GENENCOR INTERNATIONAL INC Form 10-Q May 10, 2004

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

# [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended 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 000-31167

**Genencor International, Inc.** 

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 16-1362385 (I.R.S. Employer Identification Number)

925 Page Mill Road Palo Alto, California 94304 (650) 846-7500

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

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 report(s), 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.

Class	Number of Shares Outstanding at April 30, 2004
Common	
stock,	
par	
value	
\$0.01 per	
share	59,322,668

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Unless otherwise specified, all references to the Company, we, us, our, and ourselves refer to Genencor International, Inc. or Genencor International, Inc. and its subsidiaries collectively, as appropriate in the context of the disclosure.

This Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These include statements concerning plans, objectives, goals, strategies, future events or performance and all other statements which are other than statements of historical fact, including without limitation, statements containing the words believes, anticipates, expects, estimates might, and words of a similar nature. The forward-looking statements con intends. plans, projects, will. may, this Report reflect the Company s current beliefs and expectations on the date of this Report. Actual results, performance or outcomes may differ materially from those expressed in the forward-looking statements. Some of the important factors which, in the view of the Company, could cause actual results to differ from those expressed in the forward-looking statements are discussed in Part I, Item 2 of this Report and in the Company s Annual Report on Form 10-K for the year ended December 31, 2003. The Company disclaims any obligation to update any forward-looking statement to reflect facts or circumstances after the date hereof.

# PART I. FINANCIAL INFORMATION

## **Item 1. Financial Statements**

#### **GENENCOR INTERNATIONAL, INC. AND SUBSIDIARIES**

# CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS (Amounts in thousands, except per share data)

	March 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$139,452	\$166,551
Trade accounts receivable, net	59,803	58,249
Inventories	70,234	64,159
Other current assets	36,961	36,253
Total current assets	306,450	325,212
Property, plant and equipment, net	227,008	232,902
Goodwill	29,379	29,380
Intangible assets, net	45,346	47,075
Other assets	78,521	77,853
Total assets	\$686,704	\$712,422
Liabilities, Redeemable Preferred Stock and Stockholders Equity Current liabilities:		
	\$ 5,926	\$ 5,926
Notes payable Current maturities of long-term debt	\$ 3,920 28,249	\$ 3,920 28,249
Accounts payable and accrued expenses	47,664	49,143
Other current liabilities	13,323	49,145 18,850
Other current habilities		18,830
Total current liabilities	95,162	102,168
Long-term debt	30,395	58,466
Other long-term liabilities	38,521	39,101
Total liabilities	164,078	199,735

Redeemable preferred stock: 7 1/2% cumulative series A preferred stock, without par value, authorized 1		
shares, 1 shares issued and outstanding	178,844	177,025
Stockholders equity:		
Common stock, par value \$0.01 per share, 200,000 shares authorized, 61,091 and		
60,991 shares issued at March 31, 2004 and December 31, 2003, respectively	611	610
Additional paid-in capital	360,526	359,344
Treasury stock, 1,780 shares at cost at March 31, 2004 and December 31, 2003	(21,030)	(21,030)
Deferred stock-based compensation	(913)	(1,036)
Retained earnings	11,779	589
Accumulated other comprehensive loss	(7,191)	(2,815)
Total stockholders equity	343,782	335,662
Total liabilities, redeemable preferred stock and stockholders equity	\$686,704	\$712,422

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

# GENENCOR INTERNATIONAL, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF OPERATIONS (Amounts in thousands, except per share data)

	Three months ended March 31,	
	2004	2003
Revenues:		
Product revenue Fees and royalty revenues	\$91,539 2,824	\$90,038 5,623
rees and royarty revenues	2,024	
Total revenues	94,363	95,661
Operating expenses:	74,505	95,001
Cost of products sold	50,465	50,841
Research and development	16,880	16,460
Sales, marketing and business development	8,320	7,699
General and administrative	8,502	7,801
Amortization of intangible assets	1,175	1,392
Other (income)/expense	(7,905)	705
Total operating expenses	77,437	84,898
Operating income	16,926	10,763
Non operating expenses/(income):	1 526	2 0 2 0
Interest expense Interest income	1,536 (871)	2,020 (845)
Total non operating expense/(income)	665	1,175
Income before income taxes	16,261	9,588
Provision for income taxes	3,252	3,068
Net income	\$13,009	\$ 6,520
Net income available to holders of common stock	\$11,190	\$ 4,701

Earnings per common share: Basic	\$ 0.19	\$ 0.08
Diluted	\$ 0.18	\$ 0.08
Weighted average common shares: Basic	59,266	58,499
Diluted	61,275	58,799

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

# GENENCOR INTERNATIONAL, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS (Amounts in thousands)

	Three months ended March 31,	
	2004	2003
Cash flows from operating activities:		
Net income	\$ 13,009	\$ 6,520
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	9,084	8,760
Amortization of deferred stock-based compensation	123	299
(Increase) decrease in operating assets:	120	277
Trade accounts receivable	(2,193)	(7,875)
Inventories	(6,774)	(1,569)
Other assets	5,930	248
Decrease in operating liabilities:		
Accounts payable and accrued expenses	(3,941)	(3,173)
Other liabilities	(8,936)	(3,431)
Net cash provided by/(used in) operating activities	6,302	(221)
Call flame from increding activities		
Cash flows from investing activities:	(2.701)	$(\mathbf{A} \boldsymbol{5} 4 9)$
Purchases of property, plant and equipment Proceeds from note receivable	(3,721) 125	(4,548)
Payments related to prior acquisition	(632)	
a sinch s related to prior acquisition	(032)	
Net cash used in investing activities	(4,228)	(4,548)
Cash flows from financing activities:		
Proceeds from exercise of stock options	345	164
Proceeds from employee stock purchase plan	402	345
Proceeds from notes of foreign affiliate		91
Payment of long-term debt	(28,063)	(28,061)
Not each used in financing activities	(27, 216)	(77 461)
Net cash used in financing activities	(27,316)	(27,461)

Effect of exchange rate changes on cash	(1,857)	1,915
Net decrease in cash and cash equivalents Cash and cash equivalents beginning of period	(27,099) 166,551	(30,315) 169,001
Cash and cash equivalents end of period	\$139,452	\$138,686

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

#### GENENCOR INTERNATIONAL, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED UNAUDITED FINANCIAL STATEMENTS (Amounts in thousands, except per share data)

#### **1** Basis of Presentation

The condensed consolidated unaudited financial statements should be read in conjunction with the Company s audited consolidated financial statements and related footnotes for the year ended December 31, 2003, as included in the Company s Annual Report on Form 10-K. These interim financial statements have been prepared in conformity with the rules and regulations of the U.S. Securities and Exchange Commission. Certain disclosures normally included in financial statements prepared in conformity with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to such rules and regulations pertaining to interim financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for fair presentation of the interim financial statements have been included therein. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year.

