

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2003, or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For transition period from .

Commission File Number 0-27352

**HYBRIDON, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

**04-3072298**

*(State or other jurisdiction of  
incorporation or organization)*

*(I.R.S. Employer Identification  
Number)*

**345 Vassar Street  
Cambridge, Massachusetts 02139**  
*(Address of principal executive offices)*

**(617) 679-5500**  
*(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, par value \$.001 per share

43,493,711

Class

Outstanding as of May 8, 2003

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**HYBRIDON, INC.**

**FORM 10-Q**

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# PART I — FINANCIAL STATEMENTS

## ITEM 1 – UNAUDITED FINANCIAL STATEMENTS

### HYBRIDON, INC. AND SUBSIDIARIES

#### CONSOLIDATED CONDENSED BALANCE SHEETS (UNAUDITED)

	MARCH 31, 2003	DECEMBER 31, 2002
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,479,606	\$ 4,527,500
Short-term investments	6,401,076	14,647,417
Receivables	196,675	406,313
Prepaid expenses and other current assets	538,294	191,770
Total current assets	11,615,651	19,773,000
Long-term investments	—	941,069
Property and equipment, net	515,456	534,764
	<u>\$ 12,131,107</u>	<u>\$ 21,248,833</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 654,594	\$ 831,192
Accrued expenses	709,521	828,227
Current portion of capital lease	9,964	33,591
Current portion of deferred revenue (Note 5)	84,587	442,333
Total current liabilities	1,458,666	2,135,343
9% convertible subordinated notes payable	1,306,000	1,306,000
Deferred revenue, net of current portion (Note 5)	548,200	363,360
Stockholders' equity:		
Preferred stock, \$0.01 par value		
Authorized — 5,000,000 shares		
Series A convertible preferred stock		
Designated — 1,500,000 shares		
Issued and outstanding — 677,955 and 678,362 shares at March 31, 2003 and December 31, 2002, respectively	6,780	6,784
Common stock, \$0.001 par value		
Authorized—150,000,000 shares		
Issued and outstanding—43,456,045 and 47,944,857 shares at March 31, 2003 and December 31, 2002, respectively	43,456	47,945
Additional paid-in capital	276,272,414	278,578,678
Accumulated deficit	(267,461,763)	(261,142,926)
Accumulated other comprehensive loss	—	(1,944)
Deferred compensation	(42,646)	(44,407)
Total stockholders' equity	8,818,241	17,444,130
	<u>\$ 12,131,107</u>	<u>\$ 21,248,833</u>

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

**HYBRIDON, INC. AND SUBSIDIARIES**

**CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS**

**(UNAUDITED)**

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>Revenues:</b>		
Milestone fees	\$ 150,000	\$ —
License fees	136,657	678,290
Royalty and other income	48,177	12,516
Investment income	82,693	195,963
	<u>417,527</u>	<u>886,769</u>
<b>Operating expenses:</b>		
Research and development	2,405,965	1,246,166
General and administrative (Note 10)	3,223,889	1,141,943
Stock-based compensation from repriced options(1)	5,871	(263,504)
Interest	29,385	38,033
	<u>5,665,110</u>	<u>2,162,638</u>
Loss before provision for income taxes	(5,247,583)	(1,275,869)
Income tax benefit	—	(500,000)
Net loss	(5,247,583)	(775,869)
Accretion of preferred stock dividends	(1,071,254)	(1,040,249)
Net loss applicable to common stockholders	\$ (6,318,837)	\$ (1,816,118)
Basic and diluted net loss per share (Note 3)	\$ (0.12)	\$ (0.02)
Basic and diluted net loss per share applicable to common stockholders (Note 3)	\$ (0.14)	\$ (0.04)
Shares used in computing basic and diluted loss per common share	45,700,346	45,669,571
(1) The following summarizes the allocation of stock-based compensation from repriced options:		
Research and development	\$ 5,871	\$ (129,645)
General and administrative	—	(133,859)
Total	\$ 5,871	\$ (263,504)

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

**HYBRIDON, INC. AND SUBSIDIARIES**

**CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS**

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2003	2002
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$(5,247,583)	\$ (775,869)
Adjustments to reconcile net loss to net cash used in operating activities -		
Stock repurchase expense (Note 10)	1,857,214	—
Stock-based compensation	5,871	(263,504)
Depreciation and amortization	127,895	123,554
Issuance of common stock for services rendered	54,000	—
Non-cash interest expense	29,385	38,033
Changes in operating assets and liabilities -		
Accounts receivable	209,638	(524,414)
Prepaid expenses and other current assets	(346,524)	(64,945)
Accounts payable and accrued expenses	(324,689)	383,210
Deferred revenue	(172,907)	(774,663)
Net cash (used in) operating activities	<u>(3,807,700)</u>	<u>(1,858,598)</u>
<b>Cash Flows From Investing Activities:</b>		
Maturities of held-to-maturity investments	7,700,000	2,665,000
Purchase of marketable securities	—	(12,426,018)
Proceeds from sale of available-for-sale securities	1,399,987	—
Proceeds from sale of held-to-maturity securities	—	2,038,101
Purchase of property and equipment	(17,459)	(25,698)
Net cash (used in) provided by investing activities	<u>9,082,528</u>	<u>(7,748,615)</u>
<b>Cash Flow From Financing Activities:</b>		
Repurchase of common stock (Note 10)	(5,339,489)	—
Proceeds from exercise of common stock options	40,394	32,937
Payments on capital lease	(23,627)	—
Net cash (used in) provided by financing activities	<u>(5,322,722)</u>	<u>32,937</u>
Net decrease in cash and cash equivalents	(47,894)	(9,574,276)
Cash and cash equivalents, beginning of period	4,527,500	20,923,295
Cash and cash equivalents, end of period	<u>\$ 4,479,606</u>	<u>\$ 11,349,019</u>
Supplemental disclosure of non cash financing and investing activities:		
Accretion of Series A convertible preferred stock dividends	<u>\$ 1,071,254</u>	<u>\$ 1,040,249</u>

