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, 2004

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 is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes [X] No [ ]

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 November 1, 2004: 57,227,207 shares.

ZYMOGENETICS, INC.

Quarterly Report on Form 10-Q
For the quarterly period ended September 30, 2004

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ZYMOGENETICS, INC.
BALANCE SHEETS
(in thousands)

	September 30, 2004	December 31, 2003
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 32,964	$ 97,576
Short-term investments	217,408	202,316
Receivables		
Related party	3,422	3,458
Trade	1,386	1,189
Interest and other	1,365	1,228
Prepaid expenses and other	3,860	2,777
Total current assets	260,405	308,544
Property and equipment, net	69,890	62,341
Other assets	5,372	5,024
Total assets	$335,667	$375,909
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 3,954	$ 4,808
Accrued liabilities	12,745	8,301
Deferred revenue	2,809	8,022
Total current liabilities	19,508	21,131
Construction advance from landlord	—	7,918
Lease obligation	65,839	50,570
Deferred revenue, net of current portion	4,385	4,957
Deferred lease obligations	104	59
Other noncurrent liabilities	3,599	3,359
Commitments and contingencies		
Shareholders' equity		
Common stock, no par value, 150,000 shares authorized, 53,871 and 52,494 issued and outstanding at September 30, 2004 and December 31, 2003, respectively	514,174	498,602
Non-voting common stock, no par value, 30,000 shares authorized, none issued and outstanding	—	—
Notes receivable from shareholders	—	(725)
Deferred stock-based compensation	(4,628)	(9,455)
Accumulated deficit	(266,398)	(201,033)
Accumulated other comprehensive income (loss)	(916)	526
Total shareholders' equity	242,232	287,915
Total liabilities and shareholders' equity	$335,667	$375,909

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

ZYMOGENETICS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
Revenues				
Royalties				
Related party	$ 2,567	$ 1,668	$ 5,753	$ 4,865
Other	841	657	2,428	2,220
Option fee from related party	1,875	1,875	5,625	5,625
License fees and milestone payments				
Related party	6,450	809	8,851	3,327
Other	203	3,203	3,320	4,129
Total revenues	11,936	8,212	25,977	20,166
Operating expenses				
Research and development (excludes noncash stock-based compensation expense of $1,162, $1,007, $3,807 and $3,255, respectively)	26,963	17,504	68,871	46,471
General and administrative (excludes noncash stock-based compensation expense of $328, $700, $4,015 and $2,116, respectively)	4,758	3,821	13,153	11,595
Noncash stock-based compensation expense	1,490	1,707	7,822	5,371
Total operating expenses	33,211	23,032	89,846	63,437
Loss from operations	(21,275)	(14,820)	(63,869)	(43,271)
Other income (expense)				
Investment income	1,150	1,230	3,501	5,223
Interest expense	(1,882)	(1,422)	(4,979)	(4,186)
Other gains (losses), net	5	17	(18)	(60)
Net loss	$ (22,002)	$ (14,995)	$ (65,365)	$ (42,294)
Basic and diluted net loss per share	$ (0.41)	$ (0.32)	$ (1.23)	$ (0.92)
Weighted-average number of shares used in computing net loss per share	53,762	46,221	53,225	46,037

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

ZYMOGENETICS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2004	**2003 (restated)**
Cash flows from operating activities		
Net loss	$ (65,365)	$ (42,294)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	4,003	4,215
Net loss on disposition of property and equipment	6	74
Noncash stock-based compensation	7,822	5,371
Net realized loss (gain) on sales of short-term investments	28	(966)
Amortization of premium on short-term investments	2,100	2,496
Changes in operating assets and liabilities		
Receivables	(326)	(5,879)
Prepaid expenses and other	(1,160)	(1,620)
Accounts payable	994	(1,178)
Accrued liabilities	4,444	1,232
Deferred revenue	(5,785)	(8,475)
Other noncurrent liabilities	693	687
Net cash used in operating activities	(52,546)	(46,337)
Cash flows from investing activities		
Purchases of property and equipment	(13,428)	(6,221)
Purchases of short-term investments	(206,074)	(242,562)
Proceeds from sales of property and equipment	23	62
Proceeds from sales and maturity of short-term investments	187,141	246,660
Net cash used in investing activities	(32,338)	(2,061)
Cash flows from financing activities		
Net proceeds from issuance of common stock	10,215	—
Construction advance from landlord	6,943	3,243
Proceeds from exercise of stock options	3,114	1,844
Net cash provided by financing activities	20,272	5,087
Net decrease in cash and cash equivalents	(64,612)	(43,311)
Cash and cash equivalents at beginning of period	97,576	55,579
Cash and cash equivalents at end of period	$ 32,964	$ 12,268
Supplemental Disclosure of Cash Flow Information		
Noncash investing and financing activities:		
Other noncash additions (reductions) to property and equipment	$ (1,847)	$ 1,739
Noncash settlement of notes receivable	$ 725	$ —
Noncash settlement of interest receivable	$ 22	$ —

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

ZYMOGENETICS, INC.
NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Basis of presentation

The accompanying unaudited 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.

