

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 10-Q**

(MARK ONE)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003

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  
(State or other jurisdiction of  
incorporation or organization)

91-1144498  
(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  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes  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 3, 2003: 52,441,665 shares.

**ZYMOGENETICS, INC.**

Quarterly Report on Form 10-Q  
For the quarterly period ended September 30, 2003

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**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****ZYMOGENETICS, INC.**  
**BALANCE SHEETS**  
(Unaudited)

	<b>September 30, 2003</b>	<b>December 31, 2002</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents.....	\$ 12,267,220	\$ 55,578,707
Short-term investments.....	222,527,923	229,858,985
Receivables		
Related party .....	3,034,105	388,655
Trade .....	4,832,531	1,109,687
Interest and other.....	1,728,770	2,218,341
Prepaid expenses and other assets .....	<u>2,988,891</u>	<u>2,252,879</u>
Total current assets.....	247,379,440	291,407,254
Property and equipment, net.....	21,964,507	17,252,932
Other assets.....	<u>4,601,821</u>	<u>3,572,806</u>
Total assets.....	<u>\$273,945,768</u>	<u>\$ 312,232,992</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities		
Accounts payable .....	\$ 3,877,796	\$ 3,172,193
Accrued liabilities.....	6,921,480	5,689,066
Construction advance from landlord .....	3,243,467	—
Deferred gain on sale of assets .....	959,860	959,860
Deferred revenue .....	<u>3,210,797</u>	<u>10,310,064</u>
Total current liabilities .....	18,213,400	20,131,183
Deferred gain on sale of assets, net of current portion .....	12,485,918	13,205,812
Deferred revenue, net of current portion .....	5,147,837	6,524,039
Deferred lease obligations .....	1,496,571	380,136
Other noncurrent liabilities.....	3,058,171	2,723,806
Commitments and contingencies		
Shareholders' equity		
Common stock, no par value, 150,000,000 shares authorized, 46,334,003 and 45,815,031 issued and outstanding at September 30, 2003 and December 31, 2002, respectively.....	427,159,711	427,009,984
Non-voting common stock, no par value, 30,000,000 shares authorized.....	—	—
Notes receivable from shareholders .....	(725,000)	(725,000)
Deferred stock compensation .....	(11,225,528)	(18,290,550)
Accumulated deficit .....	(182,771,086)	(141,535,635)
Accumulated other comprehensive income.....	<u>1,105,774</u>	<u>2,809,217</u>
Total shareholders' equity.....	<u>233,543,871</u>	<u>269,268,016</u>
Total liabilities and shareholders' equity .....	<u>\$273,945,768</u>	<u>\$ 312,232,992</u>

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

**ZYMOGENETICS, INC.**  
**STATEMENTS OF OPERATIONS**  
(Unaudited)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
Revenues				
Royalties				
Related party .....	\$ 1,668,439	\$ 1,555,745	\$ 4,864,952	\$ 4,147,507
Other .....	656,968	797,800	2,220,434	2,234,821
Option fee from related party .....	1,875,000	1,875,000	5,625,000	5,625,000
License fees and milestone payments				
Related party .....	808,817	1,505,000	3,327,374	2,255,000
Other .....	<u>3,203,177</u>	<u>191,927</u>	<u>4,128,592</u>	<u>4,421,454</u>
Total revenues .....	<u>8,212,401</u>	<u>5,925,472</u>	<u>20,166,352</u>	<u>18,683,782</u>
Operating expenses				
Research and development (excludes noncash stock-based compensation expense of \$1,071,269, \$982,585, \$3,450,645 and \$3,443,812, respectively) .....	19,767,471	16,425,236	52,336,476	47,126,908
General and administrative (excludes noncash stock-based compensation expense of \$635,502, \$832,927, \$1,920,482 and \$1,997,861, respectively) .....	2,887,956	3,834,710	9,561,029	12,773,757
Noncash stock-based compensation expense .....	<u>1,706,771</u>	<u>1,815,512</u>	<u>5,371,127</u>	<u>5,441,673</u>
Total operating expenses .....	<u>24,362,198</u>	<u>22,075,458</u>	<u>67,268,632</u>	<u>65,342,338</u>
Loss from operations .....	(16,149,797)	(16,149,986)	(47,102,280)	(46,658,556)
Interest and other income, net .....	<u>1,478,594</u>	<u>1,683,896</u>	<u>5,866,829</u>	<u>5,257,206</u>
Net loss .....	(14,671,203)	(14,466,090)	(41,235,451)	(41,401,350)
Preferred stock dividends and accretion on mandatorily redeemable convertible preferred stock .....	—	—	—	(1,717,865)
Net loss attributable to common shareholders .....	<u>\$ (14,671,203)</u>	<u>\$ (14,466,090)</u>	<u>\$ (41,235,451)</u>	<u>\$ (43,119,215)</u>
Basic and diluted net loss per share .....	<u>\$ (0.32)</u>	<u>\$ (0.32)</u>	<u>\$ (0.90)</u>	<u>\$ (1.04)</u>
Weighted-average number of shares used in computing basic and diluted net loss per share .....	<u>46,221,380</u>	<u>45,770,427</u>	<u>46,037,389</u>	<u>41,476,536</u>