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

# HYBRIDON, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS MARCH 31, 2003

(UNAUDITED)

### (1) Organization

Hybridon, Inc. (the Company) was incorporated in the State of Delaware on May 25, 1989. The Company is engaged in the discovery and development of novel therapeutics and diagnostics using synthetic DNA. The Company's activities are based on four technologies: CpG-like immunomodulatory oligonucleotide (IMO) technology, which uses synthetic DNA that contains specific sequences that mimic bacterial DNA to modulate responses of the immune system; antisense technology, which uses synthetic DNA to block the production of disease causing proteins at the cellular level; cancer therapy potentiation technology, which uses synthetic DNA to enhance the antitumor activity of certain marketed anticancer drugs and increase their effectiveness; and Cyclicon technology, which uses novel synthetic DNA structures for identifying gene function in drug target validation and drug discovery.

### (2) Unaudited Interim Financial Statements

The accompanying consolidated condensed financial statements included herein have been prepared by the Company, without audit, in accordance with generally accepted accounting principals for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of interim period results have been included. The Company believes that its disclosures are adequate to make the information presented not misleading. Interim results for the three month period ended March 31, 2003 are not necessarily indicative of results that may be expected for the year ended December 31, 2003. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, which was filed with the Securities and Exchange Commission on March 31, 2003.

### (3) Net Loss per Common Share

The following table sets forth the computation of basic and diluted loss per share:

	Three Months Ended March 31,	
	2003	2002
Numerator:		
Net loss	\$ (5,247,583)	\$ (775,869)
Accretion of preferred stock dividends	(1,071,254)	(1,040,249)
Numerator for basic and diluted loss applicable to common shareholders	\$ (6,318,837)	\$ (1,816,118)
Denominator for basic and diluted loss per share	45,700,346	45,669,571
Loss per share – basic and diluted		
Net loss per share	\$ (0.12)	\$ (0.02)
Accretion of preferred stock dividends	(0.02)	(0.02)
Net loss per share applicable to common stockholders	\$ (0.14)	\$ (0.04)

Basic net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three months ended March 31, 2003 and 2002, diluted net loss per common share is the same as basic net loss per common share, as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were 34,261,704 and 40,994,568 for the three months ended March 31, 2003 and 2002, respectively. These securities include stock options, warrants, convertible preferred stock and convertible debt instruments (on an as-converted basis) and are not included in the Company's calculation of diluted net loss per common share.

(4) Cash Equivalents and Investments

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at March 31, 2003 and December 31, 2002 consist of the following:

	MARCH 31, 2003	DECEMBER 31, 2002
Cash and cash equivalents		
Cash and money market funds	\$4,479,606	\$2,527,500
Corporate bonds	—	2,000,000
Total	\$4,479,606	\$4,527,500

The Company accounts for investments in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Management determines the appropriate classification of marketable securities at the time of purchase. In accordance with SFAS No. 115, investments that the Company has the positive intent and ability to hold to maturity are classified as “held to maturity” and reported at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity, which approximates fair market value. Such amortization is included in “Investment income” on the accompanying consolidated statement of operations. Investments that the Company does not have the positive intent to hold to maturity are classified as “available-for-sale” and reported at fair market value. Unrealized gains and losses associated with “available-for-sale” investments are recorded in “Accumulated other comprehensive loss” on the accompanying consolidated balance sheet. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other than temporary, and interest and dividends are included in “Investment income” on the accompanying consolidated statement of operations for all available-for-sale securities. The cost of securities sold is based on the specific identification method. For the three month period ended March 31, 2003, there was \$445 of realized gains included in “Investment income” on the accompanying consolidated statement of operations from available-for-sale securities sold in February 2003. For the three month period ended March 31, 2002, the Company sold two of its securities, issued by the same corporation, which the Company had classified as “held-to-maturity” as of December 31, 2001. The Company sold such securities when the underlying corporation’s credit rating was down-graded. In order to avoid incurring any potential losses, the Company sold these securities for approximately \$3,048,000 which was their approximate book value. There were no losses or permanent declines in value included in “investment income” for any securities in the three months ended March 31, 2003 and 2002.

Short-term investments have maturities of greater than three months and mature within one year of the balance sheet date. All of the short-term investments mature prior to June 30, 2003. The available-for-sale long-term investment held at December 31, 2002 had a maturity date in the first quarter of 2004 but was sold in the first quarter of 2003. There were no long-term investments at March 31, 2003. The Company’s investments consisted of the following at March 31, 2003 and December 31, 2002:

	March 31 2003	December 31 2002
Short-term investments		
Held-to-maturity at amortized cost:		
Government bonds	\$4,005,324	\$10,047,377
Corporate bonds	2,395,752	4,136,666
Available-for-sale corporate bonds at market	—	463,374
Total short-term investments	6,401,076	14,647,417
Long-term available-for-sale corporate bonds	—	941,069
Total	\$6,401,076	\$15,588,486

(5) Collaboration and License Agreement with Isis Pharmaceuticals, Inc.

