Facebook Inc
Form 10-Q
July 31, 2012
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

(Mark One)

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

**For the quarterly period ended June 30, 2012**

**or**

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

**For the transition period from to .**

**Commission File Number: 001-35551**

# FACEBOOK, INC.

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

| Delaware | 20-1665019 |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**1601 Willow Road, Menlo Park, California 94025**

**(Address of principal executive offices and Zip Code)**

**(650) 308-7300**

**(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 x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|---|---|---|---|
| Large accelerated filer | ¨ | Accelerated filer | ¨ |
| Non-accelerated filer | x (Do not check if a smaller reporting company) | Smaller reporting company | ¨ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer s classes of Common Stock, as of the latest practicable date.

| **Class** | **Number of Shares Outstanding** |
|---|---|
| Class A Common Stock $0.000006 par value | 674,605,171 shares outstanding as of July 25, 2012 |
| Class B Common Stock $0.000006 par value | 1,467,762,401 shares outstanding as of July 25, 2012 |

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**FACEBOOK, INC.**

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**NOTE ABOUT FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words believe, may, will, estimate, continue, anticipate, intend, expect, and similar expressions are intend forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II. Item 1A. Risk Factors in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

Unless expressly indicated or the context requires otherwise, the terms Facebook, company, we, us, and our in this document refer to Faceb Inc., a Delaware corporation, and, where appropriate, its wholly owned subsidiaries. The term Facebook may also refer to our products, regardless of the manner in which they are accessed.

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**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**FACEBOOK, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

*(In millions, except for number of shares and par value)*

*(Unaudited)*

| | June 30, 2012 | December 31, 2011 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,098 | $ 1,512 |
| Marketable securities | 8,090 | 2,396 |
| Accounts receivable, net of allowances for doubtful accounts of $17 as of June 30, 2012 and December 31, 2011 | 578 | 547 |
| Income tax refundable | 567 | 0 |
| Prepaid expenses and other current assets | 634 | 149 |
| Total current assets | 11,967 | 4,604 |
| Property and equipment, net | 2,105 | 1,475 |
| Goodwill and intangible assets, net | 809 | 162 |
| Other assets | 47 | 90 |
| **Total assets** | $ 14,928 | $ 6,331 |
| **Liabilities and stockholders equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 43 | $ 63 |
| Platform partners payable | 153 | 171 |
| Accrued expenses and other current liabilities | 441 | 296 |
| Deferred revenue and deposits | 85 | 90 |
| Current portion of capital lease obligations | 312 | 279 |
| Total current liabilities | 1,034 | 899 |
| Capital lease obligations, less current portion | 394 | 398 |
| Other liabilities | 191 | 135 |
| Total liabilities | 1,619 | 1,432 |
| Stockholders equity: | | |
| Convertible preferred stock, $0.000006 par value, issuable in series; no shares and 569 million shares authorized as of June 30, 2012 and December 31, 2011, respectively, no shares and 543 million shares issued and outstanding as of June 30, 2012 and December 31, 2011, respectively | 0 | 615 |
| Common stock, $0.000006 par value; 5,000 million and 4,141 million Class A shares authorized as of June 30, 2012 and December 31, 2011, respectively, 641 million and 117 million shares issued and outstanding as of June 30, 2012 and December 31, 2011, respectively, including 1 million outstanding shares subject to repurchase as of June 30, 2012 and December 31, 2011; 4,141 million Class B shares authorized, 1,501 million and 1,213 million shares issued and outstanding as of June 30, 2012 and December 31, 2011, | 0 | 0 |

| | | |
|---|---|---|
| respectively, including 2 million outstanding shares subject to repurchase, as of June 30, 2012 and December 31, 2011 | | |
| Additional paid-in capital | 11,684 | 2,684 |
| Accumulated other comprehensive loss | (29) | (6) |
| Retained earnings | 1,654 | 1,606 |
| Total stockholders equity | 13,309 | 4,899 |
| **Total liabilities and stockholders equity** | $ 14,928 | $ 6,331 |

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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**FACEBOOK, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

*(In millions, except per share amounts)*

*(Unaudited)*

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2012 | 2011 | 2012 | 2011 |
| **Revenue** | $ 1,184 | $ 895 | $ 2,242 | $ 1,626 |
| **Costs and expenses:** | | | | |
| Cost of revenue | 367 | 210 | 644 | 377 |
| Marketing and sales | 392 | 96 | 535 | 158 |
| Research and development | 705 | 99 | 858 | 156 |
| General and administrative | 463 | 83 | 567 | 140 |
| **Total costs and expenses** | 1,927 | 488 | 2,604 | 831 |
| **(Loss) income from operations** | (743) | 407 | (362) | 795 |
| Interest and other income (expense), net: | | | | |
| Interest expense | (10) | (9) | (24) | (17) |
| Other income (expense), net | (12) | 1 | 3 | 19 |
| (Loss) income before benefit from (provision for) income taxes | (765) | 399 | (383) | 797 |
| Benefit from (provision for) income taxes | 608 | (159) | 431 | (326) |
| **Net (loss) income** | $ (157) | $ 240 | $ 48 | $ 471 |
| Less: Net income attributable to participating securities | 0 | 81 | 21 | 160 |
| **Net (loss) income attributable to Class A and Class B common stockholders** | $ (157) | $ 159 | $ 27 | $ 311 |
| **(Loss) earnings per share attributable to Class A and Class B common stockholders:** | | | | |
| Basic | ($ 0.08) | $ 0.12 | $ 0.02 | $ 0.25 |
| Diluted | ($ 0.08) | $ 0.11 | $ 0.02 | $ 0.22 |
| **Weighted average shares used to compute (loss) earnings per share attributable to Class A and Class B common stockholders:** | | | | |
| Basic | 1,879 | 1,292 | 1,613 | 1,267 |
| Diluted | 1,879 | 1,510 | 1,792 | 1,499 |
| **Share-based compensation expense included in costs and expenses:** | | | | |
| Cost of revenue | $ 66 | $ 3 | $ 71 | $ 3 |
| Marketing and sales | 232 | 11 | 251 | 11 |
| Research and development | 545 | 35 | 605 | 39 |
| General and administrative | 263 | 15 | 282 | 18 |
| Total share-based compensation expense | $ 1,106 | $ 64 | $ 1,209 | $ 71 |

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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**FACEBOOK, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

*(In millions)*

*(Unaudited)*

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2012 | 2011 | 2012 | 2011 |
| **Net (loss) income** | $ (157) | $ 240 | $ 48 | $ 471 |
| **Other comprehensive (loss) income:** | | | | |
| Foreign currency translation adjustment | (21) | 0 | (22) | 1 |
| Change in unrealized gain (loss) on available-for-sale investments, net of tax | (1) | 0 | (1) | 0 |
| **Comprehensive (loss) income** | $ (179) | $ 240 | $ 25 | $ 472 |

## Financial Overview

Since our inception in 1993, we have used our resources primarily to conduct research and development activities for ADVEXIN therapy and, to a lesser extent, for other product candidates. At March 31, 2005, we had an accumulated deficit of $123.6 million. We anticipate we will incur losses in the future that may be greater than losses incurred in prior periods. At March 31, 2005, we had cash, cash equivalents and short-term investments of $32.6 million. During the quarter ended March 31, 2005, we used $5.9 million of cash and cash equivalents for operating activities. In addition, we used $97,000 for purchases of property and equipment and $171,000 for principal payments on notes payable to support those activities. These uses of cash were offset by the receipt of $265,000 under notes payable to finance equipment acquisitions and by the receipt of $346,000 from sales of common stock resulting from stock option exercises. We expect to incur substantial additional operating expenses and losses over the next several years as our research, development, pre-clinical testing and clinical trial activities continue and as we evolve our operations and systems to support commercialization of our product candidates. These losses, among other things, have caused and may cause our total assets, stockholders equity and working capital to decrease. Currently, we earn revenue or income from federal research grants, contract services and process development activities, the lease of a portion of our facilities to M. D.

Anderson Cancer Center and interest income on cash placed in short-term, investment grade securities. In order to fund our operating losses, we will need to raise additional funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. We do not know whether such additional financing will be available when needed, or on terms favorable to us or our stockholders.