#### 2 New Accounting Pronouncements

In December 2003, the Financial Accounting Standards Board (FASB) issued a revision of Statement of Financial Accounting Standards (SFAS) No. 132, Employers Disclosures about Pensions and Other Postretirement Benefits. The revised Statement provides required disclosures for pensions and other postretirement benefit plans and is designed to improve disclosure transparency in financial statements. The revised Statement replaces existing year-end and interim disclosure requirements. This Statement was in effect for the Company s fiscal year ending December 31, 2003 and for quarters beginning thereafter for domestic plans, and will be effective for fiscal years ending after June 15, 2004 for the Company s foreign plans.

In January 2004, the FASB issued FASB Staff Position No. FAS 106-1, Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003. This Position permits employers that sponsor postretirement benefit plans that provide prescription drug benefits to retirees to make a one-time election to defer accounting for any effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Act). Specific authoritative guidance on the accounting for the federal subsidy is pending and that guidance, when issued, could require the sponsor of such a plan to change previously reported information. The Company s financial statements do not reflect any implications of the Act due to the level of uncertainty about the forthcoming guidance.

#### 3 Pension Plans

A summary of the components of net periodic pension cost, a non-cash item, for the three months ended March 31 is as follows:

	2004	2003
Service Cost	\$ 773	\$ 701
Interest Cost	231	204
Expected return on plan assets	(272)	(179)
Net amortization	38	51

Net periodic pension cost	\$ 770	\$ 777

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#### 4 Earnings Per Share

SFAS No. 128, Earnings per Share, requires the disclosure of basic and diluted earnings per share. Basic earnings per share is computed based on the weighted average number of common shares outstanding during the period. In arriving at net income available to holders of common stock, undeclared and unpaid dividends on redeemable preferred stock of \$1,819 were deducted from net income for each quarter presented.

Diluted earnings per common share reflects the potential dilution that could occur if dilutive securities and other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the net income available to holders of common stock of the Company. As a result of stock options outstanding under the Company s 2002 Omnibus Incentive Plan and its predecessor plan, the Company s Stock Option and Stock Appreciation Right Plan, there were dilutive securities for the three months ended March 31, 2004 and 2003. The weighted-average impact of these has been reflected in the calculation of diluted earnings per common share for the respective periods presented.

The following table reflects the calculation of basic and diluted earnings per common share for the three months ended March 31:

2004

2002

	2004	2003
Net income Less: Accrued dividends on preferred stock	\$13,009 (1,819)	\$ 6,520 (1,819)
Net income available to holders of common stock	\$11,190	\$ 4,701
Weighted average common shares: Basic Effect of stock options	59,266 2,009	58,499 300
Diluted	61,275	58,799
Earnings per common share: Basic	\$ 0.19	\$ 0.08
Diluted	\$ 0.18	\$ 0.08

#### 5 Stock-Based Compensation

The Company adopted the provisions of SFAS No. 148. The Company uses the intrinsic value method to account for stock-based employee compensation in accordance with Accounting Principles Board (APB) Opinion No. 25 Accounting for Stock Issued to Employees.

On a pro forma basis, had compensation cost for the Company s stock option plans been determined based on the weighted average fair value at the grant date, the Company s net income and earnings per share would have been reduced to the pro forma amounts shown below:

	Three Months Ended March 31,	
	2004	2003
Net income available to holders of common stock, as reported Add: Stock-based employee compensation expense included in	\$11,190	\$ 4,701
reported net income available, net of related tax Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of		162
related tax effect	(1,498)	(1,300)
Pro forma net income available to holders of common stock	\$ 9,692	\$ 3,563
Earnings per common share:		
Basic as reported	\$ 0.19	\$ 0.08
Basic pro forma	\$ 0.16	\$ 0.06
Diluted as reported	\$ 0.18	\$ 0.08
Diluted pro forma	\$ 0.16	\$ 0.06

The pro forma figures in the preceding table may not be representative of pro forma amounts in future quarters.

#### 6 Inventories

Inventories consist of the following:

	March 31, 2004	December 31, 2003
Raw materials	\$ 7,990	\$ 7,682
Work-in-progress	10,738	9,106
Finished goods	51,506	47,371
Inventories	\$70,234	\$64,159

The Company sustained damage to its finished bioproducts inventory in the second quarter of 2003 as a result of an accident in a third party warehouse in Rotterdam, the Netherlands. At the end of the first quarter of 2004, the

Company reached a final settlement of its accident-related claim with its insurer totaling approximately \$21,000. This final settlement resulted in a net gain of \$8,290 for the quarter. Of the total settlement, Genencor has received cash payments of approximately \$9,350 from its insurer through March 31, 2004.

#### 7 Goodwill and Other Intangible Assets

In accordance with the provisions of SFAS No. 142, the Company does not amortize goodwill or other intangible assets with indefinite useful lives. The Company has identified such other indefinite-lived intangible assets to include certain previously acquired technology. The Company periodically evaluates its indefinite-lived intangible assets for impairment in accordance with the provisions of SFAS No. 142. The Company also has other intangible assets, such as patents, licenses, and customer lists, which will continue to be amortized using the straight-line method. These assets are expected to have no residual value once they are fully amortized.

The following table summarizes the changes in each major class of intangible assets from January 1, 2004 through March 31, 2004:

	Intangible Assets			-		
	Technology	Other Amortizable Assets	Total	Goodwill		
Balances, January 1, 2004	\$15,831	\$ 73,591	\$ 89,422	\$29,380		
Foreign currency translation and other adjustments	(4)	(792)	(796)	(1)		
Balances, March 31, 2004	\$15,827	72,799	88,626	\$29,379		
Less: Accumulated amortization		(43,280)	(43,280)			
Intangible assets, net		\$ 29,519	\$ 45,346			

Estimated fiscal year amortization expense is as follows:

2004	\$4,600
2005	4,100
2006	3,800
2007	2,500
2008	1,300

# 8 Stockholders Equity

Accumulated other comprehensive loss consists of the following:

	Foreign Currency Translation Adjustment	Securities Valuation	Accumulated Other Comprehensive Loss
Balances, December 31, 2003 Current period change	\$(2,350) (4,926)	\$ (465) 550	\$ (2,815) (4,376)

Balances, March 31, 2004	\$(7,276)	\$ 85	\$ (7,191)

The change in the marketable securities valuation adjustment for the three months ended March 31, 2004 of \$550 (\$873 pre-tax) relates to unrealized holding gains on the Company s available-for-sale securities.

#### 9 Income Taxes

The effective income tax rate for the three months ended March 31, 2004 was 20% compared to 32% for the three months ended March 31, 2003, which reflects the Company s assessment of its annual effective income tax rate. Factors affecting the Company s estimated annual effective income tax rate include increased research and development expenditures in the United States, the statutory income tax rates and mix of earnings among tax jurisdictions, amortization of certain intangible assets and other items which are not deductible for tax purposes, and research and experimentation tax credits. In addition, the estimated annual effective rate in the three months ended March 31, 2003 included the effect of estimated valuation allowances, since the Company did not anticipate having the ability to utilize certain tax credits.

#### 10 Fees and Royalty Revenues

The decrease in fees and royalty revenues of \$2,799 for the three months ended March 31, 2004 from the three months ended March 31, 2003 was primarily due to the completion of the initial stages of our strategic alliance for the development of new biomaterials with the Dow Corning Corporation.