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

**ZYMOGENETICS, INC.**  
**STATEMENTS OF CASH FLOWS**  
(Unaudited)

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2003</b>	<b>2002</b>
<b>Cash flows from operating activities</b>		
Net loss.....	\$ (41,235,451)	\$ (41,401,350)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization .....	3,113,007	4,343,586
Net loss on disposition of property and equipment .....	73,744	187,104
Noncash stock-based compensation .....	5,371,127	5,441,673
Net realized gain on sale of short-term investments.....	(966,220)	(360,266)
Amortization of premium on short-term investments .....	2,496,096	1,678,441
Amortization of deferred gain on sale of assets .....	(719,895)	—
Changes in operating assets and liabilities		
Receivables.....	(5,878,723)	419,324
Prepaid expenses and other assets .....	(1,620,103)	(650,329)
Accounts payable.....	(1,178,282)	(1,644,063)
Accrued liabilities.....	1,232,414	1,630,438
Deferred revenue .....	(8,475,469)	(6,646,871)
Deferred lease obligations .....	1,116,435	—
Other noncurrent liabilities .....	<u>334,365</u>	<u>(460,981)</u>
Net cash used in operating activities .....	<u>(46,336,955)</u>	<u>(37,463,294)</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment.....	(6,221,777)	(5,289,690)
Purchases of short-term investments .....	(242,562,574)	(192,314,186)
Proceeds from sale of property and equipment .....	62,412	31,500
Proceeds from sale and maturity of short-term investments.....	<u>246,660,317</u>	<u>103,620,131</u>
Net cash used in investing activities.....	<u>(2,061,622)</u>	<u>(93,952,245)</u>
<b>Cash flows from financing activities</b>		
Net proceeds from equity offering.....	—	110,676,704
Construction advance from landlord .....	3,243,467	—
Proceeds from exercise of stock options .....	<u>1,843,623</u>	<u>527,018</u>
Net cash provided by financing activities .....	<u>5,087,090</u>	<u>111,203,722</u>
Net decrease in cash and cash equivalents .....	(43,311,487)	(20,211,817)
Cash and cash equivalents at beginning of period.....	<u>55,578,707</u>	<u>36,393,551</u>
Cash and cash equivalents at end of period.....	<u>\$ 12,267,220</u>	<u>\$ 16,181,734</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest.....	<u>\$ 4,119</u>	<u>\$ 5,732</u>
Noncash investing and financing activities:		
Other non-cash additions to property and equipment.....	<u>\$ 1,738,961</u>	<u>\$ —</u>
Accretion on mandatorily redeemable convertible preferred stock.....	<u>\$ —</u>	<u>\$ 87,719</u>
Dividends accrued on mandatorily redeemable convertible preferred stock .....	<u>\$ —</u>	<u>\$ 1,630,146</u>
Accrued prepaid offering costs.....	<u>\$ 144,924</u>	<u>\$ —</u>
Recognition of prepaid offering costs .....	<u>\$ —</u>	<u>\$ 902,441</u>

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, 2002 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, 2002.

