ZYMOGENETICS INC
Form 10-Q
May 07, 2004
Table of Contents

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 MARCH 31, 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	**(I.R.S. Employer**
incorporation or organization)	**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 April 30, 2004: 52,878,231 shares.

Table of Contents

ZYMOGENETICS, INC.

Quarterly Report on Form 10-Q

For the quarterly period ended March 31, 2004

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ZYMOGENETICS, INC.

BALANCE SHEETS

(in thousands)

	March 31, 2004	December 31, 2003
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 57,574	$ 97,576
Short-term investments	227,424	202,316
Receivables		
Related party	1,584	3,458
Trade	1,126	1,189
Interest and other receivables	1,609	1,228
Prepaid expenses and other assets	4,515	2,777
Total current assets	293,832	308,544
Property and equipment, net	65,756	62,341
Other assets	5,218	5,024
Total assets	$ 364,806	$ 375,909
Liabilities and Shareholders Equity		
Current liabilities		
Accounts payable	$ 6,023	$ 4,808
Accrued liabilities	7,205	8,301
Deferred revenue	8,984	8,022
Total current liabilities	22,212	21,131
Construction advance from landlord	11,793	7,918
Lease obligation	50,666	50,570
Deferred revenue, net of current portion	4,766	4,957
Deferred lease obligations	70	59
Other noncurrent liabilities	3,569	3,359
Commitments and contingencies		
Shareholders equity		
Common stock, no par value, 150,000 shares authorized, 52,830 and 52,494 issued and outstanding at March 31, 2004 and December 31, 2003, respectively	499,661	498,602

Non-voting common stock, no par value, 30,000 shares authorized		
Notes receivable from shareholders	(725)	(725)
Deferred stock-based compensation	(7,742)	(9,455)
Accumulated deficit	(219,929)	(201,033)
Accumulated other comprehensive income	465	526
Total shareholders equity	271,730	287,915
Total liabilities and shareholders equity	$ 364,806	$ 375,909

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

Table of Contents

ZYMOGENETICS, INC.

STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2004	**2003**
		(restated)
Revenues		
Royalties		
Related party	$ 1,592	$ 1,619
Other	818	777
Option fee from related party	1,875	1,875
License fees and milestone payments		
Related party	1,201	1,724
Other	203	238
Total revenues	5,689	6,233
Operating expenses		
Research and development (excludes noncash stock-based compensation expense of $1,077 and $1,128 in 2004 and 2003, respectively)	20,033	15,675
General and administrative (excludes noncash stock-based compensation expense of $495 and $638 in 2004 and 2003, respectively)	2,965	3,094
Noncash stock-based compensation expense	1,572	1,766
Total operating expenses	24,570	20,535
Loss from operations	(18,881)	(14,302)
Other income (expense)		
Investment income	1,403	2,170
Interest expense	(1,422)	(1,348)
Other, net	4	9
Net loss	$ (18,896)	$ (13,471)
Basic and diluted net loss per share	$ (0.36)	$ (0.29)
Weighted-average number of shares used in computing basic and diluted net loss per share	52,701	45,871

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

4

Table of Contents

ZYMOGENETICS, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2004	**2003**
		(restated)
Cash flows from operating activities		
Net loss	$ (18,896)	$ (13,471)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,214	1,467
Net gain on disposition of property and equipment		(9)
Noncash stock-based compensation	1,572	1,766
Net realized gain on sale of short-term investments	(163)	(501)
Amortization of premium on short-term investments	683	869
Changes in operating assets and liabilities		
Receivables	1,556	(981)
Prepaid expenses and other assets	(1,932)	(2,044)
Accounts payable	(282)	520
Accrued liabilities	(1,096)	(1,409)
Deferred revenue	771	(2,752)
Deferred lease obligations	11	7
Other noncurrent liabilities	306	85
Net cash used in operating activities	(16,256)	(16,453)
Cash flows from investing activities		
Purchases of property and equipment	(3,132)	(918)
Purchases of short-term investments	(145,042)	(82,853)
Proceeds from sale of property and equipment		19
Proceeds from sale and maturity of short-term investments	119,353	67,092
Net cash used in investing activities	(28,821)	(16,660)
Cash flows from financing activities		
Construction advance from landlord	3,875	
Proceeds from exercise of stock options	1,200	340
Net cash provided by financing activities	5,075	340
Net decrease in cash and cash equivalents	(40,002)	(32,773)
Cash and cash equivalents at beginning of period	97,576	55,579
Cash and cash equivalents at end of period	$ 57,574	$ 22,806

Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ 1,422	$ 1,348
Noncash financing activities:		
Other non-cash additions to property and equipment	$ 1,497	$

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

Table of Contents

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 March 31, 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 should have been accounted for as a financing as opposed to 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 for the quarter ended March 31, 2003 (in thousands, except per share data):

	As Reported	As Restated
Property and equipment, net	$ 17,088	$ 52,395
Deferred gain on sale of asset, current	960	
Deferred gain on sale of asset, noncurrent	12,966	
Deferred lease obligations	752	35
Lease obligation		50,211
Accumulated deficit	(154,672)	(154,933)
Research and development expense	16,676	15,675

General and administrative expense	3,344	3,094
Loss from operations	(15,553)	(14,302)
Interest expense	(3)	(1,348)
Other income (expense), net	250	9
Net loss	(13,136)	(13,471)
Net loss per share basic and diluted	(0.29)	(0.29)

Table of Contents

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 for the three months ended March 31 (in thousands, except per share data):

	2004	2003 (restated)
Net loss	$ (18,896)	$ (13,471)
Weighted-average shares used in computing basic and diluted net loss per share	52,701	45,871
Basic and diluted net loss per share	$ (0.36)	$ (0.29)
Antidilutive securities not included in net loss per share calculation:		
Options to purchase common stock	10,285	9,537

3. Short-term investments

Short-term investments consisted of the following at March 31, 2004 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Type of security:				
Corporate debt securities	$ 51,577	$ 263	$ (12)	$ 51,828
Asset-backed securities	95,888	238	(149)	95,977
U.S. government and agency securities	75,424	114	(2)	75,536
Foreign government securities	4,070	13		4,083
	$ 226,959	$ 628	$ (163)	$ 227,424
Maturity date:				
Less than one year	$ 93,407			$ 93,590

Due in 1-3 years	133,552	133,834
	$ 226,959	$ 227,424

4. Stock compensation

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

Table of Contents

The following table illustrates the effect on net income and earnings per share as if the fair value based method prescribed by SFAS 123 had been applied to all outstanding and unvested awards for the quarter ended March 31 (in thousands, except per share data):

	2004	2003 (restated)
Net loss as reported	$ (18,896)	$ (13,471)
Add: employee stock-based compensation under APB 25 included in reported net loss	1,572	1,766
Deduct: employee stock-based compensation expense determined under the fair value method	(3,653)	(2,734)
Net loss attributable to common shareholders, pro forma	$ (20,977)	$ (14,439)
Basic and diluted net loss per share, as reported	$ (0.36)	$ (0.29)
Basic and diluted net loss per share, pro forma	$ (0.40)	$ (0.31)

5. Lease obligation

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 term to 15 years (in thousands):

Twelve months ending March 31,	
2005	$ 6,671
2006	7,166
2007	7,417
2008	7,676
2009	7,945
Thereafter	98,367
	$ 135,242

6. Comprehensive loss

Comprehensive loss was $19.0 million and $14.0 million for the three months ended March 31, 2004 and 2003, respectively. Comprehensive loss is composed of net loss and unrealized gains and losses on short-term investments. The net change in other comprehensive income as of March 31, 2004 was approximately $ 61,000 and included an increase in unrealized gains, which was partially offset by a reclassification adjustment for realized gains.

7. Transaction with related party

In March 2004, the Company signed a license agreement with Novo Nordisk providing them with an exclusive license to practice commercialization rights under 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 will be responsible for all development activities. As of March 31, 2004, the Company deferred $3.6 million of the execution fee to be recognized as revenue evenly throughout the remainder of 2004.