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*Mortgage Note Payable*

In May 2004, we amended the mortgage note payable related to our facilities. The original $6.0 million principal balance of our note payable was increased to $7.8 million. The proceeds from this increase were used to pay in full the principal and interest outstanding on another note payable with an original principal balance of approximately $3.3 million, which resulted in that other note being retired. In addition to this note retirement, the proceeds from this loan amendment were used to pay the costs related to this transaction of $96,000 and to add $668,000 to our cash and cash equivalents. The amended mortgage note payable bears interest at 6.25%. The note is payable in monthly installments of $56,400 until May 2006. At that time, we may extend the note to a November 2009 maturity date. Upon such extension, the interest rate is modified to the lesser of (a) 2.5% above the five-year U.S. Treasury Bond Note rate or (b) 8.5%, and principal and interest on the note become payable in equal monthly installments based on a 225-month amortization period. The principal balance outstanding on the note s extended maturity date is payable in full at that time.

*Acquisition of Magnum Therapeutics Corporation*

In October 2004, we acquired all of the outstanding capital stock of Magnum Therapeutics Corporation (Magnum), a company owned by one of our executive officers at the time of this acquisition. We paid approximately $1.75 million for the Magnum stock by (1) issuing approximately 252,000 shares of our common stock valued at approximately $1.48 million at the acquisition date and (2) assuming liabilities of approximately $272,000. With respect to the common stock we issued for the acquisition, 50% of the shares are held by an independent escrow agent for a period of one year subsequent to the acquisition date to satisfy the indemnification obligations of the selling shareholder under terms of the purchase agreement.

Magnum s primary asset is the right to receive funding under a grant from the National Institutes of Health. The grant activities and related funding will supplement research and development programs we have in progress. During the year ended December 31, 2004, we earned $1.1 million of revenue under this grant. During the quarter ended March 31, 2005, we earned $264,000 of revenue under this grant. In the event certain of Magnum s technologies result in commercial products, we may be obligated to pay royalties related to the sales of those products to certain third parties.

The results of Magnum s operations have been included with those of the Company for the period subsequent to the October 2004 acquisition date. Since Magnum is a development stage company, this acquisition has been accounted for as an asset acquisition and not a business combination.

The total purchase consideration has been allocated to the assets acquired based on their respective fair values at the date of acquisition. The following presents the fair value of the net assets acquired (in thousands):

| | |
|---|---|
| Cash and cash equivalents | $ 9 |
| Acquired grant rights | $ 1,741 |

*Sales of Common Stock*

In December 2004, we sold approximately 3.5 million shares of our common stock in a direct equity offering pursuant to a shelf registration for an aggregate purchase price of approximately $24.3 million. Our net proceeds from this transaction, after related fees and expenses, were approximately $22.9 million. The shares of common stock issued in this transaction were registered pursuant to a registration statement on Form S-3, effective August 25, 2003 (Commission File No. 333-107799) registering shares of our common stock with an aggregate offering price of $100.0 million. We may sell additional shares of our common stock pursuant to this registration statement in the future. In connection with this transaction, we will issue warrants to the placement agents representing us in this stock sale allowing them to purchase up to 225,238 shares of our common stock at a price of $6.65 per share and to purchase up to 88,707 shares of our common stock at a price of $8.00 per share. These warrants are exercisable beginning in December 2005 and expire in December 2009.

*Research Grants*

We have a Small Business Technology Transfer grant from the National Cancer Institute to support our Phase 2 clinical trial of INGN 241 in patients with metastatic melanoma. Provided we perform the work and incur the costs contemplated by this grant, it will provide up to $1.3 million of aggregate funding in future periods during the course of this clinical trial to evaluate the efficacy and biologic activity of INGN 241 in this indication.

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Magnum, our wholly-owned subsidiary, has a Small Business Innovation Research grant from the National Institutes of Health for the development of complementary adenoviral vectors for the treatment of cancer. Provided we perform the work and incur the costs contemplate by this grant, it will provide up to $869,000 of aggregate funding in future periods.

**Critical Accounting Policies**

*Use of Estimates.* The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Cash, Cash Equivalents and Short-term Investments.* Our cash, cash equivalents and short-term investments include investments in short-term, investment grade securities, which currently consist primarily of United States federal government obligations. These investments are classified as held-to-maturity and are carried at amortized cost. At any point in time, amortized costs may be greater or less than fair value. If investments are sold prior to maturity, we could incur a realized gain or loss based on the fair market value of the investments at the date of sale. We could incur future losses on investments if the investment issuer becomes impaired or the investment is downgraded.

*Intangible Assets.* Grant rights acquired, which are presented as an intangible asset on our balance sheet, resulted from our asset acquisition related to the Magnum purchase in October 2004. We amortize that asset to expense on a straight-line basis over the estimated remaining life of that asset.

*Research and Development Costs.* In conducting our clinical trials of ADVEXIN therapy and other product candidates, we procure services from numerous third-party vendors. The cost of these services constitutes a significant portion of the cost of these trials and of our research and development expenses in general. These vendors do not necessarily provide us billings for their services on a regular basis and, accordingly, are often not a timely source of information to determine the costs we have incurred relative to their services for any given accounting period. As a result, we

make significant accounting estimates as to the amount of costs we have incurred relative to these vendors in each accounting period. These estimates are based on numerous factors, including, among others, costs set forth in our contracts with these vendors, the period of time over which the vendor will render the services and the rate of enrollment of patients in our clinical trials. Using these estimates, we record expenses and accrued liabilities in each accounting period that we believe fairly represent our obligations to these vendors. Actual results could differ from these estimates, resulting in increases or decreases in the amount of expense recorded and the related accrual. We have consistently applied these estimation procedures in the past and plan to continue applying such procedures in the same manner during the foreseeable future. Our experience has been that our estimates have reasonably reflected the expenses we actually incur.

**Recently Issued Accounting Pronouncements**

See Note 4 in the Unaudited Notes to Condensed Financial Statements in the Financial Statements section above for a discussion of recently issued accounting pronouncements related to stock-based compensation.

**Results of Operations**

***Comparison of Quarters Ended March 31, 2005 and March 31, 2004***

In the following discussions in Results of Operations and Liquidity and Capital Resources, references to the 2005 period refer to the three months ended March 31, 2005 and references to the 2004 period refer to the three months ended March 31, 2004.

*Revenues*

*Contract Services, Grant and Other Revenue.* For the 2005 period, we earned revenues from (a) research grants from U.S. Government agencies and (b) third parties under agreements to provide manufacturing process development and product production services for them. In the 2004 period, we earned revenue from (a) research grants from U.S. Government agencies and (b) contract research services provided to Aventis, one of our stockholders, under an agreement through which Aventis provided funding for the conduct of a Phase 2 clinical trial of ADVEXIN therapy in breast cancer. Total contract services, grant and other revenue was $509,000 for the 2005 period compared to $109,000 for the 2004 period, an increase of 367%. This increase was primarily due to (1)

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revenue earned under the Small Business Innovation Research grant held by Magnum, our wholly-owned subsidiary, as a result of our acquisition of Magnum in October 2004, which is revenue we did not earn in the 2004 period and (2) increased contract services revenues from third parties under agreements to provide manufacturing process development and product production services for them.

*Costs and Expenses*

*Research and Development.* Research and development expenses were $5.2 million for the 2005 period, compared to $4.3 million for the 2004 period. These expenses included compensation related to the issuance of stock options of zero in the 2005 period and $44,000 in the 2004 period. This 21% increase in research and development expenses is a result of increased activity related to (1) the preparation of the Biologics License Application (BLA) for ADVEXIN therapy for filing with the FDA and (2) the production of clinical materials to support our clinical trials for ADVEXIN therapy and other product candidates.

*General and Administrative.* General and administrative expenses were $1.8 million for the 2005 period compared to $1.4 million in for the 2004 period. These expenses included compensation related to the issuance of stock options of $88,000 in the 2005 period and $39,000 in the 2004 period. This 29% increase in general and administrative expenses is due to (1) increased activities and resources necessary to support increased research and development activities, (2) increased investor relations and public relations expenses related to operating as a publicly-traded company and (3) increased compensation expense arising from certain stock options issued during 2004 as a result of the market price of our common stock being generally higher during the 2005 period than during the 2004 period.