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.

**2. Net loss per share**

Basic and diluted net loss per share has been computed based on net loss attributable 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 and shares subject to repurchase from the calculation of diluted net loss per share, as such shares are antidilutive for all periods presented.

The following table presents the calculation of basic and diluted net loss per share (unaudited):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss attributable to common shareholders..	<u>\$ (14,671,203)</u>	<u>\$ (14,466,090)</u>	<u>\$ (41,235,451)</u>	<u>\$ (43,119,215)</u>
Weighted-average shares used in computing basic and diluted net loss per share.....	<u>46,221,380</u>	<u>45,770,427</u>	<u>46,037,389</u>	<u>41,476,536</u>
Basic and diluted net loss per share.....	<u>\$ (0.32)</u>	<u>\$ (0.32)</u>	<u>\$ (0.90)</u>	<u>\$ (1.04)</u>
Securities not included in net loss per share calculation:				
Options to purchase common stock.....	9,422,449	8,026,272	9,422,449	8,026,272
Shares subject to repurchase.....	<u>—</u>	<u>13,500</u>	<u>—</u>	<u>13,500</u>
Total .....	<u>9,422,449</u>	<u>8,039,772</u>	<u>9,422,449</u>	<u>8,039,772</u>

Net loss attributable to common shareholders for the nine months ended September 30, 2002 includes preferred stock dividends and accretion on mandatorily redeemable convertible preferred stock. Upon completion of the Company's initial public offering in February 2002, the mandatorily redeemable convertible preferred stock was converted to common stock.

### 3. Short-term investments

Short-term investments consisted of the following at September 30, 2003 (unaudited):

Type of security:	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Corporate debt securities	\$ 54,724,079	\$ 424,783	\$ (10,060)	\$ 55,138,802
Asset-backed securities	79,794,393	295,142	(52,678)	80,036,857
U.S. government and agency securities	82,733,590	421,755	(11,452)	83,143,893
Foreign government securities	<u>4,170,087</u>	<u>38,284</u>	<u>—</u>	<u>4,208,371</u>
Total	<u>\$ 221,422,149</u>	<u>\$ 1,179,964</u>	<u>\$ (74,190)</u>	<u>\$222,527,923</u>

The following table summarizes contractual maturity information for the securities at September 30, 2003:

Maturity date:	Amortized Cost	Estimated Fair Value
Less than one year	\$ 128,348,706	\$ 128,894,291
Due in 1-3 years	<u>93,073,443</u>	<u>93,633,632</u>
Total	<u>\$ 221,422,149</u>	<u>\$ 222,527,923</u>

### 4. Accrued liabilities

Accrued liabilities consisted of the following:

	<u>September 30, 2003</u>	<u>December 31, 2002</u>
Vacation pay .....	\$ 2,084,206	\$ 2,021,754
Incentive compensation .....	1,764,763	171,539
Contract services .....	2,343,662	2,756,170
City and state taxes .....	151,128	255,376
Severance payments .....	260,577	73,189
Other .....	<u>317,144</u>	<u>411,038</u>
	<u>\$ 6,921,480</u>	<u>\$ 5,689,066</u>

### 5. 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 accounted for employee stock option grants under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and applied 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 the Company's stock at the date of grant over the exercise price of the option. Deferred compensation, relating to employee stock option grants awarded prior to the Company's initial public offering in February 2002, is amortized over the vesting period of the individual options, using the straight-line method. All employee stock option grants awarded subsequent to the Company's initial public offering have been granted with exercise prices equal to the fair value of the Company's common stock on the date of grant.