On May 24, 2001, the Company and Isis Pharmaceuticals, Inc. (Isis) entered into a Collaboration and License Agreement (the Isis Agreement). Under the Isis Agreement, the Company granted Isis a license, with the right to sublicense, to the Company’s antisense chemistry and delivery patents and patent applications. Isis also agreed to pay the Company a portion of specified sublicense income it receives from specified types of sublicenses of the Company’s patents and patent applications. The Company has retained the right to use the patents and patent applications in its own drug discovery and development efforts and in collaboration with third parties. Under the Isis Agreement, Isis granted the Company a license to use specified antisense patents



and patent applications, principally Isis' suite of RNase H patents. The Company has the right under the Isis Agreement to use these patents and patent applications in its drug discovery and development efforts and in specified types of collaborations with third parties.

Prior to August 14, 2002, the Company interpreted its obligations under the Isis Agreement not to be inconsequential and perfunctory. As a result, for the three months ended March 31, 2002, the Company recognized revenue under the Isis Agreement, net of amortization of the Company's payments to Isis, over the 10-year term of the Isis Agreement expiring in 2011. On August 14, 2002, the Company and Isis entered into an amendment to the Isis Agreement. As part of the amendment, each party agreed to cancel the remaining tranche payments due to the other under the Isis Agreement. In addition, the Company and Isis agreed to more specifically define and limit each party's future collaborative obligations under the Isis Agreement. As a result of this amendment, the Company was able to specifically limit the nature of its obligation and related cost of compliance under the Isis Agreement. As a result, the Company determined that such amended obligation and cost will be inconsequential. In accordance with SAB101, the Company recognized all previously deferred revenue under the Isis Agreement at the time of the amendment. For the three months ended March 31, 2003, license fee revenue includes only sublicense income received from Isis.

(6) Stock-Based Compensation Related to Repriced Options

In September 1999, the Company's Board of Directors authorized the repricing of options to purchase 5,251,827 shares of common stock to \$0.50 per share, which represented the market value on the date of the repricing. These options are subject to variable plan accounting which requires the Company to remeasure the intrinsic value of the repriced options, through the earlier of the date of exercise, cancellation or expiration, at each reporting date. For the three months ended March 31, 2003, the Company recognized approximately \$6,000 as stock compensation expense from repriced options as a result of measuring the intrinsic value of these options at the date of exercise. The Company did not have a charge or credit for the first quarter of 2003 for changes in intrinsic value because the fair market value of its common stock at March 31, 2003 was the same as the fair market value of its common stock at December 31, 2002. For the three months ended March 31, 2002, the Company recognized a credit of approximately \$264,000 as stock compensation from repriced options as a result of a decrease in the intrinsic value of these options between December 31, 2001 and March 31, 2002.

(7) Income Taxes

In March 2002, the National Stabilization and Recovery Act temporarily rescinded the AMT with respect to the use of net operating loss carryforwards to offset current taxable income. As a result, the Company received a \$450,000 refund and recognized a \$500,000 tax benefit during the three months ended March 31, 2002.

(8) Series A Convertible Preferred Stock Dividend

The holders of Series A convertible preferred stock, as of March 15 or September 15, are entitled to receive dividends payable at the rate of 6.5% per annum, payable semi-annually in arrears. Such dividends shall accrue from the date of issuance of such shares and shall be paid semi-annually on April 1 and October 1 of each year. Such dividends shall be paid, at the election of the Company, either in cash or additional duly authorized, fully paid and non assessable shares of Series A convertible preferred stock. Through March 31, 2003, the Company has always elected to pay these dividends in stock. In calculating the number of shares to be paid with respect to each dividend, the Series A convertible preferred stock is valued at \$100.00 per share. During the three months ended March 31, 2003 and March 31, 2002, total Series A dividend accretion was approximately \$1,071,000 and \$1,040,000, respectively.

(9) Related Party Transactions

In the three months ended March 31, 2003, the Company paid Pillar S.A., which is controlled by a director of the Company, \$145,000 for consulting services relating to investor relations and the repurchase of the Company's common stock from certain stockholders.

(10) Stock Repurchase

On February 14, 2003, the Company repurchased 4,643,034 shares of its common stock at a price of \$1.15 per share from two Middle Eastern stockholders and their affiliates. The fair market value of the common stock was \$0.75 per share on the date of the transaction resulting in a premium of approximately \$1,857,000 in the aggregate. The Company charged this premium to general

and administrative expense in the three month period ended March 31, 2003. The repurchased stock was retired on March 13, 2003.

(11) Stock-Based Compensation

The Company applies the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. The Company continues to account for employee stock compensation at intrinsic value, in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations, with disclosure of the effects of fair value accounting on net income or net loss and related per share amounts on a pro forma basis.