#### 11 Segment Reporting

In accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, segments were determined based on products and services provided by each segment. Accounting policies for the segments are the same as those described in Note 1, Summary of Significant Accounting Policies of the Company s Annual Report on Form 10-K for the year ended December 31, 2003. Performance of the segments is evaluated based on operating income of the segment. No items below operating income are allocated to the segments. The Company accounts for transactions, if any, between the segments as though they were transactions with third parties at approximate market prices. There were no material inter-segment transactions in the periods presented. The Company s managerial financial reporting reflects two operating segments: Bioproducts and Health Care.

The Bioproducts segment develops and delivers products and services to the industrial, consumer and agri-processing markets to a global customer base. All of the Company s current product revenues are derived from this segment.

The Health Care segment is focused on expanding the Company s current technology and product platforms into the health care market. This segment is primarily engaged in the performance of research and development, the securing of intellectual property and the establishment of strategic investments and collaborations.

The following table provides information by business segment:

				,	
		Health	Segment	Corporate and	Consolidated
	Bioproducts	Care	Subtotal	Other	Totals
Product revenue	\$91,539	\$	\$ 91,539	\$	\$91,539
Fees and royalty revenues	2,599	225	2,824		2,824
Total revenues	94,138	225	94,363		94,363
Research and development	10,976	5,904	16,880		16,880
Operating income/(loss)	23,942	(6,797)	17,145	(219)	16,926

#### For the three months ended March 31, 2004

#### For the three months ended March 31, 2003

				Corporate	Consolidated
	Bioproducts	Health Care	Segment Subtotal	and Other	Totals
Product revenue	\$90,038	\$	\$ 90,038	\$	\$90,038
Fees and royalty revenues	5,548	75	5,623		5,623
Total revenues	95,586	75	95,661		95,661

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Research and development Operating income/(loss)	10,320 19,058	6,140 (7,906)	16,460 11,152	(389)	16,460 10,763
		11			

The following table provides a reconciliation of segment information to total consolidated information:

	Three months ended March 31,		
	2004	2003	
Net income:			
Operating income/(loss) for reportable			
segment	\$17,145	\$11,152	
Other (income)/expense	219	389	
Interest expense	1,536	2,020	
Interest income	(871)	(845)	
Provision for income taxes	3,252	3,068	
Consolidated net income	\$13,009	\$ 6,520	

#### 12 Technology Transfer

During March 2004, the Company sold its therapeutic vaccine program to Innogenetics N.V. Upon transfer of certain intellectual property, contractual relationships and technologies to Innogenetics, the Company expects to recognize license fees in the second or third quarter of 2004 totaling \$10,000. The Company expects to receive further payments as development milestones are achieved. Once products are commercialized, the Company would also receive royalty payments on further product sales.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the notes to those statements included in our 2003 Annual Report on Form 10-K and the condensed consolidated unaudited financial statements and related notes included elsewhere in this Report.

#### **Executive Summary**

Leveraging over twenty years of experience, we use our molecular technologies to develop products and deliver services for varied markets, some on a global basis. Since our research and commercial expertise and competencies are at the molecular level we can produce products and deliver services to many different types of industries. Our current revenues result primarily from the sale of enzyme products as ingredients or processing aids to the cleaning, textiles, sweeteners, fuel ethanol and food, feed and specialties markets, and from research funding, fees and royalties. In the three months ended March 31, 2004, we expended \$11.0 million on our Bioproducts research and development programs. In addition to developing products for our current Bioproduct markets, we are now involved in Bioproduct research projects and programs that are directed toward providing new products and services in the emerging fields of biomaterials, biochemicals and nanobiotechnology. Furthermore, we expended \$5.9 million in the first quarter of 2004 on our Health Care programs. We believe that this diversification of our research and development expenditures will increase the probability of achieving success in our commercial portfolio and result in increased value for our stockholders.

Overall, for the three months ended March 31, 2004, net income available to common stockholders was \$11.2 million, or \$0.18 per diluted share, compared to \$4.7 million or \$0.08 per diluted share during the same period in 2003. Product revenues increased by 2% to \$91.5 million, compared to \$90.0 million in the first quarter of 2003. Total revenues for the three months ended March 31, 2004 were \$94.4 million, compared to \$95.7 million for the same period in 2003. Fees and royalty revenues were \$2.8 million in the first quarter as compared to \$5.6 million in the prior year. For the three months ended March 31, 2004, we generated \$16.9 million in operating income and \$6.3 million in cash flow from operations. We also invested \$3.7 million in purchases of property, plant and equipment and made the third of five annual installment payments of \$28.0 million on our senior debt during the quarter.

Our Bioproducts segment continues to generate all of our product revenues. In the three months ended March 31, 2004, product revenue growth was 2%, reflecting the benefits of foreign currency translation and the impact of on-going profitability improvement initiatives, including the selective pruning of specific product lines. First quarter revenue growth was also impacted by the timing of certain customer orders and our integration and rationalization of our year-end 2002 acquisition of the brewing and enzyme business of Rhodia Food UK Limited, including the disposition of non-enzyme product lines in mid-2003. We manufacture our products at our eight Bioproducts manufacturing facilities located in the United States, Finland, Belgium, China and Argentina. We conduct our sales and marketing activities through our direct sales organizations in the United States, the Netherlands, Singapore, Japan, China, United Kingdom and Argentina and through other distribution channels in selected markets and geographies. For the three months ended March 31, 2004, we derived approximately 55% of our revenues from our foreign operations.

During the first quarter, we also made significant progress on new applications within the Bioproducts segment. In the area of biodefense, we obtained an exclusive license from the U.S. Army Edgewood Chemical and Biological Center for the manufacture and sale of enzymes to decontaminate certain organophosphate-based nerve agents, such as sarin. While neutralizing chemical agents, these enzymes are non-toxic, non-corrosive and environmentally benign.

We believe these products may generate initial revenues later this year. In addition, working closely with the Health Protection Agency in the United Kingdom, we have made significant progress in the development of an enzyme-based method that effectively eliminates prion infectivity. Prions are widely seen as the causative agent of Bovine Spongiform Encephalopathy (commonly known as mad cow disease), and its human variant, Cruetzfelt-Jakob Disease. In our personal care initiative, testing and evaluation of our ingredients continued among leading consumer products companies, focusing on oral, skin and hair care applications. Research also continued on other Bioproducts projects, including Silicon Biotechnology<sup>™</sup>, our collaboration with the Dow Corning Corporation focusing on biosensors and other novel products, and the conversion of biomass to fuel ethanol.

In our Health Care segment, we launched our first clinical trial of a therapeutic product candidate during the three months ended March 31, 2004. Also, as more completely discussed under the heading Technology Transfer in this Item 2, we sold our therapeutic vaccine program to Innogenetics N.V. in March. We believe this sale is consistent with our plan to focus and further strengthen our internal research and development efforts in protein-based therapeutics. While this transaction has the potential to generate additional milestone and royalty revenues in the future, we expect to recognize license fees in the second or third quarter of 2004 totaling \$10.0 million once we have transferred certain intellectual property, contractual relationships and technologies.

