

HYBRIDON INC  
Form 10-Q/A  
May 15, 2003

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q/A**

**AMENDMENT NO. 1**

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

For the quarterly period ended September 30, 2002, or

**o**            **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 **x**

No **o**

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**

**47,532,283**

Class

Outstanding as of October 15, 2002



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This quarterly report on Form 10-Q/A references the following U.S. trademarks owned by us: Hybridon®, GEM®, Cyclicon , and IMO . This quarterly report on Form 10-Q/A also contains trademarks of other companies.

This Amendment No. 1 on Form 10-Q/A amends and restates Part I, Item 1 - Financial Statements and Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations of the Quarterly Report on Form 10-Q filed by Hybridon, Inc. on October 24, 2002 for the quarter ended September 30, 2002. These items are being amended and restated solely in order to reclassify certain direct and incremental costs related to the collaboration and license agreement, as amended, between Hybridon and Isis Pharmaceuticals, Inc. dated May 24, 2001 from License fees revenues to General and administrative expenses in the accompanying Consolidated Condensed Statements of Operations and Management's Discussion and Analysis of Financial Condition and Results of Operations. As a result of the reclassification, Hybridon's License fees revenues and General and administrative expenses each increased by \$2.1 million for the three month period ended September 30, 2002, \$2.2 million for the nine month period ended September 30, 2002, \$58,000 for the three month period ended September 30, 2001 and \$97,000 for the nine month period ended September 30, 2001. Prior to the reclassification, Hybridon had offset these direct and incremental costs against revenues.

**Table of Contents****PART I FINANCIAL STATEMENTS****ITEM 1 FINANCIAL STATEMENTS****HYBRIDON, INC. AND SUBSIDIARIES****CONSOLIDATED CONDENSED BALANCE SHEETS  
(UNAUDITED)**

	September 30, 2002	December 31, 2001
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,339,376	\$ 20,923,295
Short-term investments	17,786,454	10,910,987
Receivables	551,258	274,863
Prepaid expenses and other current assets	194,504	56,992
	<hr/>	<hr/>
Total current assets	24,871,592	32,166,137
Property and equipment, net	508,983	143,298
Deposits	15,199	
	<hr/>	<hr/>
	\$ 25,395,774	\$ 32,309,435
	<hr/>	<hr/>
<b>Liabilities and Stockholders Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,108,145	\$ 498,642
Accrued expenses	1,046,361	1,021,660
Current portion of long-term debt	299,549	288,028
Current portion of capital lease	66,049	
Current portion of deferred revenue	463,762	3,098,654
	<hr/>	<hr/>
Total current liabilities	2,983,866	4,906,984
9% convertible subordinated notes payable	1,306,000	1,306,000
Deferred revenue, net of current portion	373,944	26,129,725
Stockholders' equity (deficit):		
Preferred stock, \$0.01 par value Authorized 5,000,000 shares		
Series A convertible preferred stock Designated 1,500,000 shares		
Issued and outstanding 660,385 and 640,166 shares at		
September 30, 2002 and December 31, 2001, respectively	6,603	6,402
Common stock, \$0.001 par value Authorized 150,000,000 shares		
Issued and outstanding 47,531,083 and 45,632,525 shares at		
September 30, 2002 and December 31, 2001, respectively	47,531	45,632
Additional paid-in capital	277,547,265	273,870,458
Accumulated other comprehensive loss	(3,270)	
Accumulated deficit	(256,819,547)	(273,868,184)
Deferred compensation	(46,618)	(87,582)
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Total stockholders' equity (deficit)	20,731,964	(33,274)
	<hr/>	<hr/>
	\$ 25,395,774	\$ 32,309,435



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



**Table of Contents****HYBRIDON, INC. AND SUBSIDIARIES****CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS  
(UNAUDITED)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
<b>Revenues:</b>				
License fees	\$28,159,099	\$ 204,816	\$29,517,824	\$ 498,297
Collaborative research	10,375		10,375	
Royalty and other income	6,719	7,198	38,012	64,726
Interest income	156,184	189,549	530,163	429,392
	<u>28,332,377</u>	<u>401,563</u>	<u>30,096,374</u>	<u>992,415</u>
<b>Operating expenses:</b>				
Research and development	2,793,915	1,080,186	5,607,649	3,440,251
General and administrative	3,350,911	1,580,901	5,834,913	4,219,494
Stock-based compensation from repriced options (1)	(438,055)	(576,583)	(1,182,122)	347,197
Interest	38,263	514,451	114,559	1,101,603
	<u>5,745,034</u>	<u>2,598,955</u>	<u>10,374,999</u>	<u>9,108,545</u>
Gain (loss) on sale of securities, net		(1,171,482)		5,718,779
	<u>22,587,343</u>	<u>(3,368,874)</u>	<u>19,721,375</u>	<u>(2,397,351)</u>
Income (loss) from continuing operations				
Gain from sale of discontinued operations		1,967,830		1,967,830
	<u>22,587,343</u>	<u>(1,401,044)</u>	<u>19,721,375</u>	<u>(429,521)</u>
Income (loss) before provision for income taxes and extraordinary item				
Income tax credit (provision)			500,000	(400,000)
	<u>22,587,343</u>	<u>(1,401,044)</u>	<u>20,221,375</u>	<u>(829,521)</u>
Income (loss) before extraordinary item				
Extraordinary item:				
Loss on early retirement of 8% convertible notes payable				(1,411,876)
	<u>22,587,343</u>	<u>(1,401,044)</u>	<u>20,221,375</u>	<u>(2,241,397)</u>
Net income (loss)				
Accretion of preferred stock dividends	(1,073,544)	(5,112,651)	(3,172,738)	(7,301,684)
	<u>\$21,513,799</u>	<u>\$ (6,513,695)</u>	<u>\$17,048,637</u>	<u>\$ (9,543,081)</u>
<b>Net income (loss) per share applicable to common stockholders (Note 4):</b>				
Basic	\$ 0.45	\$ (0.16)	\$ 0.37	\$ (0.37)
Diluted	\$ 0.34	\$ (0.16)	\$ 0.29	\$ (0.37)
<b>Shares used in computing net income (loss) per common share:</b>				
Basic	47,526,698	40,210,595	46,634,914	25,853,087