The balance sheet at December 31, 2003 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. These 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, 2003.

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 period. Actual results could differ from those estimates.

The Company's financial statements for the quarter ended September 30, 2003 and the nine months ended September 30, 2003 have been restated. Subsequent to the issuance of these financial statements, in consultation with its outside auditors, the Company determined that the sale-leaseback transaction that occurred in October 2002 was not appropriately accounted for. The Company initially accounted for the transaction as a sale of the properties involved and as operating leases under the provisions of SFAS 13. Subsequently it was determined that the leases contain a specific technical provision that could, under certain remote circumstances, result in the Company's continuing ownership involvement with respect to the properties. Due to the existence of this provision, the transaction was more appropriately accounted for as a financing rather than a sale and leaseback of the properties. The following table summarizes the impact of the restatement on the Company's financial statements as reported in this Form 10-Q (in thousands, except per share data):

	Three Months Ended September 30, 2003		Nine Months Ended September 30, 2003	
	As Reported	As Restated	As Reported	As Restated
Property and equipment, net	$ 21,965	$56,563	$ 21,965	$56,563
Deferred gain on sale of asset, current	960	—	960	—
Deferred gain on sale of asset, noncurrent	12,486	—	12,486	—
Deferred lease obligations	1,497	49	1,497	49
Lease obligation	—	50,476	—	50,476
Accumulated deficit	(182,771)	(183,756)	(182,771)	(183,756)
Research and development expense	18,568	17,504	49,536	46,471
General and administrative expense	4,087	3,821	12,361	11,595
Loss from operations	(16,150)	(14,820)	(47,102)	(43,271)
Interest expense	(4)	(1,422)	(8)	(4,186)
Other income (expense), net	322	86	1,605	892
Net loss	(14,671)	(14,995)	(41,235)	(42,294)
Net loss per share—basic and diluted	(0.32)	(0.32)	(0.90)	(0.92)

2. Net loss per share

Basic and diluted net loss per share has been computed based on net loss available to common shareholders and the weighted-average number of common shares outstanding during the applicable period. The Company has excluded all outstanding options to purchase common stock as such shares are antidilutive for all periods presented.

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
Net loss	$ (22,002)	$ (14,995)	$ (65,365)	$ (42,294)
Weighted-average shares used in computing basic and diluted net loss per share	53,762	46,221	53,225	46,037
Basic and diluted net loss per share	$ (0.41)	$ (0.32)	$ (1.23)	$ (0.92)
Antidilutive securities not included in net loss per share calculation:				
Options to purchase common stock	10,308	9,422	10,308	9,422

3. Short-term investments

Short-term investments consisted of the following at September 30, 2004 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Type of security:				
Commercial paper and money market	$ 7,200	$ —	$ —	$ 7,200
Corporate debt securities	44,825	57	(217)	44,665
Asset-backed securities	76,465	68	(443)	76,090
U.S. government and agency securities	89,078	2	(382)	88,698
Foreign government securities	756	—	(1)	755
	$ 218,324	$ 127	$ (1,043)	$ 217,408
Maturity date:				
Less than one year	$ 175,308			$ 174,723
Due in 1-3 years	43,016			42,685
	$ 218,324			$ 217,408

The Company has concluded that unrealized losses are temporary due to the ability of the Company to realize the full value of its investments at maturity.

4. Stock compensation

As permitted by the provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock Based Compensation* (SFAS 123) as amended by Statement of Financial Accounting Standards

No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure* (SFAS 148), the Company has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), in accounting for employee stock option grants and apply the disclosure-only provisions of SFAS 123 to account for its employee stock option plans. Under APB 25, compensation expense is based on the excess, if any, of the estimated fair value of its stock at the date of grant over the exercise price of the option. Deferred compensation is amortized over the vesting period of the individual options, using the straight-line method