*Compensation Related to the Issuance of Stock Options.* Compensation related to the issuance of stock options was $88,000 for the 2005 period compared to $83,000 for the 2004 period. This compensation expense is relatively unchanged in the 2005 and 2004 periods since there was no significant difference between these periods in the aggregate number of stock options outstanding that give rise to this compensation expense.

See footnote 4 of the Unaudited Notes to Condensed Financial Statements in the Financial Statements section above for a discussion of our application of Statement of Financial

Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation and the expected future effects of our adoption of SFAS No. 123R, Share-Based Payment.

In addition to the future effects of our adoption of SFAS No. 123R, the amount of stock option compensation expense to be recorded in future periods may increase if additional options are issued at a price below the market price of common stock at the date of grant, the market value of our stock increases or additional options are granted to individuals or entities other than employees or directors. This compensation expense may decrease if unvested options for which deferred compensation has been recorded are subsequently forfeited or as previously recorded deferred compensation becomes fully amortized.

*Interest Income, Interest Expense and Other Income*

Interest income was $184,000 for the 2005 period compared to $67,000 for the 2004 period, an increase of 175%. This increase was primarily due to higher interest rates earned on our invested funds during the 2005 period compared to the 2004 period.

Interest expense was $150,000 for the 2005 period compared to $134,000 for the 2004 period, an increase of 12%. This increase was primarily due to additional borrowings subsequent to the 2004 period to finance equipment acquisitions.

Other income was $275,000 for the quarter ended March 31, 2005 compared to $250,000 for 2004. This income is earned primarily from our sublease of space to M. D. Anderson Cancer Center under which there were no significant changes between the 2005 period and the 2004 period.

**Liquidity and Capital Resources**

We have incurred annual operating losses since our inception, and at March 31, 2005, we had an accumulated deficit of $123.6 million. From inception through March 31, 2005, we have financed our operations primarily from the following sources:

- $49.7 million of collaborative research and development payments from Aventis;
- $41.4 million of equity sales in December 2003 and December 2004 through registered direct offerings under a shelf registration filed with the Securities and Exchange Commission;

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$39.4 million of private equity sales to Aventis;

$32.2 million of net proceeds from our initial public offering in October 2000;

$26.6 million of private equity sales, net of offering costs, to others (including $10.8 million from the private sale of our common stock in June 2003);

$16.4 million from contract services, grants, interest and other income;

$9.9 million in mortgage financing from banks for our facilities;

$7.5 million of sales of ADVEXIN therapy product to Aventis for use in later-stage clinical trials; and

$5.3 million in leases and notes payable from commercial lessors and lenders to acquire equipment pledged as collateral for those leases and notes.

At March 31, 2005, we had cash, cash equivalents and short-term investments of $32.6 million, compared to $38.2 million at December 31, 2004. Cash and cash equivalents constituted $16.6 million and $30.2 million of these amounts at March 31, 2005, and December 31, 2004, respectively. This decrease in cash and cash equivalents at March 31, 2005, as compared to December 31, 2004 was due to activity during the three months ended March 31, 2005, that included (1) $5.9 million of cash and cash equivalents used in operating activities (2) $8.2 million of cash and cash equivalents used by investing activities and, (3) $440,000 provided by financing activities. We expect to continue to focus our activities primarily on conducting Phase 3 and other clinical trials, conducting data analysis related to those trials, preparing regulatory documentation submissions to the FDA, producing ADVEXIN therapy and other clinical materials for use in our clinical trials and conducting pre-marketing activities for ADVEXIN therapy. We expect to continue our research and development of various other gene-based technologies. If ADVEXIN therapy or any of our other product candidates are approved for commercial sale by the FDA, we expect to conduct activities supporting the marketing, sales, production and distribution of those products, either ourselves or in collaboration with other parties. The majority of our expenditures for the foreseeable future will most likely be for these activities as they relate to ADVEXIN therapy. These activities may increase the rate at which we use cash in the future as compared to the cash we used for operating activities

during the quarter ended March 31, 2005. We believe our existing working capital can fund our operations for the next 18 to 21 months, although we may have to make adjustments to the scope of operations to achieve that objective and unforeseen events could shorten that time period. Our existing resources may not be sufficient to support the commercial introduction of any of our product candidates. In order to fund our operating losses, we will need to raise additional funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. We do not know whether such additional financing will be available when needed or on terms favorable to us or our stockholders.

Net cash used in operating activities was $5.9 million for the 2005 period compared to $5.3 million for the 2004 period. This increase was due to:

A larger net loss during the 2005 period compared to the 2004 period, plus

An increase in other assets during the 2005 period that was less than the increase during the 2004 period due to the 2004 period containing increases in grant funding receivable and prepaid expenses to a level that has not changed materially during subsequent periods, plus

An aggregate decrease in accounts payable and accrued liabilities during the 2005 period compared to an aggregate increase in accounts payable and accrued liabilities during the 2004 period due to variations in the timing of payments to vendors that is a function of the nature of vendors to whom we have obligations and variations in the terms of payment to them, less

Depreciation that increased in the 2005 period compared to the 2004 period due to acquisitions of property and equipment subsequent to the 2004 period, less

Compensation related to stock options that was relatively unchanged between periods due to there being no significant difference between the 2005 period as compared to the 2004 period in the number of stock options outstanding that give rise to this compensation expense, less

Amortization during the 2005 period of grant rights acquired for which there was no similar expense during the 2004 period since the rights being amortized arose in connection with our acquisition of Magnum in October 2004, less

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An increase in deferred revenue during the 2005 period that was greater than the increase during the 2004 period due to (1) an increase in payments from third parties in advance of us performing work under agreements to provide manufacturing process development services for them and (2) an increase in funding received under research grants related to prepaid expenses for which the recognition of the expense and the related grant revenue is deferred to future periods.

Net cash used in investing activities was $8.2 million for the 2005 period compared to $18.5 million for the 2004 period. This decrease was primarily due to a lower level of purchases and a higher level of maturities of short term investments during the 2005 period compared to the 2004 period. This change is due to investment activities during the 2005 period being more concentrated in government-backed securities with maturities of three months or less, which is determined by variations in the timing of the maturities of investments and our short-term needs for cash to conduct our operations.

We have no obligations at this time to purchase significant amounts of additional property or equipment, but our needs may change. It may be necessary for us to purchase larger amounts of property and equipment to support our clinical programs and other research, development and manufacturing activities. We may need to obtain debt or lease financing to facilitate such purchases. If that financing is not available, we may need to use our existing resources to fund those purchases, which could result in a reduction in the cash and cash equivalents available to fund operating activities.

Net cash provided by financing activities was $440,000 during the 2005 period compared to net cash used in financing activities of $328,000 during the 2004 period. This change was due to:

Higher proceeds from sales of common stock due to a higher level of stock option exercises in the 2005 period compared to the 2004 period;

An increase in proceeds from notes payable in the 2005 period compared to the 2004 period due to additional financing obtained during the 2005 period for recent equipment acquisitions; and

A decrease in principal payments under notes payable and capital leases in the 2005 period compared to the 2004 period due to several capital lease obligations outstanding at the beginning of the 2004 period

becoming fully paid during that period.

We have an agreement with VirRx, which began in 2002, to purchase shares of VirRx s Series A Preferred Stock. Key activity and provisions under this agreement include the following:

During the quarter ended March 31, 2005, we purchased $150,000 of VirRx s Series A Preferred Stock for cash. These purchases are recorded as research and development expense. We have agreed to purchase an additional $150,000 of this stock for cash on the first day of each quarter through January 1, 2006.

VirRx is required to use the proceeds from these stock sales in accordance with the terms of a collaboration and license agreement between VirRx and us for the development of VirRx s technologies. We may unilaterally terminate this collaboration and license agreement with 90 days prior notice, which would also terminate the requirement for us to make any additional stock purchases.