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Diluted	66,950,448	40,210,595	69,015,210	25,853,087
(1) The following summarizes the allocation of stock-based compensation from repriced options:				
Research and development	\$ (324,478)	\$ (318,643)	\$ (837,334)	\$ 290,534
General and administrative	(113,577)	(257,940)	(344,788)	56,663
Total	\$ (438,055)	\$ (576,583)	\$ (1,182,122)	\$ 347,197

**Table of Contents****HYBRIDON, INC. AND SUBSIDIARIES****CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS  
(UNAUDITED)**

	Nine Months Ended September 30,	
	2002	2001
<b>Cash Flows From Operating Activities:</b>		
Net income (loss)	\$ 20,221,375	\$ (2,241,397)
Gain from sale of discontinued operations		1,967,830
	<u>20,221,375</u>	<u>(4,209,227)</u>
Income (loss) from continuing operations, including extraordinary item	20,221,375	(4,209,227)
Adjustments to reconcile net loss to net cash used in operating activities		
Extraordinary loss on exchange of 8% convertible notes payable		1,411,876
Issuance of warrants for services rendered	74,000	
Issuance of common stock for services rendered		26,000
Gain on sale of property and equipment		(45,650)
Stock-based compensation	(1,182,122)	347,197
Depreciation and amortization	437,323	471,261
Non-cash interest expense	11,737	497,228
Changes in operating assets and liabilities		
Accounts receivable	(276,395)	(889,183)
Prepaid expenses and other assets	(152,711)	71,616
Accounts payable and accrued expenses	996,549	(227,825)
Forward contracts		971,482
Deferred revenue	(27,586,855)	14,667,360
	<u>(7,457,099)</u>	<u>13,092,135</u>
Net cash (used in) provided by operating activities	(7,457,099)	13,092,135
		<u>3,000,000</u>
<b>Cash Flows From Investing Activities:</b>		
Maturities of short-term investments	4,795,000	
Purchase of available-for-sale securities	(470,889)	
Purchase of marketable securities	(14,582,249)	(7,794,049)
Sale of marketable securities	3,047,724	
Purchase of property and equipment	(310,917)	(71,525)
Proceeds from sale of property and equipment		45,650
	<u>(7,521,331)</u>	<u>(7,819,924)</u>
Net cash used in investing activities	(7,521,331)	(7,819,924)
<b>Cash Flows From Financing Activities:</b>		
Proceeds from exercise of common stock options and sale of common stock	441,765	637,918
Principal payments on capital leases	(47,254)	
Payments on long-term debt		(6,000,000)
Decrease in restricted cash		4,000,000
	<u>394,511</u>	<u>(1,362,082)</u>
Net cash provided by (used in) financing activities	394,511	(1,362,082)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(14,583,919)</b>	<b>6,910,129</b>

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Cash and cash equivalents, beginning of period	20,923,295	1,532,155
<b>Cash and cash equivalents, end of period</b>	<b>\$ 6,339,376</b>	<b>\$ 8,442,284</b>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 58,770	\$ 360,525
Supplemental disclosure of non cash financing and investing activities:		
Exchange of 8% convertible notes payable for Series B convertible preferred stock and common stock	\$	\$ 7,944,801
Dividend from induced conversion of Series B convertible preferred stock	\$	\$ 4,100,000
Accretion of Series A and B convertible preferred stock dividends	\$ 3,172,738	\$ 3,201,684
Issuance of common stock in lieu of cash bonus	\$	\$ 88,577
Conversion of Series A preferred stock into common stock	\$ 258	\$ 613
Conversion of Series B preferred stock into common stock	\$	\$ 19,565
Issuance of stock options to non-employees	\$	\$ 20,148
Issuance of warrants in connection with consulting services	\$	\$ 569,667
Issuance of common stock as part of license agreement	\$ 1,166,379	\$
Equipment acquired under capital lease	\$ 113,303	\$

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**HYBRIDON, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS  
(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: immunomodulatory oligonucleotide (IMO) technology, which uses synthetic DNA to modulate responses of the immune system; antisense technology, which uses synthetic DNA to inhibit the production of disease-associated proteins at the cellular level; cancer therapy potentiation, which uses synthetic DNA to enhance the antitumor activity of certain marketed anticancer drugs; and Cyclicon technology, which uses novel synthetic DNA structures in drug target validation and drug discovery.

**(2) Unaudited Interim Financial Statements**

The accompanying unaudited consolidated condensed financial statements included herein have been prepared by the Company 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 and nine month periods ended September 30, 2002 are not necessarily indicative of results that may be expected for the year ended December 31, 2002. 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, 2001, which was filed with the Securities and Exchange Commission on April 1, 2002.