The following table illustrates the effect on net loss and loss per share as if the fair value method prescribed by SFAS 123 had been applied to all outstanding and unvested awards (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
Net loss as reported	$ (22,002)	$ (14,995)	$ (65,365)	$ (42,294)
Add: employee stock-based compensation under APB 25 included in reported net loss	1,490	1,707	4,596	5,371
Add: employee stock-based compensation related to the repayment of loans to purchase common stock included in reported net loss	—	—	3,226	—
Deduct: employee stock-based compensation expense determined under the fair value method	(3,932)	(3,291)	(11,629)	(9,248)
Net loss attributable to common shareholders, pro forma	$ (24,444)	$ (16,579)	$ (69,172)	$ (46,171)
Basic and diluted net loss per share, as reported	$ (0.41)	$ (0.32)	$ (1.23)	$ (0.92)
Basic and diluted net loss per share, pro forma	$ (0.45)	$ (0.36)	$ (1.30)	$ (1.00)

5. Lease obligation

In 2003, the Company exercised its option to expand one of its leased buildings and, effective May 2004, the Company assumed occupancy of the new space. As of September 30, 2004, the Company had incurred total project costs of approximately $21 million and received an advance from the landlord of $14.9 million. The Company has accounted for this transaction as a financing due to a technical provision within the lease related to condemnation, which could, under remote circumstances, result in continuing ownership involvement by the Company in the building. Under this method of accounting, the net proceeds are considered to be a long-term interest bearing liability. Rent payments under the lease are considered to be payments towards the liability and are allocated to principal and interest.

The Company has reclassified the advance from the landlord of $14.9 million as an addition to the long-term lease obligation with an annual effective interest rate of approximately 12%. At the end of the lease term, the remaining balance of the liability will approximate the net book value of the buildings leased. Upon the completion of the expansion project, the lease terms for all three buildings were reset to 15 years from the date of occupancy of the expansion space.

The following table presents the Company's scheduled payments under the capitalized building lease obligation, including the additional payments related to the expansion and the reset of the lease terms to 15 years (in thousands):

Twelve months ending September 30,	
2005	$ 7,043
2006	7,289
2007	7,544
2008	7,808

2009	8,081
Thereafter	94,180
	$ 131,945

6. Comprehensive loss

For the three and nine months ended September 30, 2004, total comprehensive loss was $21.7 million and $66.8 million, respectively. For the three and nine months ended September 30, 2003, total comprehensive loss was $15.8 million and $44.0 million, respectively. Comprehensive loss is composed of net loss and unrealized gains and losses on short-term investments. The net change in accumulated other comprehensive income (loss) for the nine months ended September 30, 2004 was approximately $1.4 million, reflecting an increase in unrealized losses on short-term investments due to increasing interest rates.

7. Transactions with related party

In March 2004, the Company signed a license agreement with Novo Nordisk providing it exclusive license rights to commercialize the Company's IL-20 intellectual property in North America. The license agreement includes an execution fee of $4.0 million, and potential milestones and royalties. Novo Nordisk is responsible for all development activities. As of September 30, 2004, $1.2 million of the execution fee was deferred and will be recognized as revenue evenly throughout the remainder of 2004.

In June 2004, the Company signed three license agreements with Novo Nordisk providing exclusive rights to commercialize the Company's intellectual property related to IL-28a, IL-29 and IL-31, outside North America. Each of the license agreements includes execution fees of $750,000 and potential milestones and royalties. Novo Nordisk is responsible for all development activities. During the quarter ended September 30, 2004, the Company satisfied all performance obligations and recognized the full $2.25 million as license fee revenue.

In September 2004, Novo Nordisk provided the Company with a notice of termination for its license to IL-20 receptor outside North America. Novo Nordisk had previously licensed this protein in September 2001 together with IL-20. The agreement provided for one of the two proteins to be considered a backup, which could be removed from the license at a later date. In terminating the license to IL-20 receptor as the backup protein, Novo Nordisk agreed to pay the Company a final milestone payment and a termination fee totaling $1.5 million, which have been recorded as milestone revenue for the period ending September 30, 2004.

8. Reclassification

Certain amounts in the financial statements have been reclassified to conform to the current period's presentation. The reclassifications had no impact on previously reported net loss.

9. Recent accounting pronouncements

In December 2003, the Financial Accounting Standards Board (FASB) issued a revised FASB Interpretation No. 46 (FIN 46R), *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51*. The FASB published the revision to clarify and amend some of the original provisions of FIN 46, which was issued in January 2003, and to exempt certain entities from its requirements. A variable interest entity (VIE) refers to an entity subject to consolidation according to the provisions of this Interpretation. FIN 46R applies to entities whose equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support provided by any parties, including equity holders, or where the equity investors (if any) do not have a controlling financial interest. FIN 46R provides that if an entity is the primary beneficiary of a VIE, the assets, liabilities, and results of operations of the VIE must be consolidated in the entity's financial statements. In addition, FIN 46R requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE provide additional disclosures. The provisions of FIN 46R became effective in the first quarter of fiscal 2004. The

adoption of this interpretation has not impacted the results of operations or the financial position of the Company.