Table of Contents

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

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 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 four 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 cost 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;

Table of Contents

- 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 57% and 61% of our total royalty revenues for the two quarterly periods ending 2004 and 2003, respectively. 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 $1.9 million for each of the two quarters presented, representing the quarterly portion 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 expires in November 2004, but Novo Nordisk has the option of extending it and paying $7.5 million annually for two additional years. If they do not extend the agreement, option fee revenue will decline to approximately $6.5 million in 2004, of which $4.6 million was included in deferred revenue at March 31, 2004, and none will be earned in future years.

License fees, milestones and other. Revenues from license fees and other up-front payments are recognized over the period we are contractually required to provide other rights or services that represent continuing obligations. The decrease of $558,000 for the first quarter in 2004 as compared to the same period in 2003 is due to the winding down of the IL-21 preclinical collaboration agreement signed with Novo Nordisk in December 2002. Our service requirement for that agreement has steadily decreased from the date of signing through the end of the service period in March 2004. This decrease was partially offset by the addition of a new agreement with Novo Nordisk for IL 20 that was signed in March 2004. The service period for this agreement will end in December 2004. For the license fees included in deferred revenue as of March 31,

2004, we expect to recognize license fee revenue of $4.2 million for the remainder of 2004 and approximately $800,000 per year thereafter through 2010. For certain license agreements that require no continuing performance of us, we record license fees as revenue upon execution of the agreement. 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 decreased for the 2004 period, we cannot be certain this trend will continue in 2004 and beyond due to the uncertain nature of the events generating the revenue.

Table of Contents

Research and development expenses. Research and development expense has been our most significant expense to date, consisting primarily of salaries and benefit expenses, costs of consumables, facility costs and contracted services. Research and development expense, net of cost reimbursements, increased by 28% for the quarter ended March 2004 as compared to the same period in 2003. Part of the increase resulted from reduced costs reimbursed by Novo Nordisk under the IL-21 preclinical collaboration agreement, which ended in March 2004. Increases over the periods reported largely resulted from significantly increased activities for the development of our four product candidates, rhThrombin, rFactor XIII, TACI-Ig and IL-21. The substantial increase in costs is largely due the costs associated with the addition of approximately 12 employees between March 31, 2003 and March 31, 2004, who are focused on product development and increases in external costs for contract manufacturing, clinical trials and preclinical testing. These trends are shown in the following table for the three months ended March 31 (in thousands).

	2004	2003
Salaries and benefits	$ 9,964	$ 8,713
Consumables	1,836	2,181
Facility costs	1,219	1,157
Contracted services	6,030	3,785
Depreciation and amortization	1,010	1,240
Subtotal	20,059	17,076
IL-21 cost reimbursement from Novo Nordisk	(26)	(1,401)
Net research and development expense	$ 20,033	$ 15,675

We anticipate that research and development expense will continue to increase in the foreseeable future as we continue to advance, and potentially expand, our internal product development programs. In 2004 we expect that a number of factors, including the following, will contribute to a 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 and rFactor XIII programs;
- 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.

Based on these factors, we estimate that research and development expense in 2004 will fall within the range of $100 million to $110 million, depending on the actual timing of these factors.

General and administrative expenses. General and administrative expense consists primarily of salaries and benefit expenses, professional fees and other corporate costs. Expenses decreased by 4% in the first quarter of 2004 as compared to the same period in 2003, largely due to a decrease in administrative personnel and legal fees. We expect to fill some of the vacated positions while others have been transferred to the development departments to adequately staff our development effort.

We anticipate that general and administrative expense will increase in 2004 and subsequent years reflecting the additional administrative requirements of supporting our product development programs as they advance toward commercialization. In addition, we will incur additional professional fees in order to comply with the requirements of the Sarbanes-Oxley Act of 2002.

Table of Contents

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. The expense decreased from the first three months of 2003 to the same period of 2004 due to cancellation of unvested options held by employees who terminated their employment with the company. We expect to amortize $6.3 million in 2004 and $3.1 million in 2005, although actual amounts may be lower if unvested options for which deferred stock-based 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.