Provided the collaboration and license agreement remains in place, we are required to make additional milestone stock purchases, either for cash or through the issuance of our common stock, upon the completion of Phase 1, Phase 2 and Phase 3 clinical trials involving technologies licensed under this agreement. We are required to make a $5.0 million cash milestone payment to VirRx, for which we receive no VirRx stock, upon approval by the FDA of a BLA for the first collaboration product based on these technologies. To the extent we have already made cash milestone payments, we may receive a credit of 50% of the Phase 2 clinical trial milestone payments and 25% of the Phase 3 clinical trial milestone payments against this $5.0 million cash milestone payment. The additional milestone stock purchases and cash payment are not anticipated to be required in the near future. We have an option to purchase all outstanding shares of VirRx at any time until March 2007.

We have fixed debt service obligations under notes payable for which the liability is reflected on our balance sheet. We used the proceeds from these notes payable to finance facilities and equipment. Aggregate payments due under these obligations are as follows (in thousands):

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| | |
|---|---|
| **Total debt service payments for April 1, 2005 through December 31, 2005:** | $ 878 |
| **Total debt service due during the year ended December 31:** | |
| 2006 | 1,051 |
| 2007 | 952 |
| 2008 | 693 |
| 2009 | 675 |
| Thereafter | 10,155 |
| Total debt service payments | 14,404 |
| Less portion representing interest | (5,836) |
| Total principal balance at March 31, 2005 | $ 8,568 |
| **Principal balance presented on the March 31, 2005 balance sheet as liabilities in these categories:** | |
| Current portion of notes payable | $ 606 |
| Notes payable, net of current portion | 7,962 |
| Total principal balance at March 31, 2005 | $ 8,568 |

We have a fixed rent obligation under a ground lease for the land on which we built our facilities. Since this is an operating lease, there is no liability reflected on our balance sheet for this item, which is in accordance with generally accepted accounting principles. We make total annual rent payments of $144,000 under this lease which will continue until the expiration of the initial term of this lease in September 2026. Future annual rental payments due under all operating leases are as follows (in thousands):

| | |
|---|---|
| April 1, 2005 through December 31, 2005 | $ 220 |
| Year ending December 31, | |
| 2006 | 242 |
| 2007 | 165 |
| 2008 | 149 |
| 2009 | 144 |
| Thereafter | 2,418 |
| Total minimum lease payments under operating leases | $ 3,338 |

In the normal course of business, we enter into various long-term agreements with vendors to provide services to us. Some of these agreements require up-front payment prior to

services being rendered, some require periodic monthly payments and some provide for the vendor to bill us for their services as they are rendered. In substantially all cases, we may cancel these agreements at any time with minimal or no penalty and pay the vendor only for services actually rendered. Regardless of the timing of the payments under these agreements, we record the expenses incurred in the periods in which the services are rendered.

Pursuant to a consulting agreement, we pay consulting fees of approximately $175,000 per annum to EJ Financial Enterprises, Inc., a company owned by the Chairman of our Board of Directors. EJ Financial Enterprises, Inc. provides us guidance on strategic product development, business development and marketing activities. We are obligated to continue paying this fee until we terminate the services of that company at our option.

We have a consulting agreement with Jack A. Roth, M.D., Chairman of the Department of Thoracic Surgery and Director of the Keck Center for Gene Therapy at The University of Texas M. D. Anderson Cancer Center. Dr. Roth is the primary inventor of the technology upon which our ADVEXIN therapy is based and numerous other technologies we utilize. We licensed Dr. Roth s inventions from M. D. Anderson Cancer Center. Dr. Roth is our Chief Medical Advisor and chairman of our scientific advisory board. His duties involve the regular interaction and consultation with our scientists and others on our behalf. As compensation for his services and responsibilities, this consulting agreement provides for payments to Dr. Roth of $200,000 per annum through the end of its term on September 30, 2009, with such future payments subject to adjustment for inflation. We may terminate this agreement at our option upon one year s advance notice. If we had terminated this agreement as of March 31, 2005, we would have been obligated to make final payments totaling $200,000. Dr. Roth is one of our stockholders.

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We have a consulting agreement with the placement agent and investment advisor who assisted us with the sale of our common stock in December 2004. We will pay them a fee of $25,000 per month through November 2005 in consideration for their ongoing assistance with business development and financial matters.

We sublease a portion of our facilities to M.D. Anderson Cancer Center under a lease with a non-cancelable term that expires in 2009. M.D. Anderson Cancer Center is obligated to pay us rent of approximately $79,000 per month until February 2006 and $13,000 per month thereafter.

**Risk Factors**

**If we are unable to commercialize ADVEXIN® therapy in various markets for multiple indications, particularly for the treatment of head and neck cancer, our business will be harmed.**

Our ability to achieve and sustain operating profitability depends on our ability to successfully commercialize ADVEXIN therapy in various markets for multiple indications, which depends in large part on our ability to commence, execute and complete clinical programs and obtain regulatory approvals for ADVEXIN therapy and other drug candidates. In particular, our ability to achieve and sustain profitability will depend in large part on our ability to commercialize ADVEXIN therapy for the treatment of head and neck cancer in the United States. We cannot assure you we will receive approval for ADVEXIN therapy for the treatment of head and neck cancer or other types of cancer or indications in the United States or in other countries or if approved that we will achieve significant level of sales. If we are unable to do so, our business will be harmed.

**If we fail to comply with FDA requirements or encounter delays or difficulties in clinical trials for our product candidates, we may not obtain regulatory approval of some or all of our product candidates on a timely basis, if at all.**

In order to commercialize our product candidates, we must obtain certain regulatory approvals. Satisfaction of regulatory requirements typically takes many years, and involves compliance with requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. To obtain regulatory approvals, we must, among other requirements, complete

clinical trials demonstrating our product candidates are safe and effective for a particular cancer type or other disease. Regulatory approval of a new drug is never guaranteed. The FDA has substantial discretion in the approval process. Despite the time and experience exerted, failure can occur at any stage, and we could encounter problems causing us to abandon clinical trials.

We have completed three Phase 2 clinical trials and are conducting two Phase 3 clinical trials of our lead product candidate, ADVEXIN therapy, for the treatment of head and neck cancer. In addition, we have completed a Phase 2 clinical trial of ADVEXIN therapy for the treatment of non-small cell lung cancer and are conducting a Phase 2 clinical trial of ADVEXIN therapy for the treatment of breast cancer. We also are conducting or have conducted several Phase 1 and Phase 2 clinical trials of ADVEXIN therapy for other types of cancer. Current or future clinical trials may demonstrate ADVEXIN therapy is neither safe nor effective.

While we have completed enrollment of patients with metastatic melanoma in a Phase 1/early Phase 2 clinical trial of INGN 241, a product candidate based on the mda-7 gene, and have initiated a follow-on Phase 2 clinical trial of INGN 241 for the same indication, our most significant clinical trial activity and experience has been with ADVEXIN therapy. We will need to continue conducting significant research and animal testing, referred to as pre-clinical testing, to support performing clinical trials for our other product candidates. It will take us many years to complete pre-clinical testing and clinical trials, and failure could occur at any stage of testing. Current or future clinical trials may demonstrate INGN 241 or our other product candidates are neither safe nor effective.

Any delays or difficulties we encounter in our pre-clinical research and clinical trials, in particular the Phase 3 clinical trials of ADVEXIN therapy for the treatment of head and neck cancer, may delay or preclude regulatory approval. Our product development costs will increase if we experience delays in testing or regulatory approvals or if we need to perform more or larger clinical trials than planned. Any delay or preclusion could also delay or preclude the commercialization of ADVEXIN therapy or any other product candidates. In addition, we or the FDA might delay or halt any of our clinical trials of a product candidate at any time for various reasons, including:

- the product candidate is less effective and/or more toxic than current therapies;

the presence of unforeseen adverse side effects of a product candidate, including its delivery system;

a longer than expected time required to determine whether or not a product candidate is effective;

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- the death of patients during a clinical trial, even if the product candidate did not cause those deaths;
- the failure to enroll a sufficient number of patients in our clinical trials;
- the inability to produce sufficient quantities of a product candidate to complete the trials; or
- the inability to commit the necessary resources to fund the clinical trials.