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

On August 14, 2002, the Company and Isis Pharmaceuticals, Inc. entered into an amendment to the Collaboration and License Agreement (the Agreement) between them dated May 24, 2001. As part of the amendment, each party agreed to cancel the remaining tranche payments due to each other under the Agreement. In addition, as part of the amendment, the Company and Isis agreed to more specifically define and limit each party's future collaborative obligations under the Agreement.

As a result of this amendment, the Company has been able to better estimate the nature of its obligation and related cost of compliance under the Agreement and has determined that such amended obligation and cost will be inconsequential. In accordance with SAB101, the Company has recognized amounts previously deferred as revenue under the original Agreement which obligated the Company to potentially engage in future activities which could have a material related cost. Revenue for the three and nine months ended September 30, 2002 includes the net of the previously unrecognized portion of the \$32.3 million of cash and Isis stock received by the Company in 2001 and the previously unrecognized portion of the \$1.9 million in cash and Company stock paid to Isis by the Company in May 2002. Prior to the amendment, the Company interpreted its obligations under the Agreement not to be inconsequential and perfunctory. As a result, for the three and nine months ended September 30, 2001, the Company recognized revenue over the 10-year term of the Agreement expiring in 2011. The Company recognized net revenues under the Agreement of approximately \$28.1 million and \$0.2 million for the three months ended September 30, 2002 and 2001, respectively, and \$29.5 million and \$0.4 million for the nine months ended September 30, 2002 and 2001, respectively.

Under the terms of EITF 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services and EITF 00-8 Accounting by a Grantee for an Equity Instrument to Be Received in Conjunction with Providing Goods or Services, the shares of common stock received from Isis under the Agreement were measured at the time of receipt. As of September 30, 2001, 357,143 shares of common stock had been issued by Isis. The Company recorded the fair value of the common stock of approximately \$6,289,000 on the date the shares became receivable to the Company.

Following the receipt of these shares, on September 10, 2001 the Company entered into a number of hedging contracts to protect against certain market risks which could reduce the value of the Isis shares while the Company was awaiting registration of the shares. In accordance with SFAS No. 133, Accounting for Hedging Instruments and Hedging Activities, these hedging contracts are derivative instruments and must be marked to fair market value with the corresponding charges recognized in earnings. The Company accrued an unrealized loss of approximately \$971,000 related to this agreement. Approximately \$702,000 of this unrealized loss is offset by a corresponding \$702,000 gain which arose from marking the stock to market. The remaining \$269,000 loss is due to the fee incurred upon execution of the forward contracts which is included in the consolidated statement of operations with an additional loss on the investment of approximately \$902,000 that was recorded prior to entering the hedging contracts.



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Additional information on the Agreement is included in Note (5) to the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2001.

**(4) Net Income (Loss) per Common Share**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
<b>Numerator:</b>				
Income (loss) from continuing operations	\$ 22,587,343	\$ (3,368,874)	\$ 20,221,375	\$ (2,797,351)
Gain on sale of discontinued operations		1,967,830		1,967,830
Extraordinary loss on exchange of 8% convertible note payable				(1,411,876)
Net income (loss)	22,587,343	(1,401,044)	20,221,375	(2,241,397)
Accretion of preferred stock dividends	(1,073,544)	(5,112,651)	(3,172,738)	(7,301,684)
Numerator for basic income (loss) applicable to common shareholders	21,513,799	(6,513,695)	17,048,637	(9,543,081)
Effect of dilutive securities:				
Dividends on Series A convertible preferred stock	1,073,544		3,172,738	
Interest expense related to convertible debt	5,991		17,742	
Numerator for diluted income (loss) applicable to common shareholders	\$ 22,593,334	\$ (6,513,695)	\$ 20,239,117	\$ (9,543,081)
<b>Denominator for basic income (loss) per share:</b>				
Weighted average common stock outstanding	47,526,698	40,210,595	46,634,914	25,853,087
Effect of dilutive securities:				
Common stock options and warrants	3,386,030		6,506,952	
Convertible debt	499,249		492,848	
Series A convertible preferred stock	15,538,471		15,380,496	
Denominator for diluted income (loss) per share	66,950,448	40,210,595	69,015,210	25,853,087
<b>Income (loss) per share- basic</b>				
Income (loss) from continuing operations	\$ 0.47	\$ (0.08)	\$ 0.44	\$ (0.11)
Income from discontinued operations		0.05		0.08
Extraordinary loss				(0.06)
Net income (loss) per share	0.47	(0.03)	0.44	(0.09)
Accretion of preferred stock dividends	(0.02)	(0.13)	(0.07)	(0.28)
Net income (loss) per share applicable to common stockholders	\$ 0.45	\$ (0.16)	\$ 0.37	\$ (0.37)
<b>Income (loss) per share- diluted</b>				
Income (loss) from continuing operations	\$ 0.34	\$ (0.08)	\$ 0.29	\$ (0.11)
Income from discontinued operations		0.05		0.08
Extraordinary loss				(0.06)

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Net income (loss) per share	0.34	(0.03)	0.29	(0.09)
Accretion of preferred stock dividends		(0.13)		(0.28)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Net income (loss) per share applicable to common stockholders	\$ 0.34	\$ (0.16)	\$ 0.29	\$ (0.37)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

Basic net income (loss) per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three and nine months ended September 30, 2001, diluted net loss per share from continuing operations 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 36,111,489 for the three and nine months ended September 30, 2001. Antidilutive securities

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include stock options, warrants, convertible preferred stock and convertible debt instruments (on an as-converted basis).