The following table illustrates the effect on net income and earnings per share as if the Company had recorded compensation expense based on the fair value method applied to all outstanding and unvested awards (unaudited):

Three Months Ended September 30,		Nine Months Ended September 30,	
2003	2002	2003	2002

Net loss attributable to common shareholders, as reported.....	\$ (14,671,203)	\$ (14,466,090)	\$ (41,235,451)	\$ (43,119,215)
Add: stock-based compensation under APB 25 included in reported net loss.....	1,706,771	1,815,512	5,371,127	5,441,673
Deduct: total stock-based compensation expense determined under the fair value method.....	<u>(3,291,125)</u>	<u>(2,573,098)</u>	<u>(9,247,809)</u>	<u>(7,266,354)</u>
Net loss attributable to common shareholders, pro forma.....	<u>\$ (16,255,557)</u>	<u>\$ (15,223,676)</u>	<u>\$ (45,112,133)</u>	<u>\$ (44,943,896)</u>
Basic and diluted net loss per share, as reported.....	<u>\$ (0.32)</u>	<u>\$ (0.32)</u>	<u>\$ (0.90)</u>	<u>\$ (1.04)</u>
Basic and diluted net loss per share, pro forma.....	<u>\$ (0.35)</u>	<u>\$ (0.33)</u>	<u>\$ (0.98)</u>	<u>\$ (1.08)</u>

## 6. Construction advance from landlord

Emerging Issues Task Force No. 97-10, *The Effect of Lessee Involvement in Asset Construction* (EITF 97-10), is applied to entities involved with certain structural elements of the construction of an asset that will be leased when construction of the asset is completed. EITF 97-10 requires the Company to be considered the owner (for accounting purposes only) of an ongoing facility expansion project during the construction period. This construction project is expected to cost approximately \$26 million, including all related equipment costs, of which approximately \$15 million will be funded by the Company's landlord. The project began in April 2003 and is scheduled to be completed in mid-2004. Over the course of the construction period, the landlord will advance a proportionate share of construction costs incurred by the Company. Upon completion of the project, the total advance will be offset against the construction costs incurred, and the net cost will be reflected as leasehold improvements and equipment. As of September 30, 2003, the Company had incurred total project costs of \$7.5 million and recorded an advance from the landlord of \$3.2 million.

## 7. Related party transactions

In December 2002, the Company entered into a collaborative agreement with Novo Nordisk for the preclinical development of Interleukin 21 (IL-21). Under the terms of the agreement, the Company and Novo Nordisk are collaborating on all research and development activities leading up to the filing of an Investigational New Drug application (IND) in the United States. Upon signing, Novo Nordisk paid an upfront fee of \$4.0 million to the Company. This amount has been deferred and is being recognized as revenue ratably over the estimated period leading to the IND filing. Novo Nordisk also agreed to pay the Company up to \$7.0 million for its 50% share of IL-21 development costs incurred from the date of the agreement through the filing of the IND. The amount reimbursed to the Company under this agreement for the nine month period ending September 30, 2003 was \$4.4 million and was recorded as an offset to the Company's research and development expenses.

## 8. Income taxes

The Company records a provision for income taxes in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (SFAS 109), which utilizes the liability method of accounting for income taxes. Deferred tax assets or liabilities are recorded for all temporary differences between financial and tax reporting. Deferred tax expense (benefit) results from the net change during the period of the deferred tax assets and liabilities. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered. In management's opinion the criteria for recognition of the deferred tax asset have not been met, therefore pursuant to SFAS 109, the Company's net deferred tax asset has been fully offset by a valuation allowance.

## 9. Segment information

Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131), establishes standards for the way public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. The Company manages and evaluates its operations in one reportable segment.