In December 2003, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. SAB 104 supersedes Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101). SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superseded as a result of the issuance of EITF 00-21. Additionally, SAB 104 rescinds the SEC's Revenue Recognition in Financial Statements Frequently Asked Questions and Answers (the FAQ) issued with SAB 101 that had been codified in SEC Topic 13, Revenue Recognition. Selected portions of the FAQ have been incorporated into SAB 104. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. The Company has applied the provisions of EITF 00-21 since July 2003 and the issuance of SAB 104 has not impacted the results of operations or the financial position of the Company.

In 2004, the Financial Accounting Standards Board's Emerging Issues Task Force (EITF) issued a position document on EITF Issue No. 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* (EITF 03-01), which is meant to provide clarity and consistency in the determination of an other-than temporary impairment of investments. In September 2004, EITF 03-01-1 was issued and deferred the effective date of this position document but maintained the disclosure requirement of EITF 03-01 for paragraphs 21 and 22. The adoption of this statement has not impacted the results of operations or the financial position of the Company.

10. Subsequent events

On September 7, 2004, the Company entered into a master agreement with Serono S.A. and Serono B.V. (together, Serono), providing for a strategic research, development and commercialization alliance with Serono. The terms of the Master Agreement and related agreements were subject to review by the United States Federal Trade Commission (FTC) and Department of Justice, under the provisions of the Clayton Act, 15 U.S.C. ss. 18a, as added by the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act). Effective October 5, 2004, the FTC granted the parties' request for early termination of the waiting period required under the HSR Act with regard to the proposed alliance. On October 12, 2004, upon closing of the transaction, the Company issued and sold to Serono 3,176,620 shares of common stock at a price per share of $15.74, for an aggregate purchase price of $50 million. Additionally, the Company entered into a strategic alliance agreement and three other product-related agreements pursuant to which Serono will pay total upfront fees of approximately $31 million plus potential milestones and royalties.

On October 4, 2004, the Company entered into a license agreement with Novo Nordisk A/S (Novo Nordisk), with respect to recombinant Factor XIII. The License Agreement provides that Novo Nordisk will develop and commercialize recombinant Factor XIII on a worldwide basis and pay the Company $15 million upon signing plus potential milestones and royalties.

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. The discussion in this report contains forward-looking statements that involve risks and uncertainties, such as our objectives, forecasts, expectations and intentions. Inaccurate assumptions and known and unknown risks and uncertainties can affect the accuracy of forward-looking statements, and our actual results could differ materially from results that may be anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Important Factors That May Affect Our Business, Our Results of Operations and Our Stock Price" as well as those discussed elsewhere in this report. When used in this document, the words "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. The cautionary statements made in this document should be read as being applicable to all related forward-looking statements wherever they appear in this document. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that may subsequently arise. Readers are urged to carefully review and consider the various disclosures made in this report and in our other reports filed with the SEC that attempt to advise interested parties of the risks and factors that may affect our business, prospects and results of operations.

Business Overview

ZymoGenetics, Inc. is 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 commercialize 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.

An important element of our strategy is that we intend to maintain all or a significant share of the commercial rights to a number of our products in North American markets. As a result, we will be required to pay a significant portion of the development costs for these product candidates. A second important element of our strategy is that we are developing a broad portfolio of product candidates to give our company more opportunities to be successful. We currently have three product candidates in clinical development and expect to add additional proteins to this portfolio in the future. Thus, we are paying a significant portion of development costs for several potential products. Assuming these product candidates progress through clinical development successfully, the costs of clinical trials are expected to increase significantly.

Our most significant financial challenges are to obtain adequate funding to cover the cost of product development, and to control spending and direct it toward product candidates that will create the most value for the company's shareholders over the long term. It can be a complex and highly subjective process to establish the appropriate balance between cash conservation and value generation. There are a number of important factors that we consider in addressing these challenges, including the following:

- the nature, timing and magnitude of financing transactions, which would typically involve issuance of equity or equity-based securities;
- the nature and timing of product development collaborations, which would typically provide for funding of a portion of the respective product development costs, as well as bring in near-term potential revenues in the form of upfront fees and milestone payments;
- the breadth of product development programs, i.e. the number of potential disease indications for which a product candidate is tested in clinical trials;
- the number of products in our development portfolio and the decision to move new product candidates into clinical development; and
- periodic assessments of the relative capital requirements, risk and value of each of our product candidates.

We expect that it will be at least four to five years before we can generate enough product-related revenues to reach cash flow breakeven. In the interim, revenues from existing relationships will help to defray our expenses, but additional funding will be required, the amount of which could be significant. We may decide to enter into additional product development collaborations, which would reduce our funding

requirements. We may also generate funding through licensing of patents that are not relevant to our product development programs.