We cannot be certain the results we observed in our pre-clinical testing will be confirmed in clinical trials or the results of any of our clinical trials will support FDA approval. Pre-clinical and clinical data can be interpreted in many different ways, and FDA officials could interpret differently data we consider promising, which could halt or delay our clinical trials or prevent regulatory approval.

Despite the FDA s designation of ADVEXIN therapy as a Fast Track product, we may encounter delays in the regulatory approval process due to additional information requirements from the FDA, unintentional omissions in our BLA for ADVEXIN therapy, or other delays in the FDA s review process. We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

Despite our submission of a BLA for ADVEXIN therapy under the FDA s accelerated approval regulations, the FDA could determine that accelerated approval is not warranted and that a traditional BLA filing must be made. Such a determination could delay regulatory approval. Additionally, accelerated approval of an application could be subject to Phase 4 or post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies could cause the product to be withdrawn from the market by the FDA on an expedited basis.

**Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.**

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or certain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures or detention, injunctions or the imposition of civil or criminal penalties.

**Failure to comply with foreign regulatory requirements governing human clinical trials and marketing approval for drugs could prevent us from selling our products in foreign markets, which may adversely affect our operating results and financial conditions.**

For marketing drugs and biologics outside the United States, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require additional testing. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approval on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or to obtain required approvals could impair our ability to develop these markets and could have a material adverse effect on our results of operations and financial condition.

**We have a history of operating losses, expect to incur significant additional operating losses and may never become profitable.**

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We have generated operating losses since we began operations in June 1993. As of March 31, 2005, we had an accumulated deficit of approximately $123.6 million. We expect to incur substantial additional operating expenses and losses over the next several years as our research, development, pre-clinical testing and clinical trial activities increase. As we expand our operations and develop systems to support commercialization of our product candidates, these losses, among other things, have had, and are expected to continue to have, an adverse impact on our total assets, stockholders equity and working capital.

We have no products that have generated any commercial revenue. Presently, we earn minimal revenue from contract services activities, grants, interest income and rent from the lease of a portion of our facilities to M. D. Anderson Cancer Center. We do not expect to generate revenues from the commercial sale of products in the near future, and we may never generate revenues from the commercial sale of products.

**If we continue to incur operating losses for a period longer than we anticipate and fail to obtain the capital necessary to fund our operations, we will be unable to advance our development program and complete our clinical trials.**

Developing a new drug and conducting clinical trials is expensive. Our product development efforts may not lead to commercial products, either because our product candidates fail to be found safe or effective in clinical trials or because we lack the necessary financial or other resources or relationships to pursue our programs through commercialization. Our capital and future revenues may not be sufficient to support the expenses of our operations, the development of commercial infrastructure and the conduct of our clinical trials and pre-clinical research.

We expect we will fund our operations over approximately the next 18 to 24 months with our current working capital, which we accumulated primarily from sale of equity securities, income from contract services and research grants, debt financing of equipment acquisitions, the lease of a portion of our facilities to M. D. Anderson Cancer Center and interest on invested funds. We may need to raise additional capital sooner, however, under various circumstances, including if we experience:

- an acceleration of the number, size or complexity of our clinical trials;

slower than expected progress in developing ADVEXIN therapy, INGN 241 or other product candidates;

higher than expected costs to obtain regulatory approvals;

higher than expected costs to pursue our intellectual property strategy;

higher than expected costs to further develop and scale up our manufacturing capability;

higher than expected costs to develop our sales and marketing capability;

faster than expected rate of progress and cost of our research and development and clinical trial activities;

a decrease in the amount and timing of milestone payments we receive from collaborators;

higher than expected costs of preparing an application for FDA approval of ADVEXIN therapy;

higher than expected costs of developing the processes and systems to support FDA approval of ADVEXIN therapy;

an increase in our timetable and costs for the development of marketing operations and other activities related to the commercialization of ADVEXIN therapy and our other product candidates;

a change in the degree of success in our Phase 3 clinical trial of ADVEXIN therapy and in the clinical trials of our other products;

the emergence of competing technologies and other adverse market developments; or

changes in or terminations of our existing collaboration and licensing arrangements.

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We do not know whether additional financing will be available when needed or on terms favorable to us or our stockholders. We may need to raise any necessary funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. To the extent we raise additional capital by issuing equity securities, our stockholders will experience dilution. If we raise funds through debt financings, we may become subject to restrictive covenants. To the extent we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms not favorable to us. If we are not able to raise additional funds, we may have to delay, reduce or eliminate our clinical trials and our development programs.

**If we cannot maintain our existing corporate and academic arrangements and enter into new arrangements, we may be unable to develop products effectively, or at all.**

Our strategy for the research, development and commercialization of our product candidates may result in our entering into contractual arrangements with corporate collaborators, academic institutions and others. We have entered into sponsored research, license and/or collaborative arrangements with several entities, including M. D. Anderson Cancer Center, the National Cancer Institute, Chiba University in Japan, VirRx and Corixa Corporation, as well as numerous other institutions that conduct clinical trials work or perform pre-clinical research for us. Our success depends upon our collaborative partners performing their responsibilities under these arrangements and complying with the regulations and requirements governing clinical trials. We cannot control the amount and timing of resources our collaborative partners devote to our research and testing programs or product candidates, or their compliance with regulatory requirements which can vary because of factors unrelated to such programs or product candidates. These relationships may in some cases be terminated at the discretion of our collaborative partners with only limited notice to us. We may not be able to maintain our existing arrangements, enter into new arrangements or negotiate current or new arrangements on acceptable terms, if at all. Some of our collaborative partners may also be researching competing technologies independently from us to treat the diseases targeted by our collaborative programs.

**If we are not able to create effective collaborative marketing relationships, we may be unable to market ADVEXIN therapy successfully or in a cost-effective manner.**

To effectively market our products, we will need to develop sales, marketing and distribution capabilities. In order to develop or otherwise obtain these capabilities, we may have to enter into marketing, distribution or other similar arrangements with third parties in order to sell, market and distribute our products successfully. To the extent we enter into any such arrangements with third parties, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of such third parties. We have no experience in marketing or selling pharmaceutical products and we currently have no sales, marketing or distribution capability. We may be unable to develop sufficient sales, marketing and distribution capabilities to commercialize our products successfully.

**Serious and unexpected side effects attributable to gene therapy may result in governmental authorities imposing additional regulatory requirements or a negative public perception of our products.**

ADVEXIN therapy and most of our other product candidates under development could be broadly described as gene therapies. A number of clinical trials are being conducted by other pharmaceutical companies involving gene therapy, including compounds similar to, or competitive with, our product candidates. The announcement of adverse results from these clinical trials, such as serious unwanted and unexpected side effects attributable to treatment, or any response by the FDA to such clinical trials, may impede the timing of our clinical trials, delay or prevent us from obtaining regulatory approval or negatively influence public perception of our product candidates, which could harm our business and results of operations and depress the value of our stock.

The United States Senate has held hearings concerning the adequacy of regulatory oversight of gene therapy clinical trials, as well as the adequacy of research subject education and protection in clinical research in general, and to determine whether additional legislation is required to protect volunteers and patients who participate in such clinical trials. The Recombinant DNA Advisory Committee, or RAC, which acts as an advisory body to the National Institutes of Health, has expanded its public role in evaluating important public and ethical issues in gene therapy clinical trials. Implementation of any additional review and reporting procedures or other additional regulatory measures could increase the costs of or prolong our product development efforts or clinical trials.

We report to the FDA and other regulatory agencies serious adverse events, including those we believe may be reasonably related to the treatments administered in our clinical trials.

Such serious adverse events, whether treatment-related or not, could result in negative public perception of our treatments and require additional regulatory review or measures, which could increase the cost of or prolong our clinical trials.

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The FDA has not approved any gene therapy product or gene-induced product for sale in the United States. The commercial success of our products will depend in part on public acceptance of the use of gene therapy products or gene-induced products, which are a new type of disease treatment for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy products or gene-induced products are unsafe, and these treatment methodologies may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy products or gene-induced products could also result in greater government regulation and stricter clinical trial oversight.