## 10. Comprehensive loss

Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income*, requires unrealized gains and losses on the Company's available-for-sale securities to be included in comprehensive income. For the three and nine months ended September 30, 2003, total comprehensive loss was \$15.5 million and \$42.9 million, respectively. For the three and nine months ended September 30, 2002, total comprehensive loss was \$13.4 million and \$40.5 million, respectively. The unrealized loss for the three and nine months ended September 30, 2003 was \$0.8 million and \$1.7 million, respectively. The unrealized gain for the three and nine months ended September 30, 2002 was \$1.0 million and \$0.9 million, respectively.

## 11. Recent accounting pronouncements

In 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations* (SFAS 143), which establishes requirements for the financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The standard is effective for fiscal years beginning after June 15, 2002, with earlier application encouraged. Adoption of this statement has not impacted the results of operations or the financial position of the Company.

In 2002, the FASB issued Statement of Financial Accounting Standards No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment to FASB Statement No. 13, and Technical Corrections* (SFAS 145). SFAS 145 eliminates the requirement in Statement of Financial Accounting Standards No. 4, (SFAS 4) that gains and losses from the extinguishments of debt be aggregated and classified as extraordinary items, net of the related income tax. The rescission of SFAS 4 is effective for fiscal years beginning after May 15, 2002. Adoption of this statement has not impacted the results of operations or the financial position of the Company.

In 2002, the FASB issued Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146). SFAS 146 requires the recognition of such costs when they are incurred rather than at the date of a commitment to an exit or disposal plan. The provisions of SFAS 146 are to be applied prospectively to exit or disposal activities initiated after December 31, 2002. Adoption of this statement has not impacted the results of operations or the financial position of the Company.

In 2002, the Emerging Issues Task Force (EITF) finalized its tentative consensus on EITF Issue No. 00-21, *Revenue Arrangements With Multiple Deliverables* (EITF 00-21), which provides guidance on the timing and method of revenue recognition for sales agreements that include delivery of more than one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. Adoption of this statement has not impacted the results of operations or the financial position of the Company.

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN 46), which addresses consolidation by business enterprises of variable interest entities that either: (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) the company will hold a significant variable interest in, or have significant involvement with, an existing variable interest entity. FIN 46 is effective as of the first interim period beginning after June 15, 2003. However, an October 2003 FASB Staff Position deferred the effective date for applying the provisions of FIN 46 for interests held by public entities in variable interest entities or potential variable interest entities created before February 1, 2003 and nonregistered investment companies. Adoption of this interpretation has not impacted the results of operations or the financial position of the Company.

In May 2003, FASB issued Statement of Financial Accounting Standards No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* (SFAS 149), effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. This rule amends SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended, to provide more consistent reporting of contracts as either derivatives or hybrid instruments. Adoption of this statement has not impacted the results of operations or the financial position of the Company.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150), effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. In October 2003, the FASB deferred certain provisions of FAS 150 relating to mandatorily redeemable non controlling interests. Adoption of this statement has not impacted the results of operations or the financial position of the Company.

## **12. Subsequent events**

In October 2003, the Company sold 6,100,000 shares of common stock in a public offering. Net proceeds from the offering amounted to approximately \$71 million.

In October 2003, the Company entered into a manufacturing agreement to produce rhThrombin for use in late-stage clinical studies and commercial sales. If the project proceeds as anticipated, the Company could be obligated to pay a maximum amount of \$29.5 million through 2005.

## **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. Except as required by law, 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 filings 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 focused on the discovery, development and commercialization of therapeutic proteins for the treatment of human disease. We have been active in the area of therapeutic proteins for over 20 years, including 12 years as a wholly owned subsidiary of Novo Nordisk A/S, a Danish pharmaceutical company. We were incorporated in the state of Washington in 1981. In 1988, Novo Nordisk acquired our outstanding capital stock and we became a wholly owned subsidiary. In November 2000, Novo Nordisk effected a significant restructuring. As part of this restructuring, we became an independent company in a transaction that included a \$150 million private placement and the reduction of Novo Nordisk's ownership to approximately 62% of our outstanding capital stock and less than 50% of our outstanding voting stock. Novo Nordisk's ownership stake has been further reduced with the completion of our initial public offering and a follow-on offering that took place in February 2002 and October 2003, respectively.