It is likely that we will continue to look for opportunities to raise equity capital as a primary means of funding our company over the next several years. The equity markets for biotechnology stocks have tended to experience long cycles during which the sale of equity securities has been extremely difficult. It is not possible to predict the timing or length of these cycles. As a result, most biotechnology companies, including ours, have adopted an opportunistic strategy of raising equity capital when it is available. We believe this strategy is important to minimizing the financial risks to our company and our shareholders.

Results of Operations

Royalties. We earn royalties on sales of certain products subject to license agreements with Novo Nordisk and several other companies. While we do not expect any change in the underlying sales trend in the future, beginning in 2005, we expect substantial reductions in insulin royalties due to patent expirations in a number of major countries. Insulin royalties represented 63% and 62% of our total royalty revenues for the three-month periods ended September 30, 2004 and 2003 and 59% and 60% of our total royalty revenues for the nine months ended September 30, 2004 and 2003, respectively. The increase in related party royalties from 2003 to 2004, for both periods reported, is primarily due to the weakening of the U.S. currency as compared to the Danish Kroner and its impact on the calculation of royalties. We have opportunities to earn royalties in the future under other existing license agreements, but we cannot be certain when, or if, products will be sold subject to those licenses.

Option fee from related party. We recognized $5.6 million for each of the nine-month periods presented, representing three quarters of the annual option fee of $7.5 million from Novo Nordisk under an option and license agreement, pursuant to which we have given them an option to license certain rights to proteins that we discover. The initial term of this agreement was scheduled to expire in November 2004, but Novo Nordisk exercised its right to extend the agreement and has committed to continue to pay $7.5 million annually for two additional years. Revenue for these annual option fees will be recognized ratably over the term of the extension period.

License fees and milestone payments. The increase in license fees and milestone payments for the three-month period ended September 30, 2004, as compared to the same period in 2003, is primarily due to recognition of revenue related to the following items:

- license fees from Novo Nordisk for rights to IL-28a, IL-29 and IL-31 outside North America;
- a portion of a license fee from Novo Nordisk for rights to IL-20 in North America;
- a milestone payment from Novo Nordisk related to the initiation of IL-21 clinical trials outside North America; and
- a final milestone payment and a termination fee from Novo Nordisk related to the termination of a license to IL-20 receptor outside North America.

The increase for the nine-month period ended September 30, 2004, as compared to the same period in 2003, is primarily due to these same factors, together with increases related to an up-front payment from the Amgen, Inc. license agreement and milestone revenue recognized from BioMimetic Pharmaceuticals. The increases in both the three and nine-month periods ended September 30, 2004 were partially offset by the expiration of the Novo Nordisk IL-21 preclinical collaboration agreement, which ended in March 2004.

Revenues from license fees and other upfront payments are recognized over the period we are contractually required to provide other rights or services that represent continuing obligations. We recognize license fees as revenue upon execution of license agreements that require no continuing performance by us. We recognize revenues from milestone payments that represent completion of separate and substantive earnings processes when the milestone is achieved and amounts are due and payable. From period to period, this revenue item can fluctuate substantially based on the completion of new licensing or collaborative agreements and the achievement of development related milestones. Although this revenue item increased for the 2004 periods, we cannot be certain this trend will continue in 2004 and beyond due to the uncertain nature of the events generating the revenue.

Research and development expenses. Research and development expenses have been our most significant expense to date, consisting primarily of salaries and benefit expenses, costs of consumables, facility costs and contracted services. Contracted services consist primarily of services related to manufacturing, preclinical studies and clinical trials. Research and development expenses, net of cost reimbursements, increased by 54% and 48% for the three and nine-month periods ended September 30, 2004, respectively, as compared to the same periods in 2003. Increases over the periods reported largely resulted from increased activities related to our clinical development projects. Part of the increase resulted from reduced costs reimbursed by Novo Nordisk under the IL-21 preclinical collaboration agreement, which ended in March 2004. These trends are shown in the following table (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
Salaries and benefits	$ 9,593	$ 7,904	$ 28,619	$ 24,379
Consumables	2,601	2,215	6,752	6,477
Facility costs	1,442	1,120	4,111	3,377
Contracted services	12,086	6,668	26,036	13,693
Depreciation and amortization	1,241	1,092	3,391	3,551
Subtotal	26,963	18,999	68,909	51,477
IL-21 cost reimbursement from Novo Nordisk	—	(1,495)	(38)	(5,006)
Net research and development expense	$ 26,963	$ 17,504	$ 68,871	$ 46,471

Research and development expense has continued to increase as we have advanced and expanded our internal product development programs. We expect this trend to continue over the remainder of 2004. A number of factors, including the following, have and will continue to contribute to the significant increase in net research and development expense as compared to 2003:

- costs related to scale-up and production of Phase 3 and commercial product for the rhThrombin program;
- costs of significantly expanded clinical trial activity, particularly with respect to rhThrombin and TACI-Ig;
- increased staffing to support expanded product development efforts, particularly in the clinical, medical, regulatory and quality areas; and
- reduced cost reimbursements from Novo Nordisk with respect to development of IL-21.

