10.2	Amended and Restated Stock Option Grant Program for Nonemployee Directors under the ZymoGenetics 2001 Stock Incentive Plan.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Management contract or compensatory plan or arrangement.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ZYMOGENETICS, INC.

Date: November 5, 2009

By: /s/ JAMES A. JOHNSON
James A. Johnson
Executive Vice President and Chief Financial Officer
(Principal Financial Officer and Authorized Officer)