With the sale of our therapeutic vaccine program, our Health Care segment is continuing to focus and expand its investment in targeted biotherapeutics. During the three months ended March 31, 2004, we advanced our first product candidate for treating cancer into Investigational New Drug Application (IND)-enabling development. The lead product candidate is based on the Antibody Directed Enzyme Prodrug Therapy (ADEPT) platform and will target colorectal carcinoma. The preliminary timeline anticipates filing an IND in 2005 followed by the launch of clinical trials. We also continued to make progress during the quarter on the validation phase of our facility for the clinical-scale manufacture of human therapeutic proteins in Rochester, New York. Our Health Care segment maintains its strategy of creating a biotherapeutics pipeline to address unmet medical needs and continues to evaluate appropriate in-licensing opportunities in development-stage molecules that would supplement its internal pipeline.

We are pleased with our progress during the first quarter of 2004. In both of our segments, we took actions during the first quarter that increased our focus on higher growth and more profitable products. We believe some of those actions reduced our rate of revenue growth in the short-term but should have a positive impact on our revenue growth and profitability in the long-term. As more completely discussed under the heading Warehouse Inventory Loss in this Item 2, we are also pleased to have settled our insurance claim from last year s third-party warehouse accident, which resulted in a net gain of \$8.3 million for the quarter.

#### **Results of Operations**

#### Comparison of the Three Months Ended March 31, 2004 and 2003

*Revenues.* Total revenues decreased \$1.3 million, or 1%, to \$94.4 million for the three-month period ended March 31, 2004 from the three-month period ended March 31, 2003, primarily due to a decrease in fees and royalty revenues partially offset by an increase in product revenue.

*Product Revenues*. Product revenues increased \$1.5 million, or 2%, to \$91.5 million for the three months ended March 31, 2004 from the three months ended March 31, 2003. For the three months ended March 31, 2004, product revenues decreased 2% due to unit volume/mix and 2% due to a decline in average prices, while the impact of foreign currency increased product revenues by 6%. The volume/mix decrease was primarily driven by decreased sales to our food, feed and specialties and sweeteners markets.

Regionally, North American product revenues decreased \$1.0 million, or 3%, to \$36.6 million for the three months ended March 31, 2004 from the three months ended March 31, 2003, driven primarily by decreased sales to our cleaning, textile, and sweeteners markets, partially offset by increased sales to our fuel ethanol and food, feed and specialties markets. Product revenues in Europe, Africa and the Middle East increased \$4.1 million, or 11%, to \$40.0 million for the three months ended March 31, 2004 from the three months ended March 31, 2003, driven primarily by increased sales to our cleaning, textile, and sweetener markets, partially offset by decreased sales to fuel ethanol and food, feed and food, feed and specialties markets. Our product revenues in the Asia Pacific region decreased \$1.6 million, or 12%, to \$11.6 million for three months ended March 31, 2004 from the three months ended March 31, 2003 due to decreased sales to our cleaning, textile, sweetener and food, feed and specialties markets. Our product revenues in Latin America remained constant at \$3.3 million for the three months ended March 31, 2003.

*Fees and Royalty Revenues.* Fees and royalty revenues decreased \$2.8 million, or 50%, to \$2.8 million, for the three months ended March 31, 2004 from the three months ended March 31, 2003.

Funded research revenues decreased \$3.0 million, or 59%, to \$2.1 million for the three months ended March 31, 2004 from the three months ended March 31, 2003. Revenues generated by research funding result from collaborative agreements with various parties, including the U.S. Government, whereby we perform research activities and receive revenues that partially reimburse us for expenses incurred. Under such agreements, we retain a proprietary interest in the products and technology developed.

Our funded research revenue as it relates to U.S. Government collaborations, primarily our efforts to develop an enzymatic process to convert biomass into bioethanol for the National Renewable Energy Laboratory, decreased \$0.1 million, or 9%, to \$1.0 million for the three months ended March 31, 2004 from the three months ended March 31, 2003. Funded research revenues provided by customers decreased \$2.9 million, or 73%, to \$1.1 million for the three months ended March 31, 2003, primarily driven by the completion of the initial stages of our strategic alliance with the Dow Corning Corporation.

Royalty revenues are based on the sales of customers products produced using our technology. Royalties increased \$0.2 million, or 40%, to \$0.7 million for the three months ended March 31, 2004 from the three months ended March 31, 2003.

License fees remained constant at less then \$0.1 million for the three months ended March 31, 2004 and the three months ended March 31, 2003. These fees are related to the sale of rights to third parties for the use of our technology and patents to manufacture products.

#### **Operating Expenses**

*Cost of Products Sold.* Cost of products sold decreased \$0.3 million, or 1%, to \$50.5 million for the three months ended March 31, 2004 from the three months ended March 31, 2003. The decrease in sales volume/mix reduced costs by \$0.4 million. Also unit production costs were \$2.9 million lower. These benefits were partially offset by the impact of the weaker U.S. Dollar against foreign currencies, primarily the Euro, of \$3.0 million.

*Gross Profit and Margins from Products Sold.* Gross profit from products sold increased \$1.9 million, or 5%, to \$41.1 million for the three months ended March 31, 2004 from the three months ended March 31, 2003. This overall increase was caused by a \$2.7

million impact due to the weaker U.S. Dollar against foreign currencies primarily the Euro and lower unit production costs of \$2.9 million. These increases were partially offset by a 2% decrease in volume/mix processed through our plants and an average price decline of 2%. As a result of these factors, gross margin on product revenue increased to 44.9% in the three months ended March 31, 2004 from 43.5% in the three months ended March 31, 2003.

*Research and Development.* Research and development expenses primarily consist of the personnel-related, consulting, and facilities costs incurred in connection with our research activities conducted in Palo Alto, California and Leiden, the Netherlands. These expenses increased \$0.4 million, or 2%, to \$16.9 million for the three months ended March 31, 2004 from the three months ended March 31, 2003, due primarily to increases in personnel-related costs, including salaries, benefits and travel expenses of \$0.4 million, facilities of \$0.2 million and supplies of \$0.1 million, partially offset by decreases in outside services of \$0.3 million and incentive compensation of \$0.1 million. As a part of total research and development expenses, estimated expenses related to research collaborations partially funded by customers decreased \$1.1 million, or 35%, to \$2.0 million for the three months ended March 31, 2003.

*Sales, Marketing and Business Development.* Sales, marketing and business development expenses primarily consist of the personnel-related and marketing costs incurred by our global sales force. These expenses increased \$0.6 million, or 8%, to \$8.3 million for the three months ended March 31, 2004 from the three months ended March 31, 2003, due primarily to increased personnel-related costs, including salaries, benefits, and travel expenses of \$0.6 million and an increase in the provision for doubtful accounts at our Chinese affiliate of \$0.2 million, partially offset by a decrease in outside services of \$0.3 million.