**(5) 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 September 30, 2002 and December 31, 2001 consist of the following:

	September 30 2002	December 31 2001
Cash and cash equivalents		
Cash and money market funds	\$ 3,839,376	\$ 20,923,295
Corporate bonds	2,500,000	
	<u>                    </u>	<u>                    </u>
Total	\$ 6,339,376	\$ 20,923,295

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. 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, which approximates fair market value and investments that the Company does not have the positive intent to hold to maturity or trade in the near future are classified as available-for-sale and reported at fair market value. Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. As of September 30, 2002, \$17,318,837 and \$467,617 of the Company's short-term investments are classified as held-to-maturity and available-for-sale, respectively. All of the Company's short-term investments as of December 31, 2001 are classified as held-to-maturity.

Short-term investments have maturities of greater than three months from purchase and mature within one year of the balance sheet date. All short-term investments mature prior to September 30, 2003. At September 30, 2002 and December 31, 2001, the Company's short-term investments consisted of the following:

	September 30 2002	December 31 2001
Short-term investments		
Held-to-maturity:		
Government bonds	\$ 12,112,765	\$ 8,928,847
Corporate bonds	5,206,072	1,982,140
Available-for-sale corporate bonds	467,617	
	<u>                    </u>	<u>                    </u>
Total	\$ 17,786,454	\$ 10,910,987

**(6) Stock-Based Compensation**

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 difference between the repriced amount of \$0.50 and the current market value of the common stock to determine the intrinsic value of the repriced options through the earlier of the date of exercise, cancellation or expiration, at each reporting date. A decrease in the intrinsic value of these options between June 30, 2001 and September 30, 2001 resulted in the credit of \$577,000 to stock compensation for the three months ended September 30, 2001. A further decrease in the intrinsic value of these options between January 1, 2002 and September 30, 2002 resulted in additional credits of \$438,000 and \$1,182,000 to stock compensation from these repriced options for the three and nine months ended September 30, 2002. Compensation expense of approximately \$347,000 for the nine months ended September 30, 2001 resulted from an increase in the intrinsic value of these options between January 1, 2001 and September 30, 2001.



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In 2000, the Company completed the sale of its Hybridon Specialty Products business to a subsidiary of Avecia, Inc. of Manchester, United Kingdom, Avecia Biotechnology, for up to \$15.0 million. The Company received approximately \$12.0 million of the \$15.0 million from the sale of HSP to Avecia in 2000. The remaining \$3.0 million was payable on September 21, 2001, subject to offset rights under the agreement to purchase HSP. As part of this transaction, the Company entered into a supply agreement whereby it may have an obligation to purchase products from Avecia Biotechnology. To the extent that Avecia Biotechnology's third-party sales of HSP product exceeded certain goals, the Company did not have any such purchase commitment. If Avecia Biotechnology's third party sales did not meet such goals, the Company was required to make purchases sufficient to cover the shortfall, subject to an agreed upon formula. The Company's commitment was on a take-or-pay basis for the fourth quarter of 2000 and each quarter of 2001. Purchases by OriGenix Technologies, Inc. and MethylGene were applied against the Company's commitment. Any unpaid amounts under this agreement would reduce the \$3.0 million contingent payment received in September 2001. The balance of the term of this agreement (through March 31, 2003) does not require minimum purchases.

To the extent that the Company made payments for a purchasing shortfall where it had no use for the related products, the Company recorded such amount as an offset against the gain recorded upon receipt of the additional \$3.0 million payment in September 2001. On June 30, 2001, the Company had accrued approximately \$1,032,000 for its purchasing shortfall. Upon receipt of the \$3.0 million payment in September 2001, the Company applied approximately \$1,032,000 toward the satisfaction of its purchasing shortfall and recognized the remaining \$1,968,000 as a gain from the sale of discontinued operations in the three and nine months ended September 30, 2001.

**(8) Income Taxes**

For the nine months ended September 30, 2001, a provision for income taxes of \$400,000 for Alternative Minimum Tax (AMT) was recorded. During 2001, the Company had a total provision for income taxes of \$500,000 for AMT and paid \$450,000. In March 2002, passage of 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 recognized a \$500,000 tax benefit in operating results and received a refund of \$450,000 during the nine months ended September 30, 2002. There is no income tax provision in the three and nine months ended September 30, 2002 since the licensing revenues recognized in 2002 were included on the Company's 2001 income tax return at which time it was offset by net operating loss (NOL) carryforwards.

**(9) 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 September 30, 2002, the Company has always chosen 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 September 30, 2002 and 2001, total Series A dividend accretion was approximately \$1,074,000 and \$1,008,000, respectively. During the nine months ended September 30, 2002 and 2001, total Series A dividend accretion was approximately \$3,173,000 and \$3,012,000, respectively.

**(10) 8% Convertible Notes Payable**

On March 5, 2001, the Company made an offer to the holders of its 8% Convertible Notes Payable (the 8% Notes) to exchange their notes in a ratio of one share of a newly-designated class of Series B convertible preferred stock for each \$100 in principal and interest of notes tendered. On March 30, 2001 holders of 8% Notes in the aggregate original principal amount of \$7,354,000 exchanged their notes for 76,046 shares of Series B convertible preferred stock. The Company recorded an extraordinary loss of \$1.4 million related to the early extinguishment of the 8% Notes in the nine months ended September 30, 2001. The extraordinary loss represents the difference between the carrying value of the 8% Notes and the fair value of the Series B convertible preferred stock, as determined by the fair market value of the common stock into which the Series B convertible preferred stock was convertible and the write-off of deferred financing costs and related legal fees.