Other income, net. 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 for the three months ended March 31 (in thousands):

	2004	2003
Weighted average amount of cash reserves	$ 287,069	$ 272,164
Effective quarterly interest rate	0.43%	0.61%
Investment income before gains and losses	1,240	1,669
Net gains on sales of investments	163	501
Investment income, as reported	$ 1,403	$ 2,170

Liquidity and Capital Resources

As of March 31, 2004, we had cash, cash equivalents and short-term investments of $285.0 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 expect to use approximately $85 million to $95 million of our cash reserves to fund our operations and capital expenditures in 2004. We believe that our existing cash resources should provide sufficient funding for approximately three years. If we complete additional collaborative development transactions, which would generate both revenues and cost reductions, we believe that these cash resources may fund our company for up to four years.

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 gains 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.

Table of Contents

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. For example, in the first quarter of 2004 upon the execution of a license agreement for IL-20, we received an upfront fee of $4.0 million, which was recorded as deferred revenue and will be recognized as revenue evenly from March through December 2004. The timing of these types of transactions is irregular and, thus, has the potential to create fluctuations in the relationship between our net loss and the amount of cash used in operating activities.

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 purchase land and expand our facilities. The following table shows the amount of cash going toward each of these types of capital expenditures as of March 31 (in thousands):

	2004	2003
Ongoing equipment/facility expenditures	$ 622	$ 397
Expansion of R&D facility, including pilot scale manufacturing plant	2,510	521
Total	$ 3,132	$ 918

The R&D facility expansion is an ongoing project, for which we have approved a total budget of approximately $26 million including all related equipment costs. To date, we have expended $17.7 million toward the project. The project will be partially funded by an allowance from our landlord expected to total approximately $15 million, which is reflected as cash flow from financing activities. The project began in April 2003 and is scheduled to be completed in mid-2004.

Cash flows from investing activities also reflect large amounts of cash used to purchase short-term investments and 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. As part of the agreement for the expansion of our R&D facility, our landlord has agreed to provide an allowance of approximately $15 million to be applied toward the cost of this ongoing project. We received $3.9 million of this amount in the first quarter of 2004 and expect to receive approximately $3 million over the remainder of the year. Additionally, our landlord has committed to loan the company $3 million to cover costs of the project not otherwise funded by the allowance.

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.

13

Table of Contents

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 March 31, 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	$ 135,242	$ 6,671	$ 14,583	$ 15,621	$ 98,367
Operating leases	9,694	1,151	2,385	2,500	3,658
Construction contract	7,976	7,976			
Manufacturing contracts	29,171	19,970	9,201		
Total	$ 182,083	$ 35,768	$ 26,169	$ 18,121	$ 102,025

The building lease obligation, which resulted from the sale-leaseback financing transaction, includes lease payments that will commence upon completion of the ongoing expansion project and that will result from a reset of the lease terms to 15 years. Operating lease terms range from one to ten years with certain renewal provisions at our option. The construction contract relates to our ongoing facility expansion project, and the amount shown above represents the remaining balance on the contract as of March 31, 2004. The manufacturing contracts includes Phase 3 and

commercial production of rhThrombin, and material production and fill and finish costs related to FXIII. The obligation for the rhThrombin agreement 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.

Recent Development

Our Chief Scientific Officer, Frank D. Collins, recently announced his intention to retire at the end of 2004. We are about to begin the recruitment process to identify and hire his replacement.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 recently agreed with Novo Nordisk that royalty payments will be made by them on a quarterly schedule based on exchange rates in effect at the end of the quarter. Therefore we no longer have any 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 under the Securities Act of 1933 (File No. 333-69190) relating to our initial public offering, was declared effective by the SEC on January 31, 2002. From the effective date of the offering through March 31, 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 and Reports on Form 8-K

(a) **Exhibits**

Exhibit

Number

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.

(b) **Reports on Form 8-K**

On February 27, 2004, the Company furnished a Current Report on Form 8-K to the SEC to report the issuance of a press release announcing the Company s results of operations and financial condition for the three and twelve months ended December 31, 2003.

Table of Contents

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: May 7, 2004

By: /s/ James A. Johnson

James A. Johnson
Senior Vice President and Chief Financial Officer
(Principal Financial Officer and Authorized Officer)