The pro forma effect of applying SFAS No. 123 for the three months ended March 31, 2003 and 2002 would be as follows:

	March 31,	
	2003	2002
Net loss applicable to common stockholders, as reported	\$(6,318,837)	\$(1,816,118)
Less: stock-based compensation expense (income) included in reported net loss	5,871	(263,504)
Add: stock-based employee compensation expense determined under fair value based method for all awards	(284,035)	(379,316)
Pro forma net income (loss) applicable to common stockholders, as adjusted for the effect of applying SFAS No. 123	\$(6,597,001)	\$(2,458,938)
Basic and diluted net loss per common shares —		
As reported	\$ (0.14)	\$ (0.04)
Pro forma	\$ (0.14)	\$ (0.05)

The effects on the three months ended March 31, 2003 and 2002 pro forma net loss and net loss per share of expensing the estimated fair value of stock options are not necessarily representative of the effects on reported net income (loss) for the years ended December 31, 2003 and 2002 and future years because of the vesting periods of stock options and the potential for issuance of additional stock options in future periods.

## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **GENERAL**

We are a leading company in the discovery and development of novel therapeutics and diagnostics using synthetic DNA. Our activities are based on four technologies:

- Our immunomodulatory oligonucleotide, or IMO, technology uses synthetic DNA that contains specific sequences that mimic bacterial DNA to modulate responses of the immune system.
- Our antisense technology uses synthetic DNA to block the production of disease causing proteins at the cellular level.
- Our cancer therapy potentiation technology uses synthetic DNA to enhance the antitumor activity of certain marketed anticancer drugs and increase their effectiveness.
- Our Cyclicon technology uses novel synthetic DNA structures, which we refer to as Cyclicons, for identifying gene function in drug target validation and drug discovery.

Since we began operations in February 1990, we have been involved primarily in research and development and manufacturing. To date, almost all of our revenues have been from collaborative and license agreements, interest income and manufacturing of synthetic DNA and reagent products by our DNA manufacturing business, known as the Hybridon Specialty Products Division, or HSP, prior to our selling HSP in September 2000.

We have incurred total losses of \$267.5 million through March 31, 2003 and expect to incur substantial operating losses in the future. In order to commercialize our therapeutic products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements. In 2003, we expect that our research and development and general and administrative expenses will be similar in amount to those expenses in 2002, excluding for this purpose the \$2.2 million in direct and incremental expenses in general and administrative expense relating to the 2002 amendment to our agreement with Isis and the \$1.9 million charged to general and administrative expenses relating to the repurchase of shares of our common stock in February 2003, as we use our cash resources that we obtained in 2000 and 2001 to continue our discovery and development programs.

### **APPLICATION OF CRITICAL ACCOUNTING POLICIES**

This management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition. Management bases its estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2002. Not all of these significant accounting policies, however, require management to make difficult, complex or subjective judgments or estimates. We believe that our accounting policies relating to revenue recognition, as described under the caption "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies" in our Annual Report on Form 10-K for the year ended December 31, 2002, fit the definition of "critical accounting estimates and judgments."

### **RESULTS OF OPERATIONS**

#### ***Three Months Ended March 31, 2003 and 2002***

Total revenues decreased by \$469,000, or 53%, from \$887,000 for the three months ended March 31, 2002 to \$418,000 for the three months ended March 31, 2003. The decrease in revenues was primarily due to a reduction in license fee revenue. The first quarter of 2002 included a portion of the revenues that we received from Isis under the Isis Agreement. Prior to August 14, 2002, we recognized this revenue over the 10 year term of the Isis Agreement. As a result of an amendment to the Isis Agreement, on August 14, 2002, we recognized all previously deferred revenue under the Isis Agreement. The decrease in license fee revenue was partially offset by sublicense income received from Isis and revenue earned from milestones reached under other agreements in the three months ended March 31, 2003. The decrease in revenues for the three months ended March 31, 2003 also reflects decreased interest income from lower cash and investment balances as we used cash to fund our discovery and development programs.

Research and development expenses increased by \$1,160,000, or 93%, from \$1,246,000 to \$2,406,000 for the three months ended March 31, 2003 compared to the same period in 2002. The increase was primarily attributable to new trials of our lead IMO compound HYB2055, expanded trials of our lead 2<sup>nd</sup> generation antisense compound GEM 231 and increased staff and associated costs in our research and discovery departments. In the three months ended March 31, 2002, our research and development expenses related primarily to the preclinical development of our IMO technology.

Our two primary research and development projects relate to:

- HYB2055 is the lead product candidate in our IMO program. In the three months ended March 31, 2003, we incurred approximately \$0.5 million in direct expenses in connection with developing HYB2055. These direct expenses included costs of payments to independent contractors and vendors for preclinical studies, drug manufacturing and related costs and patent preparation costs and related filing fees and exclude internal costs such as payroll and overhead. The IND, we submitted to the FDA covering HYB2055 became effective on March 6, 2003. In March 2003, we commenced a phase 1 trial of HYB2055 in the United Kingdom in healthy volunteers. A phase 1 trial of HYB2055 in the United States in cancer patients has commenced during the second quarter of 2003.
- GEM231 is a 2nd generation antisense compound for the treatment of cancer. In the three months ended March 31, 2003, we incurred approximately \$0.1 million in direct expenses in connection with developing GEM231. These direct expenses included costs of payments to independent contractors and vendors for clinical studies, patent preparation costs and related filing fees and drug manufacturing and related costs and exclude internal costs such as payroll and overhead. We are currently conducting a phase 1/2 clinical trial of GEM231 as a combination therapy with Camptosar. We plan to commence a phase 2 trial using this drug combination in the second half of 2003 based upon pharmacokinetic analysis and other data obtained from the ongoing phase 1/2 trial.