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**(11) Sale of MethylGene Inc. Shares**

On April 27, 2001, the Company closed the sale of 60% of its holding of shares of Class A and Class B stock of MethylGene Inc., to a group of private institutional investors located in the United States. MethylGene is a Canadian pharmaceutical research company in which the Company had a 22% ownership interest. On May 14, 2001, the Company closed the sale of the remaining 40% of its holding with three of MethylGene's other shareholders on terms similar to those agreed to by the institutional investors (\$2.85 Canadian or approximately \$1.84 US per share as of April 27, 2001). The Company received total proceeds of approximately \$7.2 million (US). During the nine months ended September 30, 2001, the Company recorded a gain for this transaction of approximately \$6.9 million, net of approximately \$300,000 in professional fees.

**(12) Early Exercise Program**

In June 2001, the Company began an early exercise program (the Early Exercise Program) to exchange its common stock for its Series B convertible preferred stock, several classes of its warrants and its remaining 8% Notes, in order to simplify the Company's capital structure and to reduce the number of outstanding securities which are exercisable for or convertible into shares of its common stock. At the completion of the Early Exercise Program in 2001, the results were as follows:

All holders of the Company's Series B convertible preferred stock exchanged their shares for 19,564,500 shares of the Company's common stock;

Holders of warrants priced between \$0.60 and \$2.40 exchanged their warrants for 4,669,808 shares of the Company's common stock; and Holders of 8% Notes, representing \$456,221 in principal and interest exchanged their 8% Notes for 1,140,448 shares of the Company's common stock.

**(13) Stockholders' Equity**

On June 19, 2002, at the Annual Meeting of the Company's stockholders, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation increasing the number of authorized shares of the Company's Common Stock from 100,000,000 shares to 150,000,000 shares.

**(14) OriGenix Technologies, Inc.**

OriGenix, a Quebec company, was formed in January 1999 by a group of institutional investors and the Company. As part of the formation of OriGenix, the Company licensed to OriGenix specific antisense compounds and other technologies. The Company originally had a 49% interest in OriGenix which it received in exchange for the license of compounds and technologies. The Company's interest was subsequently reduced to 28% upon the raising of additional funds by OriGenix. The Company accounted for its investment in OriGenix under the equity method and had reduced its investment to zero at December 31, 2001. In August 2002, OriGenix filed for bankruptcy in Canada. Upon such filings, the licensing agreement was terminated in accordance with its terms. The Company subsequently licensed the technology it had originally licensed to OriGenix to Micrologix Biotech, Inc. as part of a collaboration with Micrologix. See note 17 below.

**(15) Employee Stock Purchase Plan**

On September 1, 2002, the Company implemented its 1995 Employee Stock Purchase Plan (the Purchase Plan). Under the Purchase Plan, up to 100,000 shares of the Company's common stock may be issued to participating employees. Eligible employees may authorize an amount (a whole percentage from 1% to 10% of such employee's regular pay) to be deducted by the Company from their pay during the offering period. At the end of an offering period, participants may purchase common stock at a price equal to 85% of the lower of the fair market value per share on the first or last day of an offering period, whichever is lower. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant.

**(16) Collaboration and License Agreement with Aegera Therapeutics Inc.**

On September 13, 2002, the Company and Aegera Therapeutics Inc. entered into a Collaboration and License Agreement (the Collaboration) to research, develop, and optimize a second generation antisense drug targeted to the XIAP gene, which has been implicated in the resistance of cancer cells to chemotherapy. In addition, Hybridon licensed to Aegera, on a non-exclusive basis, rights to

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the Company's portfolio of second-generation antisense chemistries and oral antisense delivery intellectual property owned or licensed by the Company. In consideration for research, development and optimization work to be performed by the Company under the Collaboration and the license of technology by the Company, Aegera paid the Company a license and research fee. In addition, Aegera agreed to pay the Company additional research payments, milestone payments upon the achievement of specified milestones, and royalties on product sales and sublicensing, if earned. Future anticipated payments under the Collaboration could total approximately \$8.0 million if all of the milestones are achieved. Aegera will be responsible for the development costs of the drug candidate.

**(17) Collaboration and License Agreement with Micrologix Biotech Inc.**

On September 11, 2002, the Company and Micrologix Biotech Inc. entered into a Collaboration and License Agreement to develop an antisense drug candidate for the treatment of human papilloma virus (HPV). Hybridon licensed Micrologix the exclusive worldwide rights to a family of patents covering a number of antisense oligonucleotides targeted to the HPV genome and non-exclusive rights to a portfolio of antisense chemistries owned or licensed by the Company. In consideration, Micrologix agreed to pay the Company a license fee, milestone payments upon the achievement of specified milestones, and royalties on product sales and sublicensing, if earned. The total license fee and milestone payments could total approximately \$6.0 million, if all the milestones are achieved. The Micrologix collaboration and license agreement contemplates that the Company and Micrologix will enter into a stock purchase agreement relating to the payment of milestone payments under which Micrologix will issue to the Company without further consideration shares of preferred stock of Micrologix. Upon the achievement of a milestone, a portion of the shares of preferred stock would, at the option of Micrologix, either (i) be converted into common stock of Micrologix at a conversion rate based on an average market price or (ii) be redeemed by Micrologix for a cash amount equal to the milestone. In a separate transaction with OriGenix Technologies, Inc., Micrologix purchased certain clinical and pre-clinical data and other rights to ORI 1001, a drug candidate formerly under development by OriGenix. ORI 1001 was initially discovered by the Company and is in Phase I clinical study for the treatment of diseases associated with HPV. Micrologix will assume responsibility for development costs of ORI 1001.

