

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 June 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  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**

**47,525,043**

Class

Outstanding as of July 26, 2002

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**HYBRIDON, INC.**

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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 August 14, 2002 for the quarter ended June 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 \$59,000 for the three month period ended June 30, 2002, \$118,000 for the six month period ended June 30, 2002 and \$39,000 for the three and six month periods ended June 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)**

|   | <b>JUNE 30,<br/>2002</b> | <b>DECEMBER 31,<br/>2001</b> |
|---|--------------------------|------------------------------|
| <b>Assets</b>   |                          |                              |
| Current assets:   |                          |                              |
| Cash and cash equivalents   | \$ 8,769,560             | \$ 20,923,295                |
| Short-term investments  | 17,888,982               | 10,910,987                   |
| Receivables   | 307,739                  | 274,863                      |
| Prepaid expenses and other current assets   | 545,788                  | 56,992                       |
|   | <hr/>                    | <hr/>                        |
| Total current assets  | 27,512,069               | 32,166,137                   |
| Property and equipment, net   | 423,688                  | 143,298                      |
| Deposits  | 11,500                   |                              |
|   | <hr/>                    | <hr/>                        |
|   | \$ 27,947,257            | \$ 32,309,435                |
|   | <hr/>                    | <hr/>                        |
| <b>Liabilities and Stockholders Equity (Deficit)</b>  |                          |                              |
| Current liabilities:  |                          |                              |
| Accounts payable  | \$ 556,193               | \$ 498,642                   |
| Accrued expenses  | 730,650                  | 1,021,660                    |
| Current portion of long-term debt   | 299,549                  | 288,028                      |
| Current portion of capital lease  | 88,306                   |                              |
| Current portion of deferred revenue (Note 4)  | 3,098,654                | 3,098,654                    |
|   | <hr/>                    | <hr/>                        |
| Total current liabilities   | 4,773,352                | 4,906,984                    |
| 9% convertible subordinated notes payable   | 1,306,000                | 1,306,000                    |
| Deferred revenue, net of current portion (Note 4)   | 23,368,471               | 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 660,643 and 640,166 shares at June 30,<br>2002 and December 31, 2001, respectively       | 6,606                    | 6,402                        |
| Common stock, \$0.001 par value   |                          |                              |
| Authorized 150,000,000 shares   |                          |                              |
| Issued and outstanding 47,524,974 and 45,632,525 shares at June 30,<br>2002 and December 31, 2001, respectively | 47,525                   | 45,632                       |
| Additional paid-in capital  | 276,837,780              | 273,870,458                  |
| Accumulated deficit   | (278,333,346)            | (273,868,184)                |
| Deferred compensation   | (59,131)                 | (87,582)                     |
|   | <hr/>                    | <hr/>                        |
| Total stockholders deficit  | (1,500,566)              | (33,274)                     |

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\$ 27,947,257

\$ 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)**

|   | <b>THREE MONTHS ENDED<br/>JUNE 30,</b> |                     | <b>SIX MONTHS ENDED<br/>JUNE 30,</b> |                       |
|---|--|---------------------|--------------------------------------|-----------------------|
|   | <b>2002</b>                            | <b>2001</b>         | <b>2002</b>                          | <b>2001</b>           |
| <b>Revenues:</b>  |  |                     |                                      |                       |
| License fees  | \$ 680,434                             | \$ 259,481          | \$ 1,358,723                         | \$ 293,481            |
| Royalty and other income  | 18,776                                 | 32,339              | 31,293                               | 57,528                |
| Interest income   | 178,016                                | 134,714             | 373,979                              | 239,843               |
|   | <u>877,226</u>                         | <u>426,534</u>      | <u>1,763,995</u>                     | <u>590,852</u>        |
| <b>Operating expenses:</b>  |  |                     |                                      |                       |
| Research and development  | 1,567,567                              | 1,259,014           | 2,813,734                            | 2,360,065             |
| General and administrative  | 1,342,058                              | 1,292,055           | 2,484,001                            | 2,638,593             |
| Stock-based compensation from repriced options (1)                            | (480,563)                              | 923,780             | (744,067)                            | 923,780               |
| Interest  | 38,263                                 | 272,083             | 76,296                               | 587,152               |
|   | <u>2,467,325</u>                       | <u>3,746,932</u>    | <u>4,629,964</u>                     | <u>6,509,590</u>      |
| Other income  |  | 6,890,261           |                                      | 6,890,261             |
|   | <u></u>                                | <u>6,890,261</u>    | <u></u>                              | <u>6,890,261</u>      |
| (Loss) income before provision for income taxes and extraordinary item        | (1,590,099)                            | 3,569,863           | (2,865,969)                          | 971,523               |
| Income tax (provision) credit   |  | (400,000)           | 500,000                              | (400,000)             |
|   | <u></u>                                | <u>(400,000)</u>    | <u>500,000</u>                       | <u>(400,000)</u>      |
| (Loss) income before extraordinary item                                       | (1,590,099)                            | 3,169,863           | (2,365,969)                          | 571,523               |
| <b>Extraordinary item:</b>  |  |                     |                                      |                       |
| Loss on early retirement of 8% convertible notes payable                      |  |                     |                                      | (1,411,876)           |
|   | <u></u>                                | <u></u>             | <u></u>                              | <u>(1,411,876)</u>    |
| Net (loss) income   | (1,590,099)                            | 3,169,863           | (2,365,969)                          | (840,353)             |
| Accretion of preferred stock dividends  | (1,058,944)                            | (1,181,149)         | (2,099,194)                          | (2,189,033)           |
|   | <u>(2,649,043)</u>                     | <u>(1,181,149)</u>  | <u>(2,099,194)</u>                   | <u>(2,189,033)</u>    |
| Net (loss) income applicable to common stockholders                           | \$ (2,649,043)                         | \$ 1,988,714        | \$ (4,465,163)                       | \$ (3,029,386)        |
|   | <u>\$ (2,649,043)</u>                  | <u>\$ 1,988,714</u> | <u>\$ (4,465,163)</u>                | <u>\$ (3,029,386)</u> |
| <b>Net (loss) income per share applicable to common stockholders (Note 5)</b> |  |                     |                                      |                       |
| Basic   | \$ (0.06)                              | \$ 0.11             | \$ (0.10)                            | \$ (0.17)             |
|   | <u>\$ (0.06)</u>                       | <u>\$ 0.11</u>      | <u>\$ (0.10)</u>                     | <u>\$ (0.17)</u>      |
| Diluted   | \$ (0.06)                              | \$ 0.06             | \$ (0.10)                            | \$ (0.17)             |
|   | <u>\$ (0.06)</u>                       | <u>\$ 0.06</u>      | <u>\$ (0.10)</u>                     | <u>\$ (0.17)</u>      |
| <b>Shares used in computing net (loss) income per common share:</b>           |  |                     |                                      |                       |
| Basic   | 46,708,200                             | 18,854,291          | 46,189,027                           | 18,671,211            |
|   | <u>46,708,200</u>                      | <u>18,854,291</u>   | <u>46,189,027</u>                    | <u>18,671,211</u>     |
| Diluted   | 46,708,200                             | 57,173,932          | 46,189,027                           | 18,671,211            |
|   | <u>46,708,200</u>                      | <u>57,173,932</u>   | <u>46,189,027</u>                    | <u>18,671,211</u>     |

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(1) The following summarizes the allocation of stock-based compensation from repriced options:

|                            |                   |                   |                   |                   |
|----------------------------|-------------------|-------------------|-------------------|-------------------|
| Research and development   | \$ (383,211)      | \$ 609,177        | \$ (512,856)      | \$ 609,177        |
| General and administrative | (97,352)          | 314,603           | (231,211)         | 314,603           |
|                            | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Total                      | \$ (480,563)      | \$ 923,780        | \$ (744,067)      | \$ 923,780        |
|                            | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |

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



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

|  | <b>SIX MONTHS ENDED<br/>JUNE 30,</b> |                      |
|--|--------------------------------------|----------------------|
|  | <b>2002</b>                          | <b>2001</b>          |
| <b>Cash Flows From Operating Activities:</b>                               |                                      |                      |
| Net loss   | \$ (2,365,969)                       | \$ (840,353)         |
| 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 common stock for services rendered                             |                                      | 26,000               |
| Stock-based compensation   | (744,067)                            | 923,780              |
| Depreciation and amortization  | 275,851                              | 280,751              |
| Gain on sale of property and equipment                                     |                                      | (20,650)             |
| Non-cash interest expense  | 11,737                               | 250,556              |
| Changes in operating assets and liabilities                                |                                      |                      |
| Accounts receivable  | (32,876)                             | (874,200)            |
| Prepaid expenses and other assets  | (500,296)                            | 49,817               |
| Accounts payable and accrued expenses                                      | 128,885                              | (49,211)             |
| Deferred revenue   | (1,957,436)                          | 14,814,246           |
| Net cash (used in) provided by operating activities                        | <u>(5,184,171)</u>                   | <u>15,972,612</u>    |
| <b>Cash Flows From Investing Activities:</b>                               |                                      |                      |
| Maturities of short-term investments                                       | 4,345,000                            |                      |
| Purchase of marketable securities  | (14,582,249)                         | (5,995,587)          |
| Sale of marketable securities  | 3,047,724                            |                      |
| Purchase of property and equipment   | (196,807)                            |                      |
| Proceeds from sale of property and equipment                               |                                      | 20,650               |
| Net cash (used in) provided by investing activities                        | <u>(7,386,332)</u>                   | <u>(5,974,937)</u>   |
| <b>Cash Flows From Financing Activities:</b>                               |                                      |                      |
| Proceeds from exercise of common stock options                             | 441,765                              | 31,075               |
| Principal payments on capital leases                                       | (24,997)                             |                      |
| Payments on long-term debt   |                                      | (3,000,000)          |
| Decrease in restricted cash  |                                      | 4,178,750            |
| Net cash provided by financing activities                                  | <u>416,768</u>                       | <u>1,209,825</u>     |
| Net (decrease) increase in cash and cash equivalents                       | (12,153,735)                         | 11,207,500           |
| Cash and cash equivalents, beginning of period                             | 20,923,295                           | 1,532,155            |
| Cash and cash equivalents, end of period                                   | <u>\$ 8,769,560</u>                  | <u>\$ 12,739,655</u> |

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

(UNAUDITED)

|   | <b>SIX MONTHS ENDED<br/>JUNE 30,</b> |             |
|---|--------------------------------------|-------------|
|   | <b>2002</b>                          | <b>2001</b> |
| Supplemental disclosure of cash flow information:                                 |                                      |             |
| Cash paid for interest  | \$ 58,770                            | \$ 280,525  |
| Supplemental disclosure of non cash financing and investing activities:           |                                      |             |
| Exchange of 8% convertible notes payable for Series B convertible preferred stock | \$                                   | \$7,604,600 |
| Accretion of Series A and Series B convertible preferred stock dividends          | \$2,099,194                          | \$2,189,033 |
| Issuance of common stock in lieu of cash bonus                                    | \$                                   | \$ 88,577   |
| 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                           | \$          |

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

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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 (Cyclicons) 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 six month periods ended June 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) Reclassifications**

Amounts in the prior-period consolidated financial statements have been reclassified to conform with the current period's presentation.

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

The Company recognizes revenue related to its Collaboration and License Agreement with Isis Pharmaceuticals, Inc. (the Agreement) ratably over the 10-year term of the Agreement expiring in 2011. Deferred revenue on the accompanying consolidated condensed balance sheet relates to the unrecognized portion of the \$32.3 million of cash and Isis stock received by the Company in 2001, the unrecognized expenses related to the Agreement, and the net of \$1.9 million in cash and the Company's common stock paid to Isis in May 2002 and the amortization of the estimated value of all payments made or to be made by the Company to Isis. While the amounts received from Isis are not refundable under any circumstances and the Company does not believe that it will be required to expend any significant future resources under the Agreement, this revenue has been deferred based on SAB 101, which precludes revenue recognition in cases where future obligations are not interpreted to be inconsequential and perfunctory. An ongoing obligation of the Company to make two representatives available to attend semi-annual telephonic meetings of a collaboration committee with the licensee, led to the accounting treatment described above.

The first tranche payment to Isis consisting of approximately \$716,000 in cash and 1,005,499 shares of common stock having a fair market value of approximately \$1.2 million on the date of issuance are recognized over the term of the Agreement as a reduction to revenue. Direct expenses related to the Agreement are recognized over the term of the Agreement in General and administrative expense on the accompanying Consolidated Condensed Statement of Operations

Based on an agreement reached with Isis on August 14, 2002, neither party will be required to pay any additional tranche payments under the Agreement.

The Company recognized net revenues under the Agreement of approximately \$670,000 and \$245,000 for the three months ended June 30, 2002 and 2001, respectively, and \$1,338,000 and \$245,000 for the six months ended June 30, 2002 and 2001, respectively. 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.



**Table of Contents****(5) Net (Loss) Income per Common Share**

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

|   | Three Months Ended June 30, |              | Six Months Ended June 30, |                |
|---|-----------------------------|--------------|---------------------------|----------------|
|   | 2002                        | 2001         | 2002                      | 2001           |
| <b>Numerator:</b>   |                             |              |                           |                |
| (Loss) income before extraordinary item                               | \$ (1,590,099)              | \$ 3,169,863 | \$ (2,365,969)            | \$ 571,523     |
| Extraordinary loss on exchange of 8% convertible note payable         |                             |              |                           | (1,411,876)    |
| Net (loss) income   | (1,590,099)                 | 3,169,863    | (2,365,969)               | (840,353)      |
| Accretion of preferred stock dividends                                | (1,058,944)                 | (1,181,149)  | (2,099,194)               | (2,189,033)    |
| Numerator for basic (loss) income applicable to common shareholders   | (2,649,043)                 | 1,988,714    | (4,465,163)               | (3,029,386)    |
| <b>Effect of dilutive securities:</b>                                 |                             |              |                           |                |
| Dividends on Series A and B convertible preferred stock               |                             | 1,181,149    |                           |                |
| Interest expense related to convertible debt                          |                             | 96,686       |                           |                |
| Numerator for diluted (loss) income applicable to common shareholders | \$ (2,649,043)              | \$ 3,266,549 | \$ (4,465,163)            | \$ (3,029,386) |
| Denominator for basic (loss) income per share                         | 46,708,200                  | 18,854,291   | 46,189,027                | 18,671,211     |
| <b>Effect of dilutive securities:</b>                                 |                             |              |                           |                |
| Common stock options and warrants                                     |                             | 4,043,224    |                           |                |
| Convertible debt  |                             | 4,182,995    |                           |                |
| Series A and B convertible preferred stock                            |                             | 30,093,422   |                           |                |
| Denominator for diluted (loss) income per share                       | 46,708,200                  | 57,173,932   | 46,189,027                | 18,671,211     |
| <b>(Loss) income per share – basic</b>                                |                             |              |                           |                |
| (Loss) income before extraordinary item                               | \$ (0.04)                   | \$ 0.17      | \$ (0.05)                 | \$ 0.03        |
| Extraordinary loss  |                             |              |                           | (0.08)         |
| Net (loss) income per share   | (0.04)                      | 0.17         | (0.05)                    | (0.05)         |
| Accretion of preferred stock dividends                                | (0.02)                      | (0.06)       | (0.05)                    | (0.12)         |
| Net (loss) income per share applicable to common stockholders         | \$ (0.06)                   | \$ 0.11      | \$ (0.10)                 | \$ (0.17)      |
| <b>(Loss) income per share – diluted</b>                              |                             |              |                           |                |
| (Loss) income before extraordinary item                               | \$ (0.04)                   | \$ 0.06      | \$ (0.05)                 | \$ 0.03        |
| Extraordinary loss  |                             |              |                           | (0.08)         |
| Net (loss) income per share   | (0.04)                      | 0.06         | (0.05)                    | (0.05)         |
| Accretion of preferred stock dividends                                | (0.02)                      |              | (0.05)                    | (0.12)         |
| Net (loss) income per share applicable to common stockholders         | \$ (0.06)                   | \$ 0.06      | \$ (0.10)                 | \$ (0.17)      |



Basic net (loss) income per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three and six months ended June 30, 2002 and the six months ended June 30, 2001, 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 39,166,376 for the three and six months ended June 30, 2002. Total antidilutive securities were 12,092,582 for the three months ended June 30, 2001 and 54,530,048 for the six months ended June 30, 2001. 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 for the three months ended June 30, 2002 and the six months ended June 30, 2002 and 2001.



**Table of Contents****(6) 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 June 30, 2002 and December 31, 2001 consist of the following:

|                             | JUNE 30<br>2002 | DECEMBER 31<br>2001 |
|-----------------------------|-----------------|---------------------|
| Cash and cash equivalents   |                 |                     |
| Cash and money market funds | \$ 3,969,560    | \$ 20,923,295       |
| Corporate bonds             | 4,800,000       |                     |
| Total                       | \$ 8,769,560    | \$ 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. Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's short-term investments as of June 30, 2002 and December 31, 2001 are classified as held-to-maturity. On January 2, 2002 and prior to maturity, the Company sold two of its asset backed securities issued by the same corporation which the Company had classified as held-to-maturity as of December 31, 2001. On April 19, 2002 and prior to maturity, the Company sold a corporate bond which had been classified as held-to-maturity as of December 31, 2001. The Company sold such securities when it became aware that the securities' assets might be deteriorating which may lead to an early repayment of par value. In order to avoid any potential losses, the Company sold these securities for a price that approximated their book value.

Short-term investments have maturities of greater than three months and mature within one year of the balance sheet date. All short-term investments mature prior to June 30, 2003. At June 30, 2002 and December 31, 2001, the Company's short-term investments consisted of the following (at amortized cost which approximates fair market value):

|                        | JUNE 30<br>2002 | DECEMBER 31<br>2001 |
|------------------------|-----------------|---------------------|
| Short-term investments |                 |                     |
| Government bonds       | \$ 12,747,158   | \$ 8,928,847        |
| Corporate bonds        | 5,141,824       | 1,982,140           |
| Total                  | \$ 17,888,982   | \$ 10,910,987       |

**(7) 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 intrinsic value of the repriced options, through the earlier of the date of exercise, cancellation or expiration, at each reporting date. The Company recognized a credit of approximately \$481,000 and compensation expense of approximately \$924,000 for the three months ended June 30, 2002 and 2001, respectively, and a credit of approximately \$744,000 and compensation expense of approximately \$924,000 for the six months ended June 30, 2002 and 2001, respectively. A decrease in the intrinsic value of these options between December 31, 2001 and June 30, 2002 resulted in credits to stock compensation from these repriced options in 2002. Compensation expense in 2001 is a result of an increase in the intrinsic value of these options between March 31, 2001 and June 30, 2001.

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**(8) Income Taxes**

During 2001, the Company had a provision for income taxes of \$500,000 for Alternative Minimum Tax (AMT) of which \$450,000 was paid by the Company in 2001. 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 recognized a \$500,000 tax benefit in operating results during the six months ended June 30, 2002 and received a refund of \$450,000 during the three months ended June 30, 2002.

**(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 June 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 June 30, 2002 and 2001, total Series A dividend accretion was approximately \$1,059,000 and \$1,181,000, respectively. During the six months ended June 30, 2002 and 2001, total Series A dividend accretion was approximately \$2,099,000 and \$2,004,000, 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. 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.

**(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 United States institutional investors. 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 three months ended June 30, 2001, the Company recorded a gain for this transaction of approximately \$6.9 million, which includes approximately \$300,000 in professional fees. This gain is included in other income on the accompanying consolidated statement of operations.

**(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 \$456,221 in principal and interest under 8% Notes exchanged their 8% Notes for 1,140,448 shares of the Company's common stock.



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**(13) Stockholders Equity**

On June 19, 2002, at the Annual Meeting of the Company's stockholders, an amendment to the Company's Restated Certificate of Incorporation increased the number of authorized shares of the Company's Common Stock from 100,000,000 shares to 150,000,000 shares. As of June 30, 2002, 47,524,974 shares of common stock were issued and outstanding.

**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 which we refer to as Cyclicons 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 \$278.3 million through June 30, 2002 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. We expect that our research and development and general and administrative expenses will be significant in 2002 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 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 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.

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Determination of the last three criteria are 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.

During 2001, we received a total of \$32.3 million in cash and stock under our collaboration and license agreement with Isis Pharmaceuticals, Inc. This amount and future amounts due under this license agreement are non-refundable. We are recognizing the revenue on a straight-line basis over the 10-year term of the agreement, which expires in 2011. This deferral of revenue recognition is based on a continuing obligation contained in the license agreement which has been interpreted as neither inconsequential nor perfunctory according to SAB 101. We believe that the cost of performing the continuing obligation is not material. Direct expenses and cash and stock due to Isis are 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.

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 Six Months Ended June 30, 2002 and 2001***

Total revenues increased by \$450,000, or 106%, to \$877,000 for the three months ended June 30, 2002 from \$427,000 for the three months ended June 30, 2001 and increased by \$1,173,000, or 198%, to \$1,764,000 for the six months ended June 30, 2002 from \$591,000 for the six months ended June 30, 2001. The increase in revenues was primarily due to the recognition of license revenues derived from agreements with Isis Pharmaceuticals, Inc. and EpiGenesis Pharmaceuticals, Inc. which became effective during the second quarter of 2001. In connection with the Isis agreement, revenues are net of amortization of the estimated value of our stock to be issued to Isis. The increase in revenues for the three and six months ended June 30, 2002 also reflected increased interest income from higher cash and investment balances as a result of the payments received during 2001 from Isis and EpiGenesis, the sale of our interest in MethylGene, Inc. and the remaining contingent payment due us from the sale of Hybridon Specialty Products Division, or HSP.

Research and development expenses increased by \$309,000, or 25%, to \$1,568,000 for the three months ended June 30, 2002 from \$1,259,000 for the three months ended June 30, 2001 and by \$454,000, or 19%, to \$2,814,000 for the six months ended June 30, 2002 from \$2,360,000 for the six months ended June 30, 2001. The increase in both periods was primarily attributable to expanded development efforts with respect to our IMO technology.

In the three and six months ended June 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 conducting 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. We are conducting the trial at Vanderbilt University Medical Center and the University of Chicago Medical Center. We are currently seeking to add additional sites to expand this 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 enrolled patients. Our ability to fund research and development through strategic alliances will also affect our development costs.

General and administrative expenses increased by \$50,000, or 4%, to \$1,342,000 in the three months ended June 30, 2002 from \$1,292,000 for the three months ended June 30, 2001 and decreased by \$155,000, or 6%, to \$2,484,000 for the six months ended June 30, 2002 from \$2,639,000 for the six months ended June 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 decrease in general and administrative expenses for the six months ended June 30, 2002 reflects executive compensation awards approved in the first quarter of 2001 without any similar awards in the first six months of 2002 offset by higher compensation costs in the second quarter of 2002 resulting from an increase in personnel. The decrease in the six months ended June 30, 2002 is also attributed to decreased facility expenses and decreased professional fees associated with financing activities.

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 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. We recorded a credit to operating results of approximately \$481,000 and



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stock compensation expense of approximately \$924,000 for the three months ended June 30, 2002 and 2001, respectively. For the six months ended June 30, 2002, we recorded a total credit of approximately \$744,000 compared to stock compensation expense of approximately \$924,000 for the same period in 2001. The credits in 2002 resulted from a decrease in the intrinsic value of these stock options during the first half of 2002. The stock-based compensation expense in 2001 resulted from an increase in the intrinsic value of these stock options during the second quarter of 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 \$234,000, or 86%, to \$38,000 for the three months ended June 30, 2002 from \$272,000 for the three months ended June 30, 2001 and by \$511,000, or 87%, to \$76,000 for the six months ended June 30, 2002 from \$587,000 for the same period in 2001. The decreases for the three and six months ended June 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.

For the three and six months ended June 30, 2001, other income consisted of a gain recorded from Hybridon's sale of 100% of its holdings of MethylGene Inc. stock. Hybridon closed the sale of its 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). Hybridon received total proceeds of approximately \$7.2 million US. For the second quarter of 2001, Hybridon recorded a net gain for this transaction of approximately \$6.9 million, which includes approximately \$300,000 in professional fees.

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 recognized a tax benefit in operating results of \$500,000 for the six months ended June 30, 2002 compared to income tax expense of \$400,000 for the six months ended June 30, 2001. We received a refund of \$450,000 during the three months ended June 30, 2002 reimbursing us for estimated taxes paid during 2001.

We had an extraordinary loss of \$1.4 million for the six months ended June 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 June 30, 2002, we had only paid such dividends in Series A convertible preferred stock. Accordingly, during the three months ended June 30 2002 and 2001, 20,659 and 19,922 shares of our Series A convertible preferred stock were issued as dividends to the holders of our Series A preferred stock. We recorded Series A convertible preferred stock dividends of \$1,059,000 for the second quarter of 2002 and \$1,181,000 during the second quarter of 2001 and \$2,099,000 and \$2,189,000 for the six months ended June 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 loss applicable to common stockholders amounted to \$2,649,000 for the three months ended June 30, 2002 compared to our net income applicable to common stockholders of \$1,989,000 for the three months ended June 30, 2001 and net losses applicable to common stockholders of \$4,465,000 for the six months ended June 30, 2002 compared to \$3,029,000 for the six months ended June 30, 2001.

As of December 31, 2002, 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 as of June 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 HSP, prior to its sale in September 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. Based on an agreement reached with Isis on August 14, 2002, neither party will be required to pay any additional tranche payments under the collaboration and license agreement, including the final \$4.5 million payment due to us from Isis Pharmaceuticals, Inc. Under our agreement in May 2002, we paid Isis \$0.7 million in cash and issued to Isis shares of our common stock having a fair market value of \$1.2 million.



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As of June 30, 2002, we had approximately \$26.7 million in cash, cash equivalents and investments. We used \$5.2 million for operating activities during the six months ended June 30, 2002. The \$5.2 million consisted of a net loss of \$2.4 million combined with non-cash operating adjustments which include stock-based compensation and deferred revenue related to the collaboration and license agreement with Isis and EpiGenesis, an increase in prepaid expenses, and the cash portion of the May 2002 payment to Isis.

We purchased approximately \$7.2 million in short-term investments, net of sales and maturities, during the six months ended June 30, 2002.

During the first half of 2002, financing activities included proceeds from the exercise of stock options, which were offset by payments by the Company under an equipment lease.

As of June 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 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.

## **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 and 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.



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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 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.

***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.





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***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 June 30, 2002, we had incurred operating losses of approximately \$278.3 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 to fund this spending. 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 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. 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.



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### **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;

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 and 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



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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 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



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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 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.

Date: May 14, 2003

**HYBRIDON, INC**

/s/ Stephen R. Seiler

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Stephen R. Seiler  
Chief Executive Officer

Date: 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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**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. |