Because these projects are in early stage of development and given the technological and regulatory hurdles likely to be encountered in the development and commercialization of our products, the future timing and costs of our various research and development programs are uncertain.

General and administrative expenses increased by \$2,082,000, or 182%, from \$1,142,000 in the three months ended March 31, 2002 to \$3,224,000 in the three months ended March 31, 2003. This increase primarily reflects the \$1,857,000 premium over fair market value that we paid in repurchasing shares of our common stock in the first quarter of 2003 and other consulting and professional fees related to the repurchase of our common stock. General and administrative expenses consist primarily of salary expense, consulting fees and professional legal fees associated with our regulatory filing requirements and business development and also consisted of the premium over fair market value that we paid to repurchase shares of our common stock during the three months ended March 31, 2003. Amortization of direct expenses associated with our agreement with Isis is also included in general and administrative expense for the three months ended March 31, 2002.

As a result of a repricing of our stock options in September 1999, certain outstanding stock options are subject to variable plan accounting. The portion of these repriced options that remained outstanding at March 31, 2003 had the same intrinsic value that it had at December 31, 2002 since the market value per share of our common stock was the same on those two dates. During the three months ended March 31, 2003, we recorded approximately \$6,000 of expense for repriced options exercised at times when the market value per share of our common stock was higher than its value at December 31, 2002. During the three months ended March 31, 2002, we credited operating results for \$264,000 representing a decrease in the intrinsic value of these options. This credit resulted from a decrease in the market value of the Company's common stock during the first quarter of 2002. Compensation charges and credits will likely occur in the future based upon changes in the market value of our common stock.

Interest expense decreased by approximately \$9,000, or 23%, from \$38,000 to \$29,000 for the three months ended March 31, 2003 compared to the same period in 2002. The decrease for the three months ended March 31, 2003 was primarily attributable to the repayment of the balance of our 8% notes that became due in the fourth quarter of 2002.

In March 2002, the National Economic Stabilization and Recovery Act temporarily rescinded the Alternative Minimum Tax (AMT) with respect to the use of net operating loss carryforwards to offset current taxable income. As a result, we received a \$450,000 refund from taxes paid in 2001 and recognized a tax benefit of \$500,000 for the three months ended March 31, 2002.

We pay dividends on our Series A convertible preferred stock of 6.5% per annum, payable semi-annually in arrears. We have the election to pay such dividends in either cash or additional duly authorized, fully paid and non assessable shares of Series A convertible preferred stock. Through March 31, 2003, such dividends had only been paid in the form of Series A convertible preferred stock. We recorded Series A preferred stock dividends of \$1,071,000 during the first quarter of 2003 and \$1,040,000 during the first quarter of 2002. Such dividends will continue to be incurred for as long as the Series A convertible preferred stock is outstanding.

As a result of the factors discussed above, our net loss applicable to common stockholders amounted to \$6,319,000 for the three months ended March 31, 2003 and \$1,816,000 for the three months ended March 31, 2002.

## **LIQUIDITY AND CAPITAL RESOURCES**

We require cash to fund our operating expenses, to make capital expenditures and to pay debt service. We expect that our cash requirements for these uses will be substantial and will increase as we expand our operations. Historically, we have funded our cash requirements primarily through the following:

- equity and debt financing;
- manufacturing of synthetic DNA and reagent products by HSP prior to its sale in 2000;
- the sale of HSP for which we received a total of \$15.0 million in 2000 and 2001;
- license fees and research funding under collaborative and license agreements;
- interest income;
- lease financings; and
- the sale of our shareholding in MethylGene Inc. for which we received a net of \$6.9 million in 2001.

As of March 31, 2003, we had approximately \$10.9 million in cash, cash equivalents and investments, a decrease of approximately \$9.2 million from December 31, 2002.

We used \$3.8 million of cash for operating activities during the three months ended March 31, 2003, principally to fund our research and development expenses and our general and administrative expenses. The \$3.8 million primarily represents our net operating loss for the period net of the premium over fair market value that we paid in repurchasing our shares of our common stock.

We sold approximately \$1.4 million in “available-for-sale” securities and received proceeds of approximately \$7.7 million from securities that matured in the three months ended March 31, 2003.

During the three months ended March 31, 2003, we utilized \$5.3 million of our cash to repurchase approximately 4.6 million shares of our common stock at a price of \$1.15 per share. Cash from other financing activities included proceeds from the exercise of stock options, which were offset by payments by us for leasing equipment.

As of March 31, 2003, our outstanding indebtedness consisted of \$1.3 million in principal amount of 9% notes maturing in April 2004. These notes are unsecured.

As of March 31, 2003, our contractual obligations were as follows:

Contractual Obligations	Payments Due by Period			
	Total	Less than 1 year	1-3 years	4-5 years
Debt	\$1,306,000	\$ —	\$1,306,000	\$ —
Lease Commitments	2,505,000	621,000	1,222,000	662,000
Employment Agreements	3,444,000	978,000	1,956,000	510,000
Consulting & Collaboration Agreements	156,000	145,000	11,000	—
<b>Total</b>	<b>\$7,411,000</b>	<b>\$1,744,000</b>	<b>\$4,495,000</b>	<b>\$1,172,000</b>

Based on our current operating plan, we believe that our existing cash and investments will be sufficient to fund our cash requirements at least through the end of 2003. Our actual cash requirements will depend on many factors, including particularly the scope and pace of our research and development efforts and our success in entering into strategic alliances.