**(18) Related Party Transactions**

In the three and nine months ended September 30, 2002, the Company paid Pillar S.A., which is controlled by a director of the Company, \$30,000 for consulting services relating to establishing new alliances. The \$30,000 paid to Pillar is included under general and administrative expenses for the three and nine months ended September 30, 2002. Effective October 1, 2002, the Company entered into a new consulting agreement with Pillar S.A. Under the consulting agreement, Pillar S.A. will provide the Company with international investor relations services in exchange for payment of \$60,000 plus expenses, which is payable in installments of \$15,000 per month through January 31, 2003.

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**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:

immunomodulatory oligonucleotide, or IMO, technology, which uses synthetic DNA to modulate responses of the immune system;

antisense technology, which uses synthetic DNA to inhibit the production of disease-associated proteins at the cellular level;

cancer therapy potentiation, which uses synthetic DNA to enhance the antitumor activity of certain marketed anticancer drugs; and

Cyclicon technology, which uses novel synthetic DNA structures 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 \$256.8 million through September 30, 2002 and expect to incur substantial operating losses in the future. In order to commercialize our products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements. We expect that our research and development and general and administrative expenses will be significant in 2002 and 2003 as we use our cash resources to advance more rapidly our discovery and development programs.

**CRITICAL ACCOUNTING POLICIES**

This management's discussion and analysis of financial condition and results of operations presents 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 on-going 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 are believed 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.

We believe the most critical accounting policy affecting the portrayal of our financial condition is revenue recognition. We recognize revenue in accordance with SEC Staff Accounting Bulletin (SAB) No. 101. SAB 101 requires that four basic criteria be met before revenue can be recognized:

persuasive evidence of an arrangement exists;

delivery has occurred, services have been rendered or obligations have been satisfied;

the fee is fixed and determinable; and

collectibility is reasonably assured.

Determination of the last three criteria is based on management's judgments regarding the fixed nature of the fee charged for services rendered or products delivered and the collectibility of these fees. Should changes in conditions cause management to determine these criteria are not met for any future transactions, revenues recognized for any reporting period could be adversely affected.

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During 2001, we received a total of \$32.3 million in cash and stock under our collaboration and license agreement (the Agreement) with Isis Pharmaceuticals, Inc. This amount is non-refundable. Previously, we recognized the revenue related to the Agreement on a straight-line basis over the 10-year term of the Agreement, which expires in 2011. This deferral of revenue recognition was based on a continuing obligation contained in the Agreement which was interpreted as neither inconsequential nor perfunctory according to SAB 101. Direct expenses and cash and stock due to Isis were also recognized on a straight-line basis over the 10-year term of the Agreement. In May 2002, we paid Isis \$0.7 million in cash and issued to Isis 1,005,499 shares of our common stock having a fair market value of \$1.2 million on the date of issuance. In August 2002, we entered into an amendment to the Agreement that cancelled the remaining tranche payments due to each other under the Agreement and specifically defined and limited each party's future obligations under the Agreement. As a result of this amendment, we were better able to estimate the nature of our obligations under the Agreement and related cost of compliance and determined that, as amended, the obligations are inconsequential. In accordance with SAB 101, we have recognized the amounts previously deferred under the original Agreement as revenue during the third quarter of 2002.

Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2001 contains a full description of all our significant accounting policies.

**RESULTS OF OPERATIONS**

*Three and Nine Months Ended September 30, 2002 and 2001*

Total revenues increased by \$27,931,000, or 6,956% to \$28,332,000 for the three months ended September 30, 2002 from \$402,000 for the three months ended September 30, 2001 and increased by \$29,104,000, or 2,933%, to \$30,096,000 for the nine months ended September 30, 2002 from \$92,000 for the nine months ended September 30, 2001. The increase in revenues was primarily due to the one-time recognition of previously deferred license fee revenues derived from our Collaboration and License Agreement with Isis Pharmaceuticals, Inc. In connection with this Agreement, we recorded \$28,145,000 in license fee revenue, which is net of the unrecognized portion of the cash and our stock paid to Isis by us, in the three months ended September 30, 2002 and \$29,483,000 in net license fee revenue for the nine months ended September 30, 2002. No additional tranche payments are due from Isis under the Agreement.

Research and development expenses increased by \$1,714,000, or 159%, to \$2,794,000 for the three months ended September 30, 2002 from \$1,080,000 for the three months ended September 30, 2001 and by \$2,167,000, or 63%, to \$5,607,000 for the nine months ended September 30, 2002 from \$3,440,000 for the nine months ended September 30, 2001. The increase in both periods was attributable to expansion of our IMO technology development efforts, preclinical studies in preparation for a filing of an Investigational New Drug (IND) application for the lead pre-clinical candidate, HYB 2055, manufacturing of HYB 2055 for these preclinical studies, and manufacturing of our second generation antisense compound, GEM 231, for expanded Phase I/II clinical trials.

In the three and nine months ended September 30, 2002 and 2001, our research and development expenses related primarily to the preclinical development of our IMO technology, including the development of HYB 2055. We will continue to incur costs in developing our IMO technology and in continuing preclinical studies of HYB 2055. We expect to submit an IND for HYB 2055 in the first quarter of 2003. In the first quarter of 2002, we commenced a Phase I/II clinical trial of our second generation antisense compound GEM 231 in combination with irinotecan. In the third quarter of 2002, we expanded our Phase I/II clinical trial and purchased additional amounts of GEM 231 for use in the combination therapy trial.

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. The cost of clinical trials may vary significantly based on whether they are done alone or in combination with other compounds owned by third parties, the number of sites and the number of patients enrolled. Our ability to fund research and development through strategic alliances will also affect our development costs.

General and administrative expenses increased by \$1,770,000, or 112%, to \$3,351,000 in the three months ended September 30, 2002 from \$1,581,000 for the three months ended September 30, 2001 and increased by \$1,616,000, or 38%, to \$5,835,000 for the nine months ended September 30, 2002 from \$4,219,000 for the nine months ended September 30, 2001. General and administrative expenses consist primarily of salary expense, consulting fees and professional legal fees associated with our regulatory filing requirements and business development. The increase in general and administrative expenses for the three and nine months ended September 30, 2002 reflects the recognition of \$2.1 million of previously deferred expenses as a result of the August 2002 amendment to the license agreement with Isis.

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As a result of a repricing of our stock options in September 1999, certain outstanding stock options are subject to variable plan accounting which requires us to remeasure the intrinsic value of the repriced options, through the earlier of the date of exercise, cancellation or expiration, at each reporting date. We recorded a credit to operating results of approximately \$438,000 and \$577,000 for the three months ended September 30, 2002 and 2001, respectively. For the nine months ended September 30, 2002, we recorded a credit of approximately \$1,182,000 compared to stock compensation expense of approximately \$347,000 for the same period in 2001.

The credits in 2002 and the three months ended September 30, 2001 resulted from a decrease in the market value of our common stock during these periods. The stock-based compensation expense in 2001 resulted from an increase in the market value of our common stock during the nine months ended September 30, 2001. Compensation charges and credits will likely occur in the future based upon changes in the intrinsic value of our repriced options.

Interest expense decreased by \$476,000, or 93%, to \$38,000 for the three months ended September 30, 2002 from \$514,000 for the three months ended September 30, 2001 and by \$987,000, or 90%, to \$115,000 for the nine months ended September 30, 2002 from \$1,102,000 for the same period in 2001. The decreases for the three and nine months ended September 30, 2002 were mainly attributable to a \$13.7 million debt reduction during 2001 which resulted primarily from the conversion of \$7.6 million in principal amount of our 8% notes into equity and the repayment of a \$6.0 million note payable that occurred in the second and fourth quarters of 2001.

The net loss on the sale of securities for the three months ended September 30, 2002 and the net gain on the sale of securities for the nine months ended September 30, 2001 reflects an unrealized loss of \$902,000 relating to the Isis shares classified as trading securities and marked to fair value prior to the execution of forward contracts and a loss of \$269,000 relating to fees incurred upon the execution of the forward contracts. For the nine months ended September 30, 2001, the net gain on the sale of securities also consisted of a gain recorded from the sale of 100% of our holdings in the stock of MethylGene Inc. We closed the sale of our holding of shares of Class A and Class B stock of MethylGene to a group of private United States institutional investors along with three of MethylGene's other shareholders during April and May 2001 on similar terms (\$2.85 Canadian or approximately \$1.84 US per share as of April 27, 2001). We received total proceeds of approximately \$7.2 million US. In the second quarter of 2001, we recorded a net gain for this transaction of approximately \$6.9 million, net of approximately \$300,000 in expenses for professional fees.

The gain from the sale of discontinued operations for the three months ended September 30, 2001 consisted of a gain recorded during the third quarter of 2001 in connection with the disposition of assets to Avecia in September 2000. In that transaction, we were obligated to make up any shortfall in purchase orders which Avecia expected to receive in 2000 and 2001. To the extent that we previously made payments for a purchasing shortfall where we had no use for the related products, we had recorded a receivable. Upon receipt of the final \$3.0 million payment for the assets we sold to Avecia, we applied \$1,032,000 toward the receivable and recognized the remaining \$1,968,000 as a gain from the sale of discontinued operations.

In March 2002, passage of the National Economic Stabilization and Recovery Act temporarily rescinded the Alternative Minimum Tax (AMT) and altered the way net operating loss carryforwards are applied to offset current taxable income. As a result, we recognized a tax benefit in operating results of \$500,000 for the nine months ended September 30, 2002 compared to income tax expense of \$400,000 for the nine months ended September 30, 2001. We received a refund of \$450,000 during the nine months ended September 30, 2002 reimbursing us for estimated taxes paid during 2001.

We had an extraordinary loss of \$1,412,000 for the nine months ended September 30, 2001 resulting from the early extinguishment of our 8% Notes.

We pay dividends on our Series A convertible preferred stock of 6.5% per annum, payable semi-annually in arrears. We have the option to pay such dividends in either cash or additional duly authorized, fully paid and non assessable shares of Series A convertible preferred stock. Through September 30, 2002, we paid such dividends in Series A convertible preferred stock. Accordingly, during the nine months ended September 30 2002 and 2001, 20,659 and 19,922 shares of our Series A convertible preferred stock were issued as dividends to our Series A preferred stockholders. We recorded Series A convertible preferred stock dividends of \$1,074,000 for the third quarter of 2002, \$1,008,000 during the third quarter of 2001 and \$3,173,000 and \$3,011,000 for the nine months ended September 30, 2002 and 2001, respectively. 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 income applicable to common stockholders amounted to \$21,514,000 for the

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three months ended September 30, 2002 compared to our net loss applicable to common stockholders of \$6,514,000 for the three months ended September 30, 2001 and net income applicable to common stockholders of \$17,049,000 for the nine months ended September 30, 2002 compared to our net loss applicable to common stockholders of \$9,543,000 for the nine months ended September 30, 2001.

As of December 31, 2001, we had net operating loss carryforwards and tax credit carryforwards expiring in 2007 through 2020 of approximately \$210.0 million and \$4.0 million, respectively, to offset future federal taxable income, if any. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in the financial statements related to these carryforwards as of September 30, 2002. We would allocate any subsequently recognized tax benefits to operations and additional paid-in capital. Moreover, our ability to utilize these losses in future years may be limited under the change of stock ownership rules of the Internal Revenue Service.

## **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 operations with revenues from collaborative and license agreements, interest income and manufacturing of synthetic DNA and reagent products by Hybridon Specialty Products, prior to its sale in 2000, as well as from a variety of debt and equity financings, lease financings, the sale of our shareholdings in MethylGene, and the sale of HSP. As of September 30, 2002, we had approximately \$24.1 million in cash, cash equivalents and short-term investments, a decrease of approximately \$7.7 million from December 31, 2001.

We used \$7.5 million of cash for operating activities during the nine months ended September 30, 2002. The principal use of cash in such period was to fund our research and development expenses, our general and administrative expenses, and our payment to Isis in May 2002. The \$7.5 million represents our net income for the period offset by the change in deferred revenue related to the collaboration and license agreement with Isis and non-cash operating adjustments including stock-based compensation.

We purchased approximately \$7.5 million in short-term investments, net of sales and maturities, and property during the nine months ended September 30, 2002.

During the nine months ended September 30, 2002, cash from financing activities included proceeds from the exercise of stock options, which were offset by payments by us under an equipment lease.

As of September 30, 2002, our outstanding indebtedness consisted of \$0.3 million in principal amount of 8% notes maturing in November 2002 and \$1.3 million in principal amount of 9% notes maturing in April 2004. These notes are unsecured.

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 earn additional external funds through our new collaborations, and we expect to continue to seek additional external funds periodically 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. Lack of necessary funds may require us to delay, scale back or eliminate some or all of our research and development programs.

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### **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 that involve risks and uncertainties. We may, in some cases, use words such as project, believe, anticipate, plan, expect, estimate, intend, should, would, could, will, may or other words that convey uncertainty of future events or outcomes. We identify these forward-looking statements. There are a number of important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements, including those set forth below under the caption Risk Factors. These factors and the other cautionary statements made in this quarterly report should be read as being applicable to all related forward-looking statements wherever they appear in this quarterly report. If one or more of these factors materialized, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements represent our estimates only as of the date this quarterly report was filed with the Securities and Exchange Commission and should not be relied upon as representing the Company's estimates as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our estimates change.

### **RISK FACTORS**

#### **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. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to commence or complete these 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 most recent clinical trial of GEM 91, our lead first generation antisense compound at the time, we determined not to continue the development of GEM 91 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 field of drug discovery is highly competitive and characterized by rapid and significant technological change. Many of our competitors are substantially larger than us and have substantially greater capital resources, research and development staffs and facilities than us. Furthermore, many of our competitors are more experienced than us in drug discovery, development and commercialization, obtaining regulatory approvals and drug manufacturing and marketing. As a result, our competitors may discover, develop and commercialize drugs based on synthetic DNA before us. In addition, our competitors may discover, develop and commercialize drugs that render non-competitive or obsolete the drugs that we or our collaborators are seeking to develop and commercialize.



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***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. 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 expensive.

We may need to successfully 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.

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*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 September 30, 2002, we had incurred operating losses of approximately \$256.8 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 manufacturing of synthetic DNA and reagent products by HSP prior to our selling HSP in September 2000.

We expect to increase our spending significantly in order to expand our infrastructure and research and development programs. As a result, we will need to generate significant revenues or to attract external capital in the form of debt or equity to fund this spending. We cannot be certain whether or when we will become profitable or whether we will be able to attract external capital in the form of debt or equity 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 may 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. 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.

Additional financing may not be available when we need it or may not be available on favorable terms. 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 to 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;



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disagreements with collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;

contracts with our collaborators may fail to provide sufficient protection;

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.

***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 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. The cost to us of any patent litigation or other proceeding, 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 a patent litigation or



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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 required for clinical trials and 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 and 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.

*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 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.*



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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 appropriate, 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**

*Certain provisions of our charter documents, our rights agreement and Delaware law could delay or prevent the sale of our company.*

Provisions of our charter documents, our rights agreement and Delaware law may make it more difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control would result in the purchase of shares of our common stock at a premium to the market price. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest.

*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.

**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
Date: May 14, 2003	/s/ Stephen R. Seiler _____
	Stephen R. Seiler Chief Executive Officer
Date: May 14, 2003	/s/ Robert G. Andersen _____
	Robert G. Andersen Chief Financial Officer and Vice President of Operations (Principal Financial Officer)



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**CERTIFICATIONS**

I, Stephen R. Seiler, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A.
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;
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;

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/A.
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;
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;

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 officer)

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Exhibit Index

**Exhibit No.**

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.