General and administrative expenses. General and administrative expenses consist primarily of salaries and benefit expenses, professional fees and other corporate costs. Expenses increased by 25% and 13% for the three and nine-month periods in 2004, respectively, as compared to the same periods in 2003, largely due to higher costs associated with business development activities, compliance with the Sarbanes-Oxley Act, and growth in other areas supporting the company's business, particularly human resources and information technology.

We anticipate that general and administrative expenses will continue to increase in future periods, reflecting the additional administrative requirements of supporting our product development programs as they advance toward commercialization. In addition, we will continue to incur increased professional fees in order to comply with the requirements of the Sarbanes-Oxley Act of 2002.

Noncash stock-based compensation expense. In 2001 and early 2002, prior to the completion of our initial public offering, stock options were granted to employees and directors at exercise prices below the

estimated fair value of the common stock on the date of grant. As a result, we recorded total deferred stock-based compensation of $29.2 million. Deferred stock-based compensation is being amortized to expense over the vesting periods of the underlying options, generally four years, using the straight-line method. In the second quarter of 2004, we recorded a one-time compensation expense charge of $3.2 million related to the repayment of loans by certain executives with shares of common stock originally purchased with the loan proceeds. The compensation expense equaled the difference between the estimated fair value of the shares on the date of the loan payment less the exercise price or the value of the shares previously used as the basis for recording compensation expense. This increase was partially offset by the cancellation of unvested options held by employees who terminated their employment with the Company. We expect to amortize an additional $1.5 million of deferred stock-based compensation expense in 2004 and a total of $3.0 million in 2005, although actual amounts may be lower if unvested options for which deferred compensation has been recorded are subsequently cancelled. Although we have no current intention of doing so, the amount could increase if future options are granted with exercise prices below the estimated fair value of the common stock on the date of the grant.

In March, 2004, the Financial Accounting Standards Board issued an Exposure Draft, *Share-Based Payment,* that addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, *Accounting for Stock Issued to Employees,* and generally would require instead that such transactions be accounted for using a fair-value-based method. Disclosure of the effect of expensing the fair value of equity compensation is currently required under existing literature (see Note 4 to the financial statements). While the final statement is subject to change, it is currently anticipated it will become effective for periods beginning after June 15, 2005, which would be our third fiscal quarter in 2005. We are in the process of evaluating the impact this proposal will have on our financial statements.

Other income (expense). Other income (expense) consists primarily of investment income and interest expense. Investment income is generated primarily from investment of our cash reserves in investment grade, fixed-income securities. There are three primary factors affecting the amount of investment income that we report: amount of cash reserves invested, the effective interest rate, and the amount of gains or losses recognized. The following table shows how each of these factors affected investment income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Weighted average amount of cash reserves	$ 257,493	$ 240,677	$ 272,592	$ 256,472
Effective interest rate	0.46%	0.48%	1.29%	1.67%
Investment income before gains and losses	1,184	1,161	3,529	4,271
Net gain (loss) on sales of investments	(34)	69	(28)	952
Investment income, as reported	$ 1,150	$ 1,230	$ 3,501	$ 5,223

Liquidity and Capital Resources

As of September 30, 2004, we had cash, cash equivalents and short-term investments of $250.4 million, which we intend to use to fund our operations and capital expenditures over the next several years. These cash reserves are held in a variety of investment-grade, fixed-income securities, including corporate bonds, commercial paper and money market instruments. We planned to use approximately $85 million to $95 million of our cash reserves to fund our operations and capital expenditures in 2004. Through September 30, 2004, we have used approximately $66 million.

In October 2004, the Company entered into separate agreements with Serono and Novo Nordisk. The Company issued and sold to Serono 3,176,620 shares of common stock at a price per share of $15.74, for an aggregate purchase price of $50 million. Additionally, the Company entered into a strategic alliance

agreement and three other product-related agreements pursuant to which Serono pays total upfront fees of approximately $31 million plus potential milestones and royalties. The Company entered into a license agreement with Novo Nordisk with respect to recombinant Factor XIII. The License Agreement provides that Novo Nordisk will develop and commercialize recombinant Factor XIII on a worldwide basis and pay the Company $15 million upon signing plus potential milestones and royalties.

We believe that our existing cash resources, including amounts receivable from Serono and Novo Nordisk in the fourth quarter of 2004, should provide sufficient funding through late 2007. If we complete additional collaborative development transactions, which could generate both revenues and cost reductions, these cash resources could fund our company for an extended period of time.

Cash flows from operating activities. The amount of cash used to fund our operating activities generally tracks our net losses, with the following exceptions:

- noncash expenses, such as depreciation and amortization, gain or loss on sale or disposal of assets, and noncash stock-based compensation, which do not result in uses of cash;
- net realized gain and amortization of premium 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;
- changes in deferred revenue, which reflect the difference in timing between the receipt of cash from option fees, license fees and other upfront 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; and
- changes in other assets and liabilities, which generally represent temporary timing differences between the recognition of certain expenses and their payment.

Generally, with the exception of changes in deferred revenue, we do not expect these items to generate material period-to-period fluctuations in the relationship between our net loss and the amount of net cash used in operating activities. Substantial license or upfront fees may be received upon the date we enter into new licensing or collaborative agreements and be recorded as deferred revenue.

Cash flows from investing activities. Our most significant use of cash in investing activities is for capital expenditures. Our business requires us to expend a certain amount each year to adopt newly developed technologies and replace obsolete assets. In addition, we have used cash to expand our facilities. The following table shows the amount of cash going toward each of these types of capital expenditures for the nine months ended September 30 (in thousands):

	2004	**2003**
Ongoing equipment/facility expenditures	$ 4,043	$4,776
Expansion of R&D facility, including pilot scale manufacturing plant	9,385	1,445
Total	$ 13,428	$6,221

We assumed occupancy of the R&D facility expansion project on May 10, 2004. To date, we have spent approximately $21 million towards the building and related equipment costs. We have a remaining budget of $5 million for construction, equipment and validation costs, much of which we expect will be incurred over the remainder of 2004. The project was partially funded by an allowance from our landlord of $14.9 million. The term of the lease is 15 years and ends May 10, 2019. This transaction has been accounted for as a financing due to a technical provision within the leases related to condemnation, which could, under remote circumstances, result in continuing ownership involvement by us in the three buildings.

Cash flows from investing activities also reflect $18.9 million of cash used to purchase short-term investments net of amounts received 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 relevant to an understanding of our liquidity and capital resources.

Cash flows from financing activities. In May 2004, we entered into a stock purchase agreement with Amgen, Inc. under which they agreed to purchase 624,337 shares of our common stock. We received net proceeds of approximately $10 million. We received an additional $6.9 million, which represents the final installments of construction advance payments from our landlord.

We expect to incur substantial additional costs as we continue to advance and expand our product development programs. We expect these expenditures to increase over the next several years, particularly if the outcomes of clinical trials are successful. Our plans include the internal development of selected product candidates and the co-development of product candidates with collaborators where we would assume a percentage of the overall product development costs. If, at any time, our prospects for financing these programs decline, we may decide to reduce our ongoing investment in our development programs. We could reduce our investment by discontinuing our funding under existing co-development arrangements, establishing new co-development arrangements for other product candidates to provide additional funding sources or out-licensing product candidates that we might otherwise develop internally. Additionally, we could consider delaying or discontinuing development of product candidates to reduce the level of our related expenditures.

Our long-term capital requirements and the adequacy of our available funds will depend on several factors, many of which may not be in our control, including:

- results of research and development programs;
- cash flows under existing and potential future arrangements with licensees, collaborators and other parties;
- costs involved in filing, prosecuting, enforcing and defending patent claims; and
- costs associated with the expansion of our facilities.

Over the next several years we will need to seek additional funding through public or private financings, including equity financings, and through other arrangements, including collaborative arrangements. Poor financial results, 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 not be available on acceptable terms. If we raise additional funds by issuing equity or equity-based securities, 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 expansion plans, 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, 2004 we are contractually obligated to make payments as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Building lease obligation	$ 131,945	$ 7,043	$ 14,833	$ 15,889	$ 94,180
Operating leases	9,120	1,170	2,420	2,502	3,028
Manufacturing contracts	19,617	19,609	8	—	—

Total	$ 160,682	$ 27,822	$ 17,261	$ 18,391	$ 97,208

The building lease obligation, which resulted from the sale-leaseback financing transaction, reflects the reset of the lease terms to 15 years beginning May 2004. Operating lease terms range from one to ten years with certain renewal provisions at our option. The manufacturing contracts include Phase 3 and commercial production and fill and finish costs related to rhThrombin. The obligation for the rhThrombin manufacturing contract represents the base amount of the contract, assuming work proceeds as planned at the time the contract was signed. There are several points in the project at which we have the option to terminate further work, thereby reducing the amount of our commitment.