**We cannot predict the safety profile of the use of ADVEXIN therapy when used in combination with other therapies.**

Many of our trials involve the use of ADVEXIN therapy in combination with other drugs or therapies. While the data we have evaluated to date suggest ADVEXIN therapy does not increase the adverse effects of other therapies, we cannot predict if this outcome will continue to be true or whether possible adverse side effects not directly attributable to the other drugs will compromise the safety profile of ADVEXIN therapy when used in certain combination therapies.

**If we fail to adequately protect our intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing drugs.**

Our commercial success will depend in part on obtaining patent protection for our products and other technologies and successfully defending these patents against third-party challenges. Our patent position, like that of other biotechnology and pharmaceutical companies, is highly uncertain. One uncertainty is the United States Patent and Trademark Office, or PTO, or the courts, may deny or significantly narrow claims made under patents issued to us or patent applications we file. This is particularly true for patent applications or patents that concern biotechnology and pharmaceutical technologies, such as ours, since the PTO and the courts often consider these technologies to involve unpredictable sciences. Another uncertainty is any patents that may be issued or licensed to us may not provide any competitive advantage to us because they may not effectively preclude others from developing and marketing products like ours. Also, our patents may be successfully challenged,

invalidated or circumvented in the future. In addition, our competitors, many of which have substantial resources and have made significant investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use and sell our potential products either in the United States or in international markets.

Our ability to develop and protect a competitive position based on our biotechnological innovations, innovations involving genes, gene-induced therapeutic protein agents, viruses for delivering the genes to cells, formulations, gene therapy delivery systems not involving viruses, and the like, is particularly uncertain. Due to the unpredictability of the biotechnological sciences, the PTO, as well as patent offices in other jurisdictions, has often required patent applications concerning biotechnology-related inventions to be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting their scope of protection against competitive challenges. Similarly, courts have invalidated or significantly narrowed many key patents in the biotechnology industry. Thus, even if we are able to obtain patents covering commercially significant innovations, our patents may not be upheld or our patents may be substantially narrowed.

Through our exclusive license from The University of Texas System for technology developed at M. D. Anderson Cancer Center, we have obtained and are currently seeking further patent protection for adenoviral p53, including ADVEXIN therapy, and its use in cancer therapy. Further, the PTO issued us a United States patent for our adenovirus production technology as well as a related patent for purified adenoviral compositions. We also control, through licensing arrangements, four issued United States patents for combination therapy involving the p53 gene and conventional chemotherapy or radiation, two issued United States patents covering the use of adenoviral p53 in cancer therapy, one issued United States patent covering adenoviral p53 as a product, one issued United States patent covering the core DNA of adenoviral p53, one issued patent covering pharmaceutical compositions of adenoviral p53 and clinical applications of such pharmaceutical compositions, as well as three patents covering our mda-7 technology. Our competitors may challenge the validity of one or more of our patents in the courts or through an administrative procedure known as an interference, in which the PTO determines the priority of invention where two or more parties are claiming the same invention. The courts or the PTO may not uphold the validity of our patents, we may not prevail in such interference proceedings regarding our patents and none of our patents may

give us a competitive advantage. In this regard, we have been notified by the PTO that an unidentified third party is attempting to provoke an interference with one of our patents directed to adenoviral p53 therapy. We do not at present know the identity of this party and cannot assess the likelihood of an interference actually being declared. Should that party prevail in an interference proceeding, a patent may issue to that party that is infringed by, and therefore potentially preclude our commercialization of, products like ADVEXIN therapy that are used for adenoviral p53 therapy.

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Schering-Plough has filed with the European Patent Office, or EPO, an opposition against our European patent directed to combination therapy with p53 and conventional chemotherapy and/or radiation. An opposition is an administrative proceeding instituted by a third party and conducted by the EPO to determine whether a patent should be maintained or revoked in part or in whole, based on evidence brought forth by the party opposing the patent. The EPO held an initial oral proceeding in October 2003 and determined our patent should be maintained as amended. Schering-Plough has appealed this decision. Resolution of this appeal will require we expend time, effort and money. If Schering-Plough ultimately prevails in having our European patent revoked on appeal, then the scope of our protection for our product in Europe will be reduced. We would not expect, however, such a result to have a significant detrimental impact on our commercialization efforts in Europe.

**Third-party claims of infringement of intellectual property could require us to spend time and money to address the claims and could limit our intellectual property rights.**

The biotechnology and pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We are aware of a number of issued patents and patent applications related to gene therapy, the treatment of cancer and the use of the p53 and other tumor suppressor genes. Schering-Plough Corporation, including its subsidiary Canji, Inc., controls various United States applications and a European patent and applications, some of which are directed to therapy using the p53 gene, and others to adenoviruses containing the p53 gene, or adenoviral p53, and to methods for carrying out therapy using adenoviral p53. Adenoviral p53 technology underlies our ADVEXIN therapy product candidate. Furthermore, we are aware of a United States patent directed to replication-deficient recombinant adenoviral vectors apparently controlled by Transgene SA. While we believe the claims of the Transgene adenoviral vector patent are invalid or not infringed by our products, Transgene could assert a claim against us.

One of the foregoing patent applications directed to p53 therapy, which we understand is owned by The Johns Hopkins University and controlled by Schering-Plough, was involved in a PTO interference proceeding with a patent owned by Canji. This Johns Hopkins application was the United States counterpart to the European patent recently revoked in its

entirety by the EPO (see below). Priority of invention in that interference was awarded by the PTO to the Johns Hopkins inventors, leading to the issuance of a United States patent, and the Canji patent has been found unpatentable. While it is our belief that the claims of the Johns Hopkins patent are invalid and not infringed by our ADVEXIN therapy, Schering-Plough or Johns Hopkins may assert that our ADVEXIN therapy, which uses p53 therapy, infringes the claims of such patent. While we believe we would have both an invalidity and non-infringement defense against such an assertion, in the United States an issued patent enjoys a presumption of validity, which can be overcome only through clear and convincing evidence. We cannot assure you such a defense would prevail.

We may also become subject to infringement claims or litigation arising out of other patents and pending applications of our competitors, if they issue, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO interference proceedings and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how or to determine the enforceability, scope and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes are often settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, the necessary licenses may not be available to us on satisfactory terms, if at all. In particular, if we were found to infringe a valid claim of the Transgene adenoviral vector United States patent, the Johns Hopkins patent or a patent that may issue from a currently pending application, our business could be materially harmed.

We have recently been involved in patent opposition proceedings before the EPO, in which we have sought to have the EPO revoke three different European patents owned or controlled by Canji/Schering-Plough. These European patents relate to the use of a p53 gene, or the use of tumor suppressor genes, in the preparation of therapeutic products. In one opposition involving a Canji European patent directed to the use of a tumor suppressor gene, the EPO revoked the European patent in its entirety in a final, non-appealable decision. In the second opposition, involving a patent that is directed to

therapeutic and other applications of the p53 gene and that is owned by Johns Hopkins and, we understand, controlled by Schering-Plough, the EPO recently revoked the patent in its entirety. The patent owner has appealed this decision and a final hearing before the EPO Technical Board of Appeals is scheduled for June of 2005. In a third case involving the use of a p53 gene, the European patent at issue was initially upheld, but finally revoked in a hearing held in late April 2004. That revocation is also final, and non-appealable. If we do not ultimately prevail in the one remaining appeal involving the revoked Johns Hopkins patent, our competitors could seek to assert their rights by means of litigation to limit or

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stop European commercial activities involving our potential products. If our competitors are successful in any such litigation, it could have a significant detrimental effect on our ability to commercialize our potential commercial products in Europe.

**We may be subject to litigation and infringement claims that may be costly, divert management s attention, and materially harm our business.**

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. The defense and prosecution of intellectual property lawsuits, PTO interference proceedings, and related legal and administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. An adverse determination may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products, if any. These outcomes could materially harm our business, financial condition and results of operations.

**If we fail to meet our obligations under license agreements, we may lose our rights to key technologies on which our business depends.**

Our business depends in part on patents licensed from third parties. Those third-party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a

loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of product candidates could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform would be severely adversely affected.