### **Results of Operations**

*Revenues.* Revenues increased by \$2.3 million to \$8.2 million for the quarter ended September 30, 2003, from \$5.9 million for the comparable quarter of 2002. Revenues for the nine months ended September 30, 2003 increased to \$20.2 million from \$18.7 million for the comparable period in 2002. The increase in revenue for the three-month period ended September 30, 2003 was primarily due to the achievement of a milestone related to the initiation of the TACI-Ig clinical trials. This increase was partially offset by a reduction in license fees earned from proteins licensed to Novo Nordisk. The revenue increase for the nine-month period ended September 30, 2003 was primarily due to an increase in certain product royalties, primarily with respect to insulin.

*Research and development expenses.* Research and development expenses (exclusive of noncash stock-based compensation expense) increased by \$3.4 million to \$19.8 million for the quarter ended September 30, 2003, from \$16.4 million for the third quarter of 2002. Research and development expenses (exclusive of noncash stock-based compensation expense) for the nine-month period ended September 30, 2003 increased to \$52.3 million from \$47.1 million for the comparable period in 2002. The increases in research and development expenses for both the three-month and nine-month periods ended September 30, 2003 period were primarily due to increased expenses associated with our product development programs, including those resulting from higher development staffing levels and external contracts for process development and manufacturing of the company's product candidates. In addition, we experienced an increase in occupancy costs resulting from the sale and leaseback of our headquarters completed during the fourth quarter of 2002. These increases were partially offset by cost reimbursement from Novo Nordisk under the IL-21 collaboration agreement signed in December 2002. Novo Nordisk agreed to pay up to \$7.0 million for its 50% share of

IL-21 development costs incurred from January 1, 2003 through the filing of an Investigational New Drug application. Novo Nordisk's share of the costs for the three and nine month periods ended September 30, 2003 was \$1.3 million and \$4.4 million, respectively and was recorded as an offset to research and development expense.

*General and administrative expenses.* General and administrative expenses (exclusive of noncash stock-based compensation expense) decreased by \$0.9 million to \$2.9 million for the quarter ended September 30, 2003, from \$3.8 million for the third quarter of 2002. General and administrative expenses (exclusive of noncash stock-based compensation expense) for the nine-month period ended September 30, 2003 decreased to \$9.6 million from \$12.8 million for the comparable period in 2002. The decrease in general and administrative expenses for the three-month period ended September 30, 2003 was primarily due to a decrease in legal fees and other external costs. The decrease in the nine-month period ended September 30, 2003 was due in part to the postponement of construction of a pilot manufacturing facility, which resulted in the write-off of capitalized design and engineering costs totaling \$1.6 million in the second quarter of 2002. Additionally, there was a decrease in the level of spending on consumables, legal fees and other external costs. The decreases in both periods were partially offset by increased occupancy costs resulting from the sale and leaseback transaction completed during the fourth quarter of 2002.

*Noncash stock-based compensation expense.* Noncash stock-based compensation expense decreased by \$0.1 million to \$1.7 million for the quarter ended September 30, 2003, from \$1.8 million for the third quarter of 2002. Noncash stock-based compensation expense for the each of the nine-month periods ended September 30, 2003 and 2002, was \$5.4 million. Noncash stock-based compensation expense is recognized over the vesting period of the underlying options, generally four years, using the straight-line method and resulted from the granting of stock options prior to our January 2002 initial public offering with estimated fair values exceeding the exercise prices of the options.

*Interest and other income, net.* Interest and other income decreased by \$0.2 million to \$1.5 million for the quarter ended September 30, 2003, from \$1.7 million for the third quarter of 2002. Interest and other income for the nine months ended September 30, 2003 increased to \$5.9 million from \$5.3 million for the comparable period in 2002. The decrease in interest and other income for the quarter ended September 30, 2003 was primarily due to a decrease in the average interest rate earned on our investments. The increase in the nine-month period ended September 30, 2003 was primarily due to gains realized on the sale of certain short-term investments. Additionally, the amortization of the deferred gain related to the sale of our facilities in 2002 contributed to the increase.