Important Factors That May Affect Our Business, Our Results of Operations and Our Stock Price

A summary of important factors that may affect our business, our results of operations and our stock price follows. You should refer to our Annual Report or Form 10-K for the year ended December 31, 2003 for a more thorough discussion of these factors. The risks and uncertainties identified below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the risks identified in the factors below actually occur, our business, financial condition and operating results could be materially adversely affected.

Product Development Risks

- We have limited experience in developing products.
- Any failure or delay in commencing or completing clinical trials for product candidates could severely harm our business.
- Clinical trials may fail to demonstrate the safety and effectiveness of our product candidates, which could prevent or significantly delay their regulatory approval.
- We may be unable to satisfy the rigorous government regulations relating to the development and commercialization of our product candidates.
- Because we currently do not have the capability to manufacture materials for clinical trials or for commercial sale, we will have to rely on third parties to manufacture our potential products, and we may be unable to obtain required quantities in a timely manner or on acceptable terms, if at all.
- We may not be successful in developing internal manufacturing capabilities or complying with applicable manufacturing regulations.
- Because we will depend on third parties to conduct laboratory tests and clinical trials, we may encounter delays in or lose some control over our efforts to develop product candidates.
- Because we currently have no sales or marketing capabilities, we may be unable to successfully commercialize our potential products.

Technological Risks

- Our bioinformatics-based discovery strategy is unproven, and we may not be able to discover any genes or proteins of commercial value.
- The availability of novel genomic data continues to decrease, which negatively affects our ability to discover entirely novel therapeutic proteins.

Intellectual Property Risks

- Our patent applications may not result in issued patents, and our competitors may commercialize the discoveries we attempt to patent.
- Third parties may infringe our patents or challenge their validity or enforceability.
- We may be subject to patent infringement claims, which could result in substantial costs and liability and prevent us from commercializing our potential products.
- Issued patents may not provide us with any competitive advantage or provide meaningful protection against competitors.
- The patent field relating to therapeutic protein-based products 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 proteins that we discovered.
- We expect to incur significant expenses in applying for patent protection and prosecuting our patent applications.
- We may be unable to protect our unpatented proprietary technology and information.

General Business Risks

- Our plan to use collaborations to leverage our capabilities may not be successful.
- We may not be able to generate any revenue from product candidates developed by collaborators or licensees if they are unable to successfully develop those candidates.
- Novo Nordisk has substantial rights to license proteins we discover, which may limit our ability to pursue other collaboration or licensing arrangements or benefit from our discoveries.
- Environmental and health and safety laws may result in liabilities, expenses and restrictions on our operations.

Financial and Market Risks

- We anticipate incurring additional losses and may not achieve profitability.
- If we do not obtain substantial additional funding on acceptable terms, we may not be able to continue to grow our business or generate enough revenue to recover our investment in research and development.
- Our operating results are subject to fluctuations that may cause our stock price to decline.

Industry Risks

- Many of our competitors have substantially greater capabilities and resources than we do and may be able to develop and commercialize products before we do.
- Our product candidates, even if approved by the FDA or foreign regulatory agencies, may not achieve market acceptance among hospitals, insurers or patients.
- If the health care system or reimbursement policies change, the prices of our potential products may fall or our potential sales may decline.
- Negative public opinion and increased regulatory scrutiny of genetic and clinical research may limit our ability to conduct 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 may be required to defend lawsuits or pay damages in connection with alleged or actual harm caused by our product candidates.

Other Risks

- Our stock price may be volatile.

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

- Provisions in our charter documents could prevent or frustrate any attempts to replace our current board of directors or management by shareholders.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is 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, including United States government and agency securities, high-grade United States corporate bonds, asset-backed securities, commercial paper and money market funds. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have 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)) as of the end of the period covered by this report, have concluded that as of such date our disclosure controls and procedures were effective. No change was made to our internal control over financial reporting in connection with this evaluation that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

(d) **Use of Proceeds from Sale of Registered Securities**

Our Registration Statement (File No. 333-69190) under the Securities Act of 1933 (the "Securities Act") relating to our initial public offering, was declared effective by the SEC on January 31, 2002. From the effective date of the offering through September 30, 2004, we have invested the net proceeds from the offering in a variety of investment grade, fixed income securities, including corporate bonds, commercial paper and money market instruments.

Item 6. Exhibits

Exhibit Number	
10.1	Employment agreement, dated August 29, 2004, between the Company and Douglas E. Williams.
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	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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 6, 2004

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