We do not expect to generate significant additional funds internally until we successfully complete development and obtain marketing approval for products, either alone or in collaboration with third parties, which we expect will take many years. We expect to continue to seek additional external funds from collaborations with other biotechnology companies or pharmaceutical companies and from additional debt, equity and lease financings. We believe that the key factors that will affect our internal and external sources of cash are:

- the success of our clinical and preclinical development programs;
- the receptivity of the capital markets to financings by biotechnology companies; and
- our ability to enter into strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

We may not be successful in generating funds internally or from external sources. If we are unable to obtain additional extended funds in 2003, we may be required to delay, scale back or eliminate some or all of our research and development programs.

## FORWARD-LOOKING STATEMENTS

This quarterly 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. All statements, other than statements of historical facts, included or incorporated in this report regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “projects,” “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. In addition, any forward-looking statements represent our estimates only as of the date that this quarterly report is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

## RISK FACTORS

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. We believe that the material factors that we discuss below could cause or contribute to such material differences.

### Risks Relating to Our Business, Strategy and Industry

***If our clinical trials are unsuccessful, or if they are significantly delayed, we may not be able to develop and commercialize our products.***

In order to obtain regulatory approvals for the commercial sale of our products, we will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. In 2003, we commenced phase 1 clinical trials in the United Kingdom for HYB2055, our lead IMO compound, and we are currently conducting a phase 1/2 clinical trial of GEM231, our 2nd generation antisense compound for the treatment of cancer. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to complete these trials or commence and complete any other clinical trials.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. Furthermore, we, one of our collaborators, or a regulatory agency with jurisdiction over the trials, may suspend clinical trials at any time if the subjects or patients participating in such trials are being exposed to unacceptable health risks, or for other reasons. As an example, in 1997, after reviewing the results from the clinical trial of GEM91, our lead antisense compound at the time, we determined not to continue the development of GEM91 and suspended clinical trials of this product candidate.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. Patient accrual is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the nature of the study, the existence of competitive clinical trials and the availability of alternative treatments. Delays in planned patient enrollment may result in increased costs and prolonged clinical development.

We may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show our potential products to be both safe and efficacious. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

***We face substantial competition which may result in others discovering, developing or commercializing drugs before or more successfully than us.***

The biotechnology industry is highly competitive and characterized by rapid and significant technological change. We face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our technologies. Other of these organizations have developed and are marketing products, or are pursuing other technological approaches designed to produce products, that are competitive with our product candidates in the therapeutic effect these competitive products have on diseases targeted by our product candidates.

Many of our competitors are substantially larger than we are and have greater capital resources, research and development staffs and facilities than we have. In addition, many of our competitors are more experienced than we are in drug discovery, development and commercialization, obtaining regulatory approvals and drug manufacturing and marketing.

We anticipate that the competition with our products and technologies will be based on, among other things, product efficacy, safety, reliability, availability, price and patent position. The timing of market introduction of our products and competitive products will also affect competition among products. We also expect the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market to be an important competitive factor. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes and to secure sufficient capital resources for the period between technological conception and commercial sales.

***Because the products that we may develop will be based on new technologies and therapeutic approaches, the market may not be receptive to these products upon their introduction.***

The commercial success of any of our products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. Many of the products that we are developing are based upon new technologies or therapeutic approaches that are relatively new and unproven. As a result, it may be more difficult for us to achieve market acceptance of our products. Our efforts to educate the medical community on these potentially unique approaches may require greater resources than would be typically required for

products based on conventional technologies or therapeutic approaches. The safety, efficacy, convenience and cost-effectiveness of our products as compared to competitive products will also affect market acceptance.

***Competition for technical and management personnel is intense in our industry and we may not be able to sustain our operations or grow if we are unable to attract and retain key personnel.***

Our success is highly dependent on the retention of principal members of our technical and management staff, including Stephen Seiler and Sudhir Agrawal. Mr. Seiler, our Chief Executive Officer, has extensive experience in the pharmaceutical industry and as an investment banker and provides strategic leadership for us. The loss of Mr. Seiler's services would be detrimental to the execution of our strategic plan. Dr. Agrawal serves as our President and Chief Scientific Officer. Dr. Agrawal has made significant contributions to the field of nucleic acid chemistry and is named as an inventor on over 200 U.S. patents and patent applications. Dr. Agrawal provides the scientific leadership for our research and development activities and directly supervises our research staff. The loss of Dr. Agrawal's services would be detrimental to our ongoing scientific progress.

We are a party to employment agreements with each of Mr. Seiler and Dr. Agrawal, but each of these agreements may be terminated by us or the employee for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Mr. Seiler or Dr. Agrawal.

Furthermore, our future growth will require hiring a significant number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

### **Regulatory Risks**

***We may not be able to obtain marketing approval for products resulting from our development efforts.***

All of the products that we are developing will require additional research and development, extensive preclinical studies and/or clinical trials and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, and is expensive. Since our inception, we have conducted clinical trials of five compounds. In 1997, we determined not to continue clinical development of GEM91. The other four compounds are still in development. Currently, we are conducting clinical trials on two of these compounds, GEM231 and HYB2055.