## **Liquidity and Capital Resources**

As of September 30, 2003, we had \$234.8 million in cash, cash equivalents and short-term investments, a decrease of \$50.6 million from \$285.4 million on December 31, 2002. These amounts do not reflect the approximately \$71 million of net proceeds from a common stock offering completed in October 2003. The decrease through September largely resulted from the use of cash to fund our operations for the first nine months of 2003.

Net cash used in operating activities for the nine months ended September 30, 2003 and 2002 was \$46.3 million and \$37.5 million, respectively. Cash used in operations was greater than our net loss for the nine-month period ended September 30, 2003, primarily due to the amortization of deferred revenue, increases in our receivables associated with the achievement of certain development milestones and increases in prepaid expenses associated with our development programs, partially offset by non-cash items, such as depreciation and amortization, non-cash stock-based compensation and the amortization of premiums on short-term investments. Deferred revenue decreased from \$16.8 million at December 31, 2002 to \$8.4 million at September 30, 2003. The decrease in deferred revenue is primarily due to the company's policy of deferring certain upfront and milestone payments and amortizing these amounts over the related development period. Cash used in operating activities for the nine months ended September 30, 2002 was less than our net loss due to non-cash items, such as depreciation and amortization and non-cash stock-based compensation expense and was partially offset by amortization of deferred revenue. We expect to continue to use cash to fund our operating activities in the future. This use of cash is expected to increase over time as we continue to expand our research and development activities and move product candidates into and through clinical trials.

Net cash used in investing activities for the nine months ended September 30, 2003 and 2002 was \$2.1 million and \$94.0 million, respectively. Net cash used in investing activities in the 2003 period included capital expenditures of \$6.2 million less the net proceeds of \$4.1 million from the purchase, sale and maturity of short-term investments. Net cash used in investing activities in the 2002 period included \$88.7 million for purchases of short-term investments, net of proceeds from sales and maturities, and \$5.3 million for capital expenditures. Our capital expenditures are expected

to increase in 2003 and 2004 as a result of the expansion of our existing research and development facilities. The expansion project is expected to cost approximately \$26 million, including all related equipment costs, and will be partially funded by a tenant improvement allowance from our landlord expected to total approximately \$15 million. The project began in April 2003 and is scheduled to be completed in mid-2004.

Net cash provided by financing activities for the nine months ended September 30, 2003 and 2002 was \$5.1 million and \$111.2 million, respectively. Net cash provided by financing activities in the 2003 period consisted of proceeds from the exercise of stock options by employees of \$1.9 million and the construction advance from our landlord associated with the facility expansion project of \$3.2 million. Net cash provided by financing activities in the 2002 period included net proceeds of \$110.7 million (excluding \$0.9 million of offering costs paid in 2001) from our initial public offering completed in February 2002 and proceeds of \$0.5 million from the exercise of stock options by employees.

We expect to incur substantial costs as we continue to advance our research and development programs, particularly as we move product candidates into and through clinical trials. We expect these expenditures to increase over the next several years. For example, we recently entered into a manufacturing agreement to produce rhThrombin for late-stage clinical studies and commercial sales, under which we could be obligated to pay up to \$29.5 million through 2005. 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. We believe that our existing cash resources, including the net proceeds of the common stock offering completed in October 2003, will provide sufficient funding to support our operations into 2006. If we are successful in completing additional collaborative development transactions, which would generate both revenues and cost reductions, we believe that our cash resources would fund our operations into 2007. If, at any time, our prospects for financing our operations 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 not be available when we need it, or may not be available on acceptable terms. If we raise additional funds by issuing equity or convertible debt 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.

### **Recent accounting pronouncements**

In 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations* (SFAS 143), which establishes requirements for the financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The standard is effective for fiscal years beginning after June 15, 2002, with earlier application encouraged. Adoption of this statement has not impacted our results of operations or the financial position of our Company.

In 2002, the FASB issued Statement of Financial Accounting Standards No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment to FASB Statement No. 13, and Technical Corrections* (SFAS 145). SFAS 145 eliminates the requirement in Statement of Financial Accounting Standards No. 4, (SFAS 4) that gains and losses from the extinguishments of debt be aggregated and classified as extraordinary items, net of the related income tax. The rescission of SFAS 4 is effective for fiscal years beginning after May 15, 2002. Adoption of this statement has not impacted our results of operations or the financial position of our Company.

In 2002, the FASB issued Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146). SFAS 146 requires the recognition of such costs when they are incurred rather than at the date of a commitment to an exit or disposal plan. The provisions of SFAS 146 are to be applied prospectively to exit or disposal activities initiated after December 31, 2002. Adoption of this statement has not impacted our results of operations or the financial position of our Company.

In 2002, the Emerging Issues Task Force (EITF) finalized its tentative consensus on EITF Issue No. 00-21, *Revenue Arrangements With Multiple Deliverables* (EITF 00-21), which provides guidance on the timing and method of revenue recognition for sales agreements that include delivery of more than one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. Adoption of this statement has not impacted our results of operations or the financial position of our Company.

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN 46), which addresses consolidation by business enterprises of variable interest entities that either: (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) the company will hold a significant variable interest in, or have significant involvement with, an existing variable interest entity. FIN 46 is effective as of the first interim period beginning after June 15, 2003. However, an October 2003 FASB Staff Position deferred the effective date for applying the provisions of FIN 46 for interests held by public entities in variable interest entities or potential variable interest entities created before February 1, 2003 and nonregistered investment companies. Adoption of this interpretation has not impacted the results of operations or the financial position of our Company.

In May 2003, FASB issued Statement of Financial Accounting Standards No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* (SFAS 149), effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. This rule amends SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended, to provide more consistent reporting of contracts as either derivatives or hybrid instruments. Adoption of this statement has not impacted our results of operations or the financial position of our Company.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150), effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. In October 2003, the FASB deferred certain provisions of FAS 150 relating to mandatorily redeemable non controlling interests. Adoption of this statement has not impacted our results of operations or the financial position of our Company.

## Contractual Obligations

As of September 30, 2003 we are contractually obligated to make payments as follows:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
	(Amounts in thousands)				
Operating leases	\$ 126,791	\$ 6,346	\$ 15,306	\$ 16,384	\$ 88,755
Construction commitments	20,239	20,239	—	—	—

Total	<u>\$ 147,030</u>	<u>\$ 26,585</u>	<u>\$ 15,306</u>	<u>\$ 16,384</u>	<u>\$ 88,755</u>
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Operating lease terms range from one to fifteen years with certain renewal provisions at our option. In April 2003, we began a construction project to expand our research and development facilities. The related construction commitments are expected to total approximately \$26 million of which, approximately \$15 million will be funded by our landlord (amounts included in the table above are shown at gross). Lease payments with respect to the expansion will commence upon the completion of construction, estimated to be June 2004. The above table excludes commitments under the rhThrombin manufacturing agreement since the agreement became effective subsequent to the reporting date.

### **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, 2002 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 do not know whether we will be able to discover any genes or proteins of commercial value.
- We may not be able to develop commercially viable products from the key protein categories on which we focus.
- The availability of novel genomic data continues to decrease, which 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 existing 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. Certain of our royalty revenue agreements are denominated in foreign currency, estimated during the year and settled at year-end. A 10% appreciation in the U.S. Dollar as of September 30, 2003 would have resulted in a decrease of approximately \$600,000 in royalty revenue and receivable. We have no other 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 September 30, 2003, 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

10.1	Employment Agreement, dated September 17, 2003, between the Company and Fredrik Henell.
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 August 7, 2003, 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 six months ended June 30, 2003.

**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 11, 2003

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