**Competition and technological change may make our product candidates and technologies less attractive or obsolete.**

We compete with pharmaceutical and biotechnology companies, including Canji, Inc. and Genvec, Inc., which are pursuing forms of treatment similar to ours for the diseases ADVEXIN therapy and our other product candidates target. We are aware Canji, with its parent Schering-Plough, has in the past been involved in research and/or development of adenoviral p53 products and has numerous patents and patent applications relating to adenoviral p53 therapy. We understand Schering-Plough has stopped its adenoviral p53 clinical trials, and it is unknown whether these parties are continuing their adenoviral p53 research and/or development efforts. We are also aware a Chinese pharmaceutical company, SiBioNo GeneTech, Inc., has recently announced it has received regulatory approval from the Chinese drug regulatory agency to market an adenoviral p53 product only in China. We control an issued Chinese patent covering adenoviral p53, and a number of pending Chinese applications directed to p53 therapy and adenoviral production. We do not at present know whether SiBioNo s adenoviral p53 product is covered by patent protection or whether it infringes our Chinese patent or pending applications. We understand enforcement of patents in China is unpredictable and we do not know if monetary damages could be recovered from SiBioNo GeneTech if its product infringes our patent or patent applications. Patent enforcement and respect of international patent standards, rules and laws have not historically been a key characteristic of the Chinese government and patent system. Further, geopolitical developments, including trade and tariff disputes between the government of China and the United States Department of Commerce could add additional uncertainty to any effort to enforce patents, recover damages, if any, or engage in the sales and marketing of patented or non-patented products in China. We also may face competition from companies that may develop internally or acquire competing technology from universities and other research institutions. As these companies develop or acquire their technologies, they may develop competitive positions that may prevent or limit our product commercialization efforts.

Some of our competitors are established companies with greater financial and other resources than ours. Other companies may succeed in developing products earlier than we do, obtaining FDA approval for products before we do or developing products that are more effective than our product candidates. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or non-competitive or result in treatments or cures superior to any therapy developed by us.

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**Even if we receive regulatory approval to market our ADVEXIN therapy, INGN 241, INGN 225 or other product candidates, we may not be able to commercialize them profitably.**

Our profitability will depend on the market s acceptance of ADVEXIN therapy, INGN 241, INGN 225, if approved, and our other product candidates. The commercial success of our product candidates will depend on whether:

- they are more effective than alternative treatments;
- their side effects are acceptable to patients and doctors;
- insurers and other third-party healthcare payers will provide adequate reimbursement for them;
- we produce and sell them at a profit; and
- we market ADVEXIN therapy, INGN 241, INGN 225 and other product candidates effectively.

**Because the target patient populations for the primary indication of ADVEXIN therapy, our lead product candidate, are small, we must achieve significant market share and obtain high per-patient prices for our products to achieve profitability.**

ADVEXIN therapy, our lead product candidate for the treatment of recurrent squamous cell cancer of the head and neck, targets diseases with small patient populations. As a result, our per-patient prices must be relatively high in order to recover our development costs and achieve profitability. We estimate the annual incidence for squamous cell cancer of the head and neck is 40,000 patients in the United States. We believe we will need to market worldwide to achieve significant market penetration. In addition, we are developing other drug candidates to treat cancers with small patient populations. Due to the expected costs of treatment for ADVEXIN therapy, we may be unable to obtain sufficient market share for our drug products at a price high enough to continue our product development efforts.

**If we are unable to manufacture our products in sufficient quantities or obtain regulatory approvals for our manufacturing facilities, or if our manufacturing process is found to infringe a valid patented process or processes of another company, then we may be unable to meet demand for our products and lose potential revenues.**

To complete our clinical trials and commercialize our product candidates, if approved, we will need access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We have used manufacturing facilities we constructed in Houston, Texas to manufacture ADVEXIN therapy, INGN 241 and other product candidates for currently planned clinical trials. We anticipate our facilities are suitable for the initial commercial launch of ADVEXIN therapy. We have no experience manufacturing ADVEXIN therapy, INGN 241 or any other product candidates in the volumes necessary to support commercial sales. If we are unable to manufacture our product candidates in clinical or, when necessary, commercial quantities, then we will need to rely on third-party manufacturers to produce our products for clinical and commercial purposes. These third-party manufacturers must receive FDA approval before they can produce clinical material or commercial product. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority than ours. In addition, we may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms. There are a limited number of contract manufacturers who currently have the capability to produce ADVEXIN therapy, INGN 241 or our other product candidates, and the inability of any of these contract manufacturers to deliver our required quantities of product candidates timely and at commercially reasonable prices would negatively affect our operations.

Before we can begin commercially manufacturing ADVEXIN therapy, INGN 241 or any other product candidate, we must obtain regulatory approval of our manufacturing facilities and process. Manufacturing of our product candidates for clinical and commercial purposes must comply with the FDA s CGMP requirements, and foreign regulatory requirements. The CGMP requirements govern quality control and documentation policies and procedures. In complying with CGMP and foreign regulatory requirements, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure the product meets applicable specifications and other requirements. We must also pass a FDA inspection prior to FDA approval.

Our current manufacturing facilities have not yet been subject to an FDA or other regulatory inspection. Failure to pass a pre-approval inspection may significantly delay FDA approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. Further, the FDA and foreign regulatory authorities have the authority to perform

unannounced periodic inspections of our manufacturing facilities

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to ensure compliance with CGMP and foreign regulatory requirements. Our facilities in Houston, Texas are our only manufacturing facilities. If these facilities were to incur significant damage or destruction, then our ability to manufacture ADVEXIN therapy, INGN 241 or any other product candidates would be significantly hampered, and our pre-clinical testing, clinical trials and commercialization efforts would be delayed.

In order to produce our products in the quantities we believe will be required to meet anticipated market demand, if our products are approved, we will need to increase, or scale-up, our production process. If we are unable to do so, or if the cost of this scale-up is not economically viable to us, we may not be able to produce our products in a sufficient quantity to meet the requirements of future demand.

Canji controls a United States patent and the corresponding international applications, including a European counterpart, relating to the purification of viral or adenoviral compositions. While we believe our manufacturing process does not infringe this patent, Canji could still assert a claim against us. We may also become subject to infringement claims or litigation if our manufacturing process infringes upon other patents. The defense and prosecution of intellectual property suits and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain.

**We rely on a limited number of suppliers for some of our manufacturing materials. Any problems experienced by such suppliers could negatively affect our operations.**

We rely on third-party suppliers for most of the equipment, materials and supplies used in the manufacturing of ADVEXIN therapy, INGN 241 and our other product candidates. Some items critical to the manufacture of these product candidates are available from only a limited number of suppliers or vendors. We do not have supply agreements with these key suppliers. To mitigate the related supply risk, we maintain inventories of these items. Any significant problem experienced by one or more of this limited number of suppliers could result in a delay or interruption in the supply of materials to us until the supplier cures the problem or until we locate an alternative source of supply. Such problems would likely lead to a delay or interruption in our manufacturing operations or could require a significant modification to our manufacturing process, which could impair our ability to manufacture our product candidates in a timely manner and negatively affect our operations.

**If product liability lawsuits are successfully brought against us, we may incur substantial damages and demand for our product candidates may be reduced.**

The testing and marketing of medical products is subject to an inherent risk of product liability claims. Regardless of their merit or eventual outcome, product liability claims may result in:

decreased demand for our product candidates;

injury to our reputation and significant media attention;

withdrawal of clinical trial volunteers;

substantial delay in FDA approval;

costs of litigation; and

substantial monetary awards to plaintiffs.

We currently maintain product liability insurance with coverage of $5.0 million per occurrence with a $15.0 million annual aggregate limit. This coverage may not be sufficient to protect us fully against product liability claims. We intend to expand our product liability insurance coverage beyond clinical trials to include the sale of commercial products if we obtain marketing approval for any of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or limit the commercialization of our products.

**We use hazardous materials in our business, and any claims relating to improper handling, storage or disposal of these materials could harm our business.**

Our business involves the use of a broad range of hazardous chemicals and materials. Environmental laws impose stringent civil and criminal penalties for improper handling, disposal and storage of these materials. In addition, in the event of an improper or

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unauthorized release of, or exposure of individuals to, hazardous materials, we could be subject to civil damages due to personal injury or property damage caused by the release or exposure. A failure to comply with environmental laws could result in fines and the revocation of environmental permits, which could prevent us from conducting our business.

**Our stock price may fluctuate substantially.**

The market price for our common stock will be affected by a number of factors, including:

- progress and results of our pre-clinical and clinical trials;
- announcement of technological innovations by us or our competitors;
- developments concerning proprietary rights, including patent and litigation matters;
- publicity regarding actual or potential results with respect to products under development by us or by our competitors;
- regulatory developments;
- the announcement of new products by us or our competitors;
- quarterly variations in our or our competitors results of operations;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;
- developments in our industry; and
- general market conditions and other factors.

In addition, stock prices for many companies in the technology and emerging growth sectors have experienced wide fluctuations that have often been unrelated to the operating performance of such companies.

**If we do not progress in our programs as anticipated, our stock price could decrease.**

For planning purposes, we estimate the timing of a variety of clinical, regulatory and other milestones, such as when a certain product candidate will enter clinical development, when a clinical trial will be completed or when an application for regulatory approval will be filed. Some of our estimates are included in this Quarterly Report on Form 10-Q. Our estimates are based on present facts and a variety of assumptions. Many of the underlying assumptions are outside of our control. If milestones are not achieved when we expect them to be, investors could be disappointed, and our stock price may decrease.

**Any acquisition we might make may be costly and difficult to integrate, may divert management resources or dilute stockholder value.**

As part of our business strategy, we may acquire assets or businesses principally relating to or complementary to our current operations, and we have in the past evaluated and discussed such opportunities with interested parties. Any acquisitions we undertake will be accompanied by the risks commonly encountered in business acquisitions. These risks include, among other things:

potential exposure to unknown liabilities of acquired companies;

the difficulty and expense of assimilating the operations and personnel of acquired businesses;

diversion of management time and attention and other resources;

loss of key employees and customers as a result of changes in management;

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the incurrence of amortization expenses; and

possible dilution to our stockholders.

In addition, geographic distances may make the integration of businesses more difficult. We may not be successful in overcoming these risks or any other problems encountered in connection with any acquisitions.

**If we lose key personnel or are unable to attract and retain additional, highly skilled personnel required to develop our products or obtain new collaborations, our business will suffer.**

We depend, to a significant extent, on the efforts of our key employees, including senior management and senior scientific, clinical, regulatory, manufacturing and other personnel. The development of new therapeutic products requires expertise from a number of different disciplines, some of which is not widely available. We depend upon our scientific staff to discover new product candidates and to develop and conduct pre-clinical studies of those new potential products. Our clinical and regulatory staff is responsible for the design and execution of clinical trials in accordance with FDA requirements and for the advancement of our product candidates toward FDA approval. Our manufacturing staff is responsible for designing and conducting our manufacturing processes in accordance with the FDA s CGMP requirements. The quality and reputation of our scientific, clinical, regulatory and manufacturing staff, especially the senior staff, and their success in performing their responsibilities, are a basis on which we attract potential funding sources and collaborators. In addition, our Chief Executive Officer and other executive officers are involved in a broad range of critical activities, including providing strategic and operational guidance. The loss of these individuals, or our inability to retain or recruit other key management and scientific, clinical, regulatory, manufacturing and other personnel, may delay or prevent us from achieving our business objectives. We face intense competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

**Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected financial reporting fluctuations and affect our reported results of operations**.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant

effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, (SFAS No. 123R) is effective for us beginning the first quarter of fiscal year 2006. This statement requires that employee stock-based compensation be measured based on its fair-value on the grant date and treated as an expense that is reflected in the financial statements over the related service period. While we are currently evaluating the impact on our consolidated financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS No. 123R will have a significant impact on our results of operations for 2005 and subsequent periods.

**Some of our insiders are parties to transactions with us that may cause conflicting obligations.**

Dr. John N. Kapoor, the Chairman of our Board of Directors, is also associated with EJ Financial Enterprises, Inc., a health care investment firm which is wholly owned by him, and therefore may have conflicts of interest in allocating his time among us and his other business activities, and he may have legal obligations to multiple entities. We have entered into a consulting agreement with EJ Financial. The consulting agreement provides we will pay EJ Financial $175,000 per year for certain management consulting services, which is based on anticipated time spent by EJ Financial personnel on our affairs. EJ Financial is also involved in the management of health care companies in various fields, and Dr. Kapoor is involved in various capacities with the management and operation of these companies. In addition, EJ Financial is involved with other companies in the cancer field. Although these companies are pursuing different therapeutic approaches for the treatment of cancer, discoveries made by one or more of these companies could render our products less competitive or obsolete.

David Parker, Ph.D., J.D., our Vice President, Intellectual Property, is a partner with the law firm Fulbright & Jaworski LLP, which provides legal services to us as our primary outside counsel for intellectual property matters.

In October 2004, we acquired all of the outstanding capital stock of Magnum Therapeutics Corporation (Magnum), a company owned by one of our executive officers. We paid

approximately $1.75 million for the Magnum stock by (1) issuing approximately

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252,000 shares of our common stock valued at approximately $1.48 million at the acquisition date and (2) assuming liabilities of approximately $272,000. With respect to the common stock we issued for the acquisition, 50% of the shares are held by an independent escrow agent for a period of one year subsequent to the acquisition date to satisfy the indemnification obligations of the selling shareholder under terms of the purchase agreement. Magnum s primary asset is the right to receive funding under a research grant from the National Institutes of Health. Such grant activities and related funding will supplement research and development programs we have in progress. During the year ended December 31, 2004, we earned $1.1 million of revenue under this grant. In the event certain of Magnum s technologies result in commercial products, we may be obligated to pay royalties related to the sales of those products to certain third parties.

We have relationships with Jack A. Roth, M.D., and M. D. Anderson Cancer Center, both of whom are affiliated with The Board of Regents of the University of Texas System, one of our stockholders. For more information concerning these relationships, see the notes to our consolidated financial statements and the footnotes thereto as of December 31, 2004, and for the year then ended, included in our Annual Report on Form 10-K, as filed with the SEC on March 15, 2005.

We believe the foregoing transactions with insiders were and are in our best interests and the best interests of our stockholders. However, the transactions may cause conflicts of interest with respect to those insiders.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Our exposure to market risk for changes in interest rates relates primarily to our fixed rate long-term debt and short-term investments in investment grade securities, which consist primarily of federal government obligations. Investments are classified as held-to-maturity and are carried at amortized cost. We do not hedge interest rate exposure or invest in derivative securities. A hypothetical 100-basis point decrease in the interest rates of our investments at the investment balances as of March 31, 2005 would decrease our interest income by approximately $327,000 per year and approximately $82,000 per quarter.

At March 31, 2005, the fair value of our fixed-rate debt approximated its carrying value based upon discounted future

cash flows using current market prices.

**Item 4. Controls and Procedures**

*Evaluation of disclosure controls and procedures.* Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

*Changes in internal control over financial reporting.* There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II**

**OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are involved from time to time in legal proceedings relating to claims arising out of our operation in the ordinary course of business, including actions relating to intellectual property rights.

We do not believe that the outcome of any present, or all litigation in the aggregate, other than our opposition of a European patent controlled by Canji discussed under Risk Factors , will have a material effect on our business. You can read the discussion of our opposition of the patents under Risk Factors.

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**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

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

None.

**Item 5. Other Information**

Pursuant to Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for disclosing the non-audit services approved by the Audit Committee to be performed by Ernst & Young LLP, our independent auditors. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. Except as set forth below, the services approved by the Audit Committee are each considered by the Audit Committee to be audit-related services closely related to the financial audit process. Each of the services was pre-approved by the Audit Committee.

The Audit Committee has also pre-approved additional engagements of Ernst & Young LLP for the non-audit services of preparation of state and federal tax returns.

**Item 6. Exhibits.**

| Exhibit Number | Description of Document |
|---|---|
| 31.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. 1350, as |

Adopted Pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934 the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

INTROGEN THERAPEUTICS, INC.

May 10, 2005 By: /s/ James W. Albrecht, Jr.
James W. Albrecht, Jr.
*On behalf of the Registrant and as Chief Financial Officer (Principal Financial and Accounting Officer)*

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