*General and Administrative*. General and administrative expenses include the costs of our corporate executive, finance, information technology, legal, human resources, and communications functions. In total, these expenses increased \$0.7 million, or 9%, to \$8.5 million for the three months ended March 31, 2004 from the three months ended March 31, 2003, due primarily to increases in outside services of \$0.8 million, partially offset by decreased personnel-related costs, including salaries, benefits and travel expenses of \$0.1 million.

*Amortization of Intangible Assets.* We amortize our definite-lived intangible assets, consisting primarily of patents, licenses and customer lists, on a straight-line basis over their estimated useful lives. Amortization expense decreased \$0.2 million, or 14%, to \$1.2 million for the three months ended March 31, 2004 from the three months ended March 31, 2003.

*Other Expense and Income.* Other income for the three months ended March 31, 2004 was \$7.9 million as compared with other expense of \$0.7 million for the three months ended March 31, 2003. The increase in other income for the three months ended March 31, 2004 was primarily driven by the \$8.3 million net gain resulting from the final settlement of our insurance claim related to the warehouse accident in Rotterdam, the Netherlands that occurred in the second quarter of 2003.

#### Non Operating Expense and Income

*Interest Income*. Interest income was \$0.9 million for the three months ended March 31, 2004, which was an increase of less than \$0.1 million from the three months ended March 31, 2003.

*Income Taxes.* The effective income tax rate was 20% for the three months ended March 31, 2004, compared to 32% for the three months ended March 31, 2003, which reflects our assessment of the annual effective income tax rate. Factors that affect our estimated annual effective income tax rate include increased research and development expenditures in the United States, the statutory income tax rates in foreign jurisdictions and the relative amount of income in each jurisdiction, other operating expense increases and other items which are not deductible for tax

purposes, and research and experimentation tax credits. In addition, the estimated annual effective rate for the three months ended March 31, 2003 included the effect of estimated valuation allowances, since we did not anticipate having the ability to utilize certain tax credits.

#### **Financial Results by Segment**

Our managerial financial reporting provides information that aligns with the two-segment structure of Bioproducts and Health Care. Accordingly, we have provided financial data in this financial segment-reporting for the three months ended March 31, 2004 and 2003.

The Bioproducts segment develops and delivers products and services for the industrial, consumer and agri-processing markets to a global customer base. All of our current product revenues are derived from this segment. For the three months ended March 31, 2004, the Bioproducts segment achieved operating income of \$23.9 million as compared to operating income of \$19.1 million for the three months ended March 31, 2003.

The Health Care segment is primarily engaged in the performance of research and development, securing intellectual property and the establishment of strategic investments and collaborations in support of our product objectives in the health care market. For the three months ended March 31, 2004, the Health Care segment experienced an operating loss of \$6.8 million as compared to an operating loss of \$7.9 million for the three months ended March 31, 2003.

#### Warehouse Inventory Loss

We sustained damage to our finished bioproducts inventory in the second quarter of 2003 as a result of an accident in a third party warehouse in Rotterdam, the Netherlands. At the end of the first quarter of 2004, we reached final settlement of our accident-related claim with our insurer totaling approximately \$21.0 million. This settlement resulted in a net gain of \$8.3 million for the quarter. Of the total settlement, we have received cash payments of approximately \$9.4 million from our insurer through March 31, 2004.

#### **Technology Transfer**

During March 2004, we sold our therapeutic vaccine program to Innogenetics N.V., a biotechnology company with a long-term commitment to therapeutic vaccine strategies. Upon transfer of certain intellectual property, contractual relationships and technologies to Innogenetics, we expect to recognize license fees in the second or third quarter of 2004 totaling \$10.0 million. We expect to receive further payments as development milestones are achieved. Once products are commercialized, we will also receive royalty payments on future product sales.

#### Liquidity and Capital Resources

Our funding needs consist primarily of capital expenditures, research and development activities, sales and marketing expenses, and general corporate purposes. We have financed our operations primarily through cash from the sale of products, the sale of stock, research and development funding from partners, government grants, and short-term and long-term borrowings.

We believe that our current cash and cash equivalent balances plus funds to be provided from our current year operating activities, together with those available under our lines of credit, will satisfy our funding needs over the next twelve months. Factors that could negatively impact our cash position include, but are not limited to, future levels of product revenues, fees and royalty revenues, expense levels, capital expenditures, acquisitions, and foreign currency exchange rate fluctuations.

As of March 31, 2004, cash and cash equivalents totaled \$139.5 million. The funds were invested in short-term instruments, including A-1/P-1 and A-2/P-2 rated commercial paper, AAA/Aaa and AA/Aa2 rated medium term notes, as rated by Standard & Poor and Moody s, respectively. Additionally the funds were invested in institutional money market funds, auction rate preferred securities and bank deposits.

Cash provided by operations was \$6.3 million for the three months ended March 31, 2004 and cash used by operations was \$0.2 million for the three months ended March 31, 2003. The increase of \$6.5 million for the year ended March 31, 2004 from the three months ended March 31, 2003, was driven by increases in operating earnings, net of non-cash items such as depreciation and amortization, partially offset by changes in operating assets and

#### liabilities.

Cash used in investing activities was \$4.2 million and \$4.6 million for the three months ended March 31, 2004 and 2003, respectively. This decrease of \$0.4 million was driven primarily by a \$0.8 million decrease in capital spending for the three months ended March 31, 2004. This was partially offset by \$0.6 million of additional payments related to the 2002 year-end acquisition of the brewing and enzyme business of Rhodia Food UK Limited. Capital expenditures for the first quarter were \$3.7 million in 2004

compared with \$4.5 million in 2003. A significant portion of this spending included process improvement projects at our manufacturing and research and development facilities and information technology enhancements. During the three months ended March 31, 2003, construction continued on our facility for the clinical-scale manufacture of human therapeutic proteins in Rochester, New York. Construction of this facility was completed during the three months ended September 30, 2003.

Cash used in financing activities was \$27.3 million and \$27.5 million for the three months ended March 31, 2004 and 2003, respectively, which primarily consisted of our \$28.0 million annual installment payments made on our senior debt in each period. No dividends were paid to common stockholders during the three months ended March 31, 2004. While we are permitted to pay dividends, we currently intend to retain future earnings to finance the expansion of our business. Any future determination to pay cash dividends to our common stockholders will be at the discretion of our board of directors and will depend upon our financial condition, results of operations, capital requirements, general business conditions and other factors that the board of directors may deem relevant, including covenants in our debt instruments that may limit our ability to declare and pay cash dividends on our capital stock. Covenants in our senior note agreement restrict the payment of dividends or other distributions in cash or other property to the extent the payment puts us in default of these covenants. Such covenants include, but are not limited to, maintaining a debt to total capitalization of no greater than 55% and a maximum ratio of debt to earnings before interest, taxes, depreciation and amortization (EBITDA) of 3.5:1.

At March 31, 2004, we had a \$40.0 million revolving credit facility with a syndicate of banks, which is available for general corporate purposes. The credit facility, which consists of a credit agreement, makes available to the Company \$40.0 million of committed borrowings and expires on December 23, 2006. The credit facility fees were 0.30% on the amount of unborrowed principal under the agreement for the three months ended March 31, 2004. As of March 31, 2004, there were no borrowings under the facility.

Our long-term debt consists primarily of the 6.82% senior notes issued in 1996 to certain institutional investors. The remaining principal amount of these notes is \$56.0 million. Annual installment payments of \$28.0 million commenced on March 30, 2002. We are currently in compliance with the financial covenants included in the senior note agreement.

#### **New Accounting Pronouncements**

In December 2003, the FASB issued a revision of SFAS No. 132, Employers Disclosures about Pensions and Other Postretirement Benefits. The revised Statement provides required disclosures for pensions and other postretirement benefit plans and is designed to improve disclosure transparency in financial statements. The revised Statement replaces existing year-end and interim disclosure requirements. This Statement was in effect for our fiscal year ending December 31, 2003 and for quarters beginning thereafter for domestic plans, and will be effective for fiscal years ending after June 15, 2004 for our foreign plans.

In January 2004, the FASB issued FASB Staff Position No. FAS 106-1, Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003. This Position permits employers that sponsor postretirement benefit plans that provide prescription drug benefits to retirees to make a one-time election to defer accounting for any effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Act). Specific authoritative guidance on the accounting for the federal subsidy is pending and that guidance, when issued, could require the sponsor of such a plan to change previously reported information. Our financial statements do not reflect any implications of the Act due to the level of uncertainty about the forthcoming guidance.

#### **Market Risk**

Foreign currency risk and interest rate risk are the primary sources of our market risk. To date foreign operations, mainly denominated in Euros, accounted for approximately 55% of our revenues for the three months ended March 31, 2004. We believe that we mitigate this risk by locating our manufacturing facilities so that the costs are denominated in the same currency as our product revenues. We may manage the foreign currency exposures that remain through the use of foreign currency forward contracts, currency options and off-setting currency positions in assets and liabilities where deemed appropriate. We do not use these instruments for speculative purposes.

As of March 31, 2004, cash and cash equivalents totaled \$139.5 million. Of this amount, \$79.6 million was denominated in Euros. The remainder, or \$59.9 million, was primarily denominated in U.S. Dollars. Short-term debt was mainly comprised of our fourth installment of \$28.0 million due March 30, 2005 under our 6.82% senior notes discussed under the heading Liquidity and Capital Resources in this Report. To the extent U.S. Dollar and Euro interest rates fluctuate either up or down, the return on the cash

investments will also fluctuate. To the extent such Euro cash investments remain outstanding, we will be subject to the risks of future foreign exchange fluctuations and the impact on the translation of these cash investments into U.S. Dollars.

#### Interest Rates

Our interest income is sensitive to changes in the general level of short-term interest rates primarily in the United States and Europe. In this regard, changes in the U.S. Dollar and Euro currency rates affect the interest earned on our cash equivalents, short-term investments, and long-term investments. Our interest expense is generated primarily from fixed rate debt. The \$56.0 million 6.82% senior notes outstanding at March 31, 2004 mature evenly in installments of \$28.0 million per year. The two remaining installments are due March 30, 2005 and 2006.

#### Foreign Currency Exposure

We conduct business throughout the world. During the three months ended March 31, 2004, we derived approximately 55% of our revenues and approximately 45% of our operating income from foreign operations. Economic conditions in countries where we conduct business and changing foreign currency exchange rates affect our financial position and results of operations. We are exposed to changes in foreign exchange rates in Europe, Latin America, and Asia. The Euro and Argentine Peso present our most significant foreign currency exposure risk. Changes in foreign currency exchange rates, especially the strengthening of the U.S. Dollar, may have an adverse effect on our financial position and results of operations as they are expressed in U.S. Dollars. Our manufacturing and administrative operations for Latin America are located in Argentina. A significant part of our Latin American revenues are denominated in U.S. Dollars. Net foreign exchange loss from U.S. Dollar/Euro and U.S. Dollar/Argentine Peso transactions were \$0.2 million for the three-month period ended March 31, 2004.

Management monitors foreign currency exposures and may in the ordinary course of business enter into foreign currency forward contracts or options contracts related to specific foreign currency transactions or anticipated cash flows. These contracts generally cover periods of nine months or less and are not material. For the three months ended March 31, 2004, foreign currency contracts had an approximately neutral impact on our statement of operations. We do not hedge the translation of financial statements of consolidated subsidiaries that maintain their local books and records in foreign currencies.

#### **Risk Factors**

Biotechnology and especially the development of products for the health care market are areas of intense competition and high risk. While we believe that our business is unique in its history and areas of focus, the risk factors described below or other risks not known to us now or that we currently believe to be immaterial may have a material and adverse effect on our business, financial condition, results of operations, or the price of our common stock.

# If we fail to develop products for the health care and bioproducts markets, we may not achieve a return on our research and development expenditures or realize product revenues from these markets.

A key element of our business strategy is to utilize our technologies for the development and delivery of new products to the health care market and new sectors of the bioproducts market. We intend to continue to invest heavily in research and development to develop products for these markets. The successful development of these products, especially those in the health care market, is highly uncertain and is dependent on numerous factors, many of which are beyond our control, and may include the following:

The product may be ineffective or have undesirable side effects in preliminary and commercial testing or, specifically in the health care area, in preclinical and clinical trials;

The product may fail to receive necessary governmental and regulatory approvals, or such regulatory approvals may be delayed significantly;

The product may not be economically viable because of manufacturing costs or other factors;

The product may not gain acceptance in the marketplace; or

The proprietary rights of others or competing products or technologies for the same application may preclude us from commercializing the product.

Due to these factors we may never achieve a return on our research and development expenditures or realize product revenues from the health care and new bioproducts markets that we are targeting.

# If we fail to enter into strategic alliances with partners in our target markets or fail to independently raise additional capital, we will not have the resources necessary to capitalize on all of the market opportunities available to us.

We do not currently possess the resources necessary to independently develop and commercialize products for all of the market opportunities that may result from our technologies. We intend to form strategic alliances with industry leaders in our target markets to gain access to funding for research and development, expertise in areas we lack and distribution channels. We may fail to enter into the necessary strategic alliances or fail to commercialize the products anticipated from the alliances. Our alliances could be harmed if:

We fail to meet our agreed upon research and development objectives;

We disagree with our strategic partners over material terms of the alliances, such as intellectual property or manufacturing rights; or

Our strategic partners become competitors or enter into agreements with our competitors.

New strategic alliances that we enter into, if any, may conflict with the business objectives of our current strategic partners and negatively impact existing relationships. In addition, to capitalize on the market opportunities we have identified, we may need to seek additional capital, either through private or public offerings of debt or equity securities. Due to market and other conditions beyond our control, we may not be able to raise additional capital on acceptable terms or conditions, if at all.

# If the demand for protein degrading enzymes decreases or if major customers reduce or terminate business with us, our revenues could significantly decline.

Our largest selling family of products, protein degrading enzymes, or proteases, accounted for approximately 48% of our 2003 product revenues. If the demand for proteases decreases or alternative proteases render our products noncompetitive, our revenues could significantly decline.

In addition, our five largest customers collectively accounted for approximately 53% of our 2003 product revenues, with our largest customer, The Procter & Gamble Company, accounting for more than 35% of such revenues. Our five largest customers in 2003 were Broin Group; Cargill, Incorporated; Danisco Animal Nutrition the feed ingredients business unit of Danisco A/S; The Procter & Gamble Company; and Reckitt Benckiser, plc. Any one of these customers may reduce their level of business with us. Should any of our largest customers decide to reduce or terminate business with us, our revenues and profitability could decline significantly.

We have arrangements of various durations with our major customers and are routinely involved in discussions regarding the status of these relationships. These discussions may lead to extensions or new commercial arrangements, or may be unsuccessful. Our customer relationships involve uncertainty by virtue of economic conditions, customer needs, competitive pressures, our production capabilities and other factors. Consequently, we expect that our customer base will continue to change over time as will the nature of our relationships with individual customers, including major customers.

# We intend to acquire businesses, technologies and products; however, we may fail to realize the anticipated benefits of such acquisitions and we may incur costs that could significantly negatively impact our profitability.

In the future, we may acquire other businesses, technologies and products that we believe are a strategic fit with our business. If we undertake any transaction of this sort, we may not be able to successfully integrate any businesses, products, technologies or personnel that we might acquire without a significant expenditure of operating, financial and management resources, if at all. Further, we may fail to realize the anticipated benefits of any acquisition. Future acquisitions could dilute our stockholders interest in us and could cause us to incur substantial debt, expose us to contingent liabilities and could negatively impact our profitability.

# If we are unable to secure or maintain adequate intellectual property protection or become involved in an intellectual property dispute, it could significantly harm our financial results and ability to compete.

The patent positions of biotechnology companies, including our patent positions, can be highly uncertain and involve complex legal and factual questions, and, therefore, enforceability is uncertain. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that we protect our technologies with valid and enforceable patents or as trade secrets. We rely in part on trade secret protection for our confidential and proprietary information by entering into confidentiality agreements and non-disclosure policies with our employees and consultants. Nonetheless, confidential and proprietary information may be disclosed, and others may independently develop substantially equivalent information and techniques or otherwise gain access to our trade secrets.

We file patent applications in the United States and in foreign countries as part of our strategy to protect our proprietary products and technologies. The loss of significant patents or the failure of patents to issue from pending patent applications that we consider significant could impair our operations. In addition, third parties could successfully challenge, invalidate or circumvent our issued patents or patents licensed to us so that our patent rights would not create an effective competitive barrier. Further, we may not obtain the patents or licenses to technologies that we will need to develop products for our target markets. The laws of some foreign countries may also not protect

our intellectual property rights to the same extent as United States law.

Extensive litigation regarding patents and other intellectual property rights is common in the biotechnology industry. In the ordinary course of business, we periodically receive notices of potential infringement of patents held by others and patent applications that may mature to patents held by others. The impact of such claims of potential infringement, as may from time to time become known to us, are difficult to assess. In the event of an intellectual property dispute, we may become involved in litigation. Intellectual property litigation can be expensive and may divert management s time and resources away from our operations. The outcome of any such litigation is inherently uncertain. Even if we are successful, the litigation can be costly in terms of dollars spent and diversion of management time.

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If a third party successfully claims an intellectual property right to technology we use, it may force us to discontinue an important product or product line, alter our products and processes, pay license fees, pay damages for past infringement or cease certain activities. Under these circumstances, we may attempt to obtain a license to this intellectual property; however, we may not be able to do so on commercially reasonable terms, or at all. In addition, regardless of the validity of such a claim, its mere existence may affect the willingness of one or more customers to use or continue to use our products and, thereby, materially impair our business.

Those companies with which we have entered or may enter into strategic alliances encounter similar risks and uncertainties with respect to their intellectual property. To the extent that any such alliance companies suffer a loss or impairment of their respective technologies, we may suffer a corresponding loss or impairment that may materially and adversely affect our investments.

Also, our patent portfolio includes patents that are nearing the end of their period of protection. While we do not expect to experience a material adverse effect related to patent expirations in the near term, the expiration of patents may submit us to new competition and price pressures that may lead to a significant loss of product revenue.

# Foreign currency fluctuations and economic and political conditions in foreign countries could cause our revenues and profits to decline.

In 2003, we derived approximately 55% of our product revenues from our foreign operations. Our foreign operations generate sales and incur expenses in local currency. As a result, we are exposed to market risk related to unpredictable interest rates and foreign currency exchange rate fluctuations. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the U.S. Dollar and the currencies in which we do business could cause our revenues and profits to decline.

Product revenues denominated in Euros accounted for approximately 37% of our total product revenues in 2003, and the fluctuations in the currency exchange rate against the U.S. Dollar can have a significant impact on our reported product revenues.

We expect to continue to operate in foreign countries and that our international sales will continue to account for a significant percentage of our revenues. As such, we are subject to certain risks arising from our international business operations that could be costly in terms of dollars spent, the diversion of management s time, and revenues and profits, including:

Difficulties and costs associated with staffing and managing foreign operations;

Unexpected changes in regulatory requirements;

Difficulties of compliance with a wide variety of foreign laws and regulations;

Changes in our international distribution network and direct sales forces;

Political trade restrictions and exchange controls;

Political, social, or economic unrest including armed conflict and acts of terrorism;

Labor disputes including work stoppages, strikes and embargoes;

Inadequate and unreliable services and infrastructure;

Import or export licensing or permit requirements; and

Greater risk on credit terms and long accounts receivable collection cycles in some foreign countries.

# If the ownership of our common stock continues to be highly concentrated, it may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

After our initial public offering and continuing to the present, Eastman Chemical Company and Danisco A/S and their affiliates, which we refer to as our majority stockholders, each own in excess of 40% of our outstanding common stock. Moreover, pursuant to a Stockholder Agreement, as amended, among Eastman, Danisco and us, each of our majority stockholders also has the right to nominate three of our ten directors. The majority stockholders will therefore have the ability, in the event they act together, to control fundamental corporate transactions requiring stockholder approval, including the election of our directors, the approval of merger transactions involving us, and the sale of all or substantially all of our assets or other business combination transactions. The concentration of ownership of our common stock may have the effect of either delaying or preventing a change to our control favored by our other stockholders. In addition, the majority stockholders and us with respect to the allocation of corporate opportunities and between the majority stockholders and us with respect to the allocation of corporate opportunities and between the majority stockholders and other stockholders.

#### If stockholders sell large numbers of shares of our common stock, our stock price could decline.

The market price of our common stock could decline as a result of sales of our stock into the public market or the perception that these sales could occur. Our two majority stockholders, for example, hold more than 80% of our common stock, and all of these shares are subject to registration rights. In addition, we have a significant number of stock options outstanding with our officers, directors and employees pursuant to our 2002 Omnibus Incentive Plan, approved by our stockholders in May 2002, and its predecessor plan.

#### Our stock price has been, and may continue to be, particularly volatile.

The stock market from time to time, has experienced significant price and volume fluctuations that are unrelated to the operating performance of companies. The market prices for securities of biotechnology companies, including ours, have been highly volatile in the period since our initial public offering in July 2000 and may continue to be highly volatile in the future. Our stock may be affected by this type of market volatility, as well as by our own performance. The following factors, among other risk factors, may have a significant effect on the market price of our common stock:

Developments in our relationships with current or future strategic partners;

Conditions or trends in the biotechnology industry;

Announcements of technological innovations or new products by us or our competitors;

Announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

Developments in patent or other intellectual proprietary rights or announcements relating to these matters;

Investor concern regarding the public acceptance of the safety of biotechnology products or announcements relating to these matters;

Litigation or governmental proceedings or announcements relating to these matters;

Economic and other external factors or other disaster or crisis;

Future royalties from product sales, if any, by our licensees;

Sales of our common stock or other securities in the open market; and

Period-to-period fluctuations in our operating results.

# We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline, causing investor losses.

A large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed. Accordingly, if product revenue declines or does not grow as we anticipate or non-product revenue declines due to the expiration or termination of strategic alliance agreements or the failure to obtain new agreements or grants, we may not be able to correspondingly reduce our operating expenses in any particular quarter. Our quarterly revenue and operating results have fluctuated in the past and are likely to do so in the future. If our operating results in some quarters fail to meet the expectations of stock market analysts and investors, our stock price would likely decline. Some of the factors that could cause our revenue and operating results to fluctuate include:

The ability and willingness of strategic partners to commercialize products derived from our technology or containing our products on expected timelines;

Our ability to successfully commercialize products developed independently and the rate of adoption of such products;

Fluctuations in consumer demand for products containing our technologies or products, such as back to school sales of blue jeans and other denim products, resulting in an increase in the use of textile processing enzymes, and fluctuations in laundry detergent use due to promotional campaigns run by consumer products companies; and

Fluctuations in geographic conditions including currency and other economic conditions such as economic crises in Latin America or Asia and increased energy and related transportation costs.

We also have incurred significant infrequently occurring charges within given quarters, such as those incurred in conjunction with restructuring activities and recognized investment income/expense from available-for-sale marketable securities.

#### Concerns about genetically engineered products could result in our inability to commercialize products.

We produce a significant amount of our products from genetically modified microorganisms. We cannot predict public attitudes and acceptance of existing or future products made from genetically modified microorganisms. As a result, if we are not able to overcome the ethical, legal and social concerns relating to safety and environmental hazards of genetic engineering, the general public may not accept our products and this may prevent us from commercializing products dependent on our technologies or inventions. In addition, public attitudes may influence laws and regulations governing the ownership or use of genetic material, which could result in greater government regulation of genetic research and bioengineered products.

#### If we are subject to a costly product liability damage claim or award, our profits could decline.

We may be held liable if any product we develop, or any product that a third party makes with the use or incorporation of any of our products, causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Our current product liability insurance may not cover our potential liabilities. Inability to obtain sufficient insurance coverage in the future at an acceptable cost or otherwise to protect against potential liability claims could prevent or inhibit the commercialization of products developed by us or our strategic partners. If a third party sues us for any injury caused by our products, our liability could exceed our insurance coverage amounts and total assets and our profits could decline.

# If we are subject to costly environmental liability due to the use of hazardous materials in our business, our profits could decline.

Our research and development processes involve the controlled use of hazardous materials, including chemical, radioactive and biological materials. Our operations also generate potentially hazardous waste. We cannot eliminate entirely the risk of contamination or the discharge of hazardous materials and any resultant injury from these materials. Federal, state, local and foreign laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. Third parties may sue us for any injury or contamination resulting from our use or the third party s use of these materials. Any accident could partially or completely shut down our research and manufacturing facilities and operations. In addition, if we are required to comply with any additional applicable environmental laws and regulations, we may incur additional costs, and any such current or future environmental regulations may impair our research, development or production efforts.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

The information presented in Item 2 of Part I of this Report on Form 10-Q under the heading Market Risk is hereby incorporated by reference.

#### **Item 4. Controls and Procedures**

#### Disclosure Controls and Internal Controls

Disclosure Controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934 (Exchange Act), such as this Report, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure Controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Internal Controls are procedures which are designed with the objective of providing reasonable assurance that (1) our transactions are properly authorized; (2) our assets are safeguarded against unauthorized or improper use; and (3) our transactions are properly recorded and reported, all to permit the preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America. Accordingly, a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

#### Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Report, we carried out an evaluation, under the supervision and with the participation of our management, including Jean-Jacques Bienaimé, our Chairman, Chief Executive Officer and President, and Raymond J. Land, our Senior Vice President and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, Mr. Bienaimé and Mr. Land concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Report.

#### Changes in Internal Controls Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the first quarter of 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### **Item 1. Legal Proceedings**

Nothing to report

#### Item 2. Change in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

The information presented in Item 2 of Part I of this Report on Form 10-Q under the heading Liquidity and Capital Resources is hereby incorporated by reference. The Company s Registration Statement on Form S-1 (Registration No. 333-36452) was effective as of July 27, 2000.

#### Item 3. Defaults Upon Senior Securities

Nothing to report

#### Item 4. Submission of Matters to a Vote of Security Holders

Nothing to report

#### **Item 5. Other Information**

Nothing to report

#### Item 6. Exhibits and Reports on Form 8-K

#### a. Exhibits

- Plan of acquisition, reorganization, arrangement, liquidation or succession
  +2.1 Transfer Agreement between the Company and Innogenetics N.V. dated March 29, 2004
- (10) Material Contracts
  10.1 Letter Agreement, dated February 11, 2003, between Dow Corning Corporation and the Company
- (31) Rule 13a-14(a)/15d-14(a) Certifications
  - 31.1 Rule 13a-14(a)/15(d)-14(a) Certification of Chief Executive Officer
  - 31.2 Rule 13a-14(a)/15(d)-14(a) Certification of Chief Financial Officer
- (32) Section 1350 Certifications
  32.1 Section 1350 Certifications of each of the Chief Executive Officer and the Chief Financial Officer
- + Confidential treatment requested as to certain information which has been omitted from the agreement and which has been separately filed with the Securities and Exchange Commission pursuant to an application for such treatment.

#### b. Reports on Form 8-K

On February 12, 2004 the Company filed a Current Report on Form 8-K regarding its press release concerning financial results for the fourth quarter and full year of 2003. The report included condensed financial statements and other financial information.

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# **SIGNATURES**

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

	GENENCOR INTERNATIONAL, INC.
May 6, 2004	By: /s/ Raymond J. Land
Date	Raymond J. Land Senior Vice President and Chief Financial Officer (Principal Financial Officer)
May 6, 2004	By: /s/ Darryl L. Canfield
Date	Darryl L. Canfield Vice President and Corporate Controller (Chief Accounting Officer)
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## EXHIBIT INDEX

Exhibit Number	Description
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31.2	Rule 13a-14(a)/15(d)-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certifications of each of the Chief Executive Officer and the Chief Financial Officer

+ Confidential treatment requested as to certain information which has been omitted from the agreement and which has been separately filed with the Securities and Exchange Commission pursuant to an application for such treatment.