We may need to address a number of technological challenges in order to complete development of our products. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

***If we fail to comply with the extensive regulatory requirements to which our products are subject, we could be subject to adverse consequences and penalties.***

The testing, manufacturing, labeling, advertising, promotion, export, and marketing, among other things, of our products are subject to extensive regulation by governmental authorities in Europe, the United States, and elsewhere throughout the world.

In general, there can be no assurance that submission of materials requesting permission to conduct clinical trials will result in authorization by the FDA or equivalent foreign regulatory agency to commence clinical trials, or that once clinical trials have begun, testing will be completed successfully within any specific time period, if at all, with respect to any of our products. Once trials are complete and an application for marketing approval has been submitted to the relevant regulatory agency, the regulatory agency may deny the application if applicable regulatory criteria are not satisfied, or may require additional testing or information.

If regulatory approval of a product is granted, such approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. As to any product for which we obtain marketing approval, the product, the facilities at which the product is manufactured, any post-approval clinical data and our promotional activities will be subject to continual review and periodic inspections by the FDA and other regulatory agencies.



Both before and after approval is obtained, violations of regulatory requirements may result in various adverse consequences, including the regulatory agency's delay in approving, or refusal to approve a product, suspension or withdrawal of an approved product from the market, operating restrictions, or the imposition of civil or criminal penalties.

***We have only limited experience in regulatory affairs and our products are based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.***

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals. Moreover, the products that result from our research and development programs will likely be based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional drugs. As a result, we may experience a longer regulatory process in connection with any product that we develop based on these new technologies or new therapeutic approaches.

### **Risks Relating to Our Financial Results and Need for Financing**

***We have incurred substantial losses and expect to continue to incur losses. We will not be successful unless we reverse this trend.***

We have incurred losses in every year since our inception. As of March 31, 2003, we had incurred operating losses of approximately \$267.5 million. We expect to continue to incur substantial operating losses in future periods. We have received no revenues from the sale of drugs. To date, almost all of our revenues have been from collaborative and license agreements, interest income and the sale of manufactured synthetic DNA and reagent products by HSP prior to our selling HSP in September 2000. We cannot be certain whether or when we will become profitable because of the significant uncertainties with respect to our ability to generate revenues from the sale of products and from any potential strategic alliances.

***We will need additional financing, which may be difficult to obtain. Our failure to obtain necessary financing or doing so on unattractive terms could adversely affect our discovery and development programs and other operations.***

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drugs. We will also require substantial funds to conduct regulatory activities and to establish commercial manufacturing, marketing and sales capabilities. Additional financing may not be available when we need it or may not be available on favorable terms.

We believe that, based on our current operating plan, our existing cash resources, after reflecting the stock repurchase, will be sufficient to fund our cash requirements at least through the end of 2003. If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail one or more of our discovery or development programs. For example, we significantly curtailed expenditures on our research and development programs during 1999 and 2000 because we did not have sufficient funds available to advance these programs at planned levels. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain of our technologies, drug candidates or drugs which we would otherwise pursue on our own.

If we raise additional funds by issuing equity securities, further dilution in our then existing stockholders will result. In addition, the terms of the financing may adversely affect the holdings or the rights of such stockholders.

### **Risks Relating to Collaborators**

***We need to establish collaborative relationships in order to succeed.***

An important element of our business plan is entering into collaborative relationships for the development and commercialization of products based on our discoveries. We face significant competition in seeking appropriate collaborators. Moreover, these arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish collaborative relationships or other alternative arrangements.

Reliance on collaborative relationships poses a number of risks, including the following:

- we cannot effectively control whether our collaborators will devote sufficient resources to our programs or products;
- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;

- disagreements with collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if one of these collaborators fails to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- collaborators have considerable discretion in electing whether to pursue the development of any additional drugs and may pursue technologies or products either on their own or in collaboration with our competitors; and
- collaborators with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products that they develop.

Given these risks, it is possible that any collaborative arrangements into which we enter may not be successful. Previous collaborative arrangements to which we were a party with F. Hoffmann-La Roche and G.D. Searle & Co. both were terminated prior to the development of any product. Failure of these efforts could delay our drug development or impair commercialization of our products.

### **Risks Relating to Intellectual Property**

***If we are unable to obtain patent protection for our discoveries, the value of our technology and products will be adversely affected. If we infringe patent or other intellectual property rights of third parties, we may not be able to develop and commercialize our products or the cost of doing so may increase.***

Our patent positions, and those of other drug discovery companies, are generally uncertain and involve complex legal, scientific and factual questions.

Our ability to develop and commercialize drugs depends in significant part on our ability to:

- obtain patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect trade secrets.

We do not know whether any of our patent applications or those patent applications which we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent, which could adversely affect our ability to protect future drug development and, consequently, our operating results and financial position.

***Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our development and commercialization costs, or prevent us from developing or marketing products.***

We may not have rights under some patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop, manufacture, sell or import certain of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third party patents issued in

the United States and abroad or those that might issue from United States and foreign patent applications. In such event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

***We may lose our rights to patents, patent applications or technologies of third parties if our licenses from these third parties are terminated.***

We are party to eleven royalty-bearing license agreements under which we have acquired rights to patents, patent applications and technology of third parties. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance and other obligations on us. Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2006 to 2021. If one or more of these licenses is terminated, we may be delayed in our efforts to develop and market the products that are covered by the applicable license or licenses.

***We may become involved in expensive patent litigation or other proceedings, which could result in our incurring substantial costs and expenses or substantial liability for damages or require us to stop our development and commercialization efforts.***

There has been substantial litigation and other proceedings regarding the patent and other intellectual property rights in the biotechnology industry. We may become a party to patent litigation or other proceedings regarding intellectual property rights. For instance, in the fourth quarter of 2002, we became involved in an interference declared by the United States Patent and Trademark Office involving a patent application exclusively licensed by us from University of Massachusetts Medical Center and three patents issued to the National Institutes of Health. The cost to us of any patent litigation or other proceeding, including the NIH interference, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

### **Risks Relating to Product Manufacturing, Marketing and Sales**

***We have no experience selling, marketing or distributing products and no internal capability to do so.***

If we receive regulatory approval to commence commercial sales of any of our products, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we have no experience. To market any of our products directly, we would need to develop a marketing and sales force with technical expertise and with supporting distribution capability. Alternatively, we could engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities or gain market acceptance for our products. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third parties and there can be no assurance that our efforts will succeed. If in the future we elect to perform sales, marketing and distribution functions for such types of products ourselves, we would face a number of additional risks, including the need to recruit a large number of additional experienced marketing and sales personnel.

***Because we have limited manufacturing experience, we will be dependent on third-party manufacturers to manufacture products for us or will be required to incur significant costs and devote significant efforts to establish our own manufacturing facilities and capabilities.***

We have limited manufacturing experience and no commercial scale manufacturing capabilities. In order to continue to develop our products, apply for regulatory approvals and commercialize products, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for preclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties to produce materials that may be required for the commercial production of our products.

There are a limited number of manufacturers that operate under the FDA's good manufacturing practices regulations capable of manufacturing our products. As a result, we may have difficulty finding manufacturers for our products with adequate capacity for our needs. If we are unable to arrange for third party manufacturing of our products on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us, the potential that third party manufacturers will develop know-how owned by such third party in connection with the production of our products that is necessary for the manufacture of our products and reliance upon third party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

***If we fail to obtain an adequate level of reimbursement for our products by third party payors, there may be no commercially viable markets for our products.***

The availability and levels of reimbursement by governmental and other third party payors such as health maintenance organizations, Medicaid, medical insurance companies, medical plan administrators, pharmacy benefit managers, physician and hospital alliances and other physician organizations affect the market for healthcare products. These third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. We may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system. Further proposals are likely. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain collaborators and market our products.

We expect to experience pricing pressures in connection with the sale of our drugs due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

***We face a risk of product liability claims and may not be able to obtain insurance.***

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing and marketing of human therapeutic drugs. Although we have product liability and clinical trial liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

### **Risks Relating to an Investment in Our Common Stock**

***Provisions in our charter documents, our rights agreement and provisions of Delaware law may prevent a change in control or management that stockholders may consider desirable.***

Section 203 of the Delaware General Corporation Law and our charter, by-laws and rights agreement contain provisions that might enable our management to resist a takeover of our company. These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

***Our common stock is considered a "penny stock" and may be difficult to sell.***

The SEC has adopted regulations which generally define “penny stock” to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. Presently, the market price of our common stock is substantially less than \$5.00 per share and therefore is designated as a “penny stock” according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of investors to sell their shares. In addition, since our common stock is traded on the OTC Bulletin Board, investors may find it difficult to obtain accurate quotations of our common stock.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Historically, our primary exposures have been related to nondollar-denominated operating expenses in Europe. As of March 31, 2003, we have no assets and liabilities related to nondollar denominated currencies.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operational needs and maximize yield. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We do not own derivative financial investment instruments in our investment portfolio.

### **ITEM 4. CONTROLS AND PROCEDURES**

Within the 90-day period prior to the filing of this Quarterly Report on Form 10-Q, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO and Chief Financial Officer, or CFO, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and are operating in an effective manner.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

**HYBRIDON, INC.**

**PART II**

**OTHER INFORMATION**

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

*(a) Exhibits*

The list of Exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by this reference.

*(b) Reports on Form 8-K*

On February 14, 2003, the Company filed a Current Report on Form 8-K with the Securities and Exchange Commission reporting that the Company had repurchased 4,643,034 shares of its common stock at a price of \$1.15 per share for an aggregate purchase price of \$5,339,489.

## SIGNATURES

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.

### HYBRIDON, INC

/s/ Stephen R. Seiler

Date: May 14, 2003

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Stephen R. Seiler  
Chief Executive Officer  
(Principal Executive Officer)

/s/ Robert G. Andersen

Date: May 14, 2003

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Robert G. Andersen  
Chief Financial Officer and Vice President of Operations  
(Principal Financial and Accounting Officer)

## CERTIFICATIONS

I, Stephen R. Seiler, certify that:

1. I have reviewed this quarterly report on Form 10-Q.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 14, 2003

/s/ Stephen R. Seiler

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Stephen R. Seiler  
Chief Executive Officer  
(Principal Executive Officer)

I, Robert G. Andersen, certify that:

1. I have reviewed this quarterly report on Form 10-Q.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 14, 2003

/s/ Robert G. Andersen

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Robert G. Andersen  
Chief Financial Officer and  
Vice President of Operations  
(Principal Financial and Accounting Officer)



## Exhibit Index

<b>Exhibit No.</b>	
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|------|---|
| 99.1 | Certification Pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 99.2 | Certification Pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |