INTROGEN THERAPEUTICS INC
Form 10-Q
May 15, 2002

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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 MARCH 31, 2002

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____.

COMMISSION FILE NUMBER: 000-21291

INTROGEN THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

DELAWARE	74-2704230
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

301 CONGRESS AVENUE, SUITE 1850
AUSTIN, TEXAS 78701
(Address of principal executive offices, including zip code)

(512) 708-9310
(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 shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No
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As of March 31, 2002, the Registrant had 21,454,865 shares of its common stock, $0.001 par value, issued and outstanding.

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INTROGEN THERAPEUTICS, INC.

QUARTERLY REPORT ON FORM 10-Q

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PART I
FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

DECEMBER

	2001
ASSETS	
Current Assets:	
Cash and cash equivalents	$ 37,39
Short-term investments	11,42
Accounts receivable	13
Other current assets	67
Total current assets	49,63
Property and equipment, net of accumulated depreciation of $6,405,884 and $6,893,365, respectively	10,44
Other assets	34
Total assets	$ 60,42
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current Liabilities:	
Accounts payable	$ 94
Accrued liabilities	4,02
Deferred revenue	
Current portion of capital lease obligations and notes payable	1,48
Total current liabilities	6,46
Capital lease obligations, net of current portion	95
Notes payable, net of current portion	8,07
Deferred revenue, long-term	36
Commitments and contingencies	
Stockholders' Equity:	
Series A non-voting convertible preferred stock, $.001 par value, 100,000 shares authorized, 100,000 shares issued and outstanding	
Common stock, $.001 par value; 50,000,000 shares authorized, 21,446,363 and 21,454,865 shares issued and outstanding, respectively	2
Additional paid-in capital	94,54
Deferred compensation	(2,48
Accumulated deficit	(47,51
Total stockholders' equity	44,56
Total liabilities and stockholders' equity	$ 60,42

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

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	THREE MONTHS ENDED MARC	
	2001	2
Contract manufacturing, grant and other revenue	$ 24,442	$
Costs and expenses:		
Research and development	3,784,509	6
General and administrative	1,204,479	1
Loss from operations	(4,964,546)	(8
Interest income	106,230	
Interest expense	(221,805)	
Other income	162,411	
Net loss	$ (4,917,710)	$ (7
Net loss per share, basic and diluted	$ (0.23)	$
Shares used in computing basic and diluted net loss per share	21,268,187	21

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

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	THREE MONTHS ENDED MA	
	2001	
Cash flows from operating activities:		
Net loss	$ (4,917,710)	$
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	542,200	

Compensation related to issuance of stock options	392,176	
Adjustment to investments	500,000	
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	699,910	
Decrease (increase) in inventory	750,000	
Decrease (increase) in other assets	56,436	
Increase (decrease) in accounts payable	(397,021)	
Increase (decrease) in accrued liabilities	103,974	
Increase (decrease) in deferred revenue	(1,051,000)	
Net cash used in operating activities	(3,321,035)	
Cash flows from investing activities:		
Purchases of property and equipment	(459,633)	
Purchases of short-term investments	(23,407,897)	
Maturities of short-term investments	28,417,278	
Net cash provided by investing activities	4,549,748	
Cash flows from financing activities:		
Proceeds from sale of common stock	24,392	
Proceeds from issuance of notes payable	1,331,231	
Principal payments under capital lease obligations and notes payable	(190,114)	
Net cash provided by (used in) financing activities	1,165,509	
Net increase (decrease) in cash	2,394,222	
Cash, beginning of period	4,699,663	
Cash, end of period	$ 7,093,885	$
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 241,553	$

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

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. FORMATION AND BUSINESS:

Introgen Therapeutics, Inc., a Delaware corporation, and its subsidiaries (Introgen) develop gene therapy products for the treatment of cancer. Introgen's lead product candidate, ADVEXIN(R) gene therapy, combines the naturally occurring p53 tumor suppressor gene with Introgen's adenoviral delivery system. Introgen is conducting Phase III clinical trials of ADVEXIN gene therapy in head and neck cancer, has completed a Phase II clinical trial in non-small cell lung cancer, is conducting a Phase I/II clinical trial in breast cancer, and is conducting several Phase I clinical trials in other types of cancer. Introgen is

developing additional gene therapy product candidates, notably those based on the mda-7 and PTEN genes, as well as associated vector technologies for delivering the gene-based products into target cells. Introgen's INGN 241 product candidate, which combines the mda-7 gene with Introgen's gene delivery system, is undergoing safety testing in a Phase I clinical trial. Introgen is developing therapies for cancer and other diseases based on the use of genes as therapeutic agents, which may offer safer and more effective treatments than are currently available.

Introgen manufactures its own gene therapy-based products for use in clinical trials. Introgen has not generated any significant revenues from unaffiliated third parties, nor is there any assurance of future product revenues. Introgen's research and development activities involve a high degree of risk and uncertainty, and its ability to successfully develop, manufacture and market its proprietary products is dependent upon many factors. These factors include, but are not limited to, the need for additional financing, the reliance on collaborative research and development arrangements with corporate and academic affiliates, and the ability to develop manufacturing, sales and marketing experience. Additional factors include uncertainties as to patents and proprietary technologies, competitive technologies, technological change and risk of obsolescence, development of products, competition, government regulations and regulatory approval, and product liability exposure. As a result of the aforementioned factors and the related uncertainties, there can be no assurance of Introgen's future success.

Since its inception in 1993, Introgen has used its resources primarily to conduct research and development activities for ADVEXIN gene therapy and, to a lesser extent, for other product candidates. At March 31, 2002, Introgen had an accumulated deficit of approximately $55.5 million. Introgen anticipates that it will incur losses in the future that are likely to be greater than cumulative losses incurred in prior years. Introgen expects that cash needed for operating activities may increase as it continues its ADVEXIN gene therapy Phase III clinical trials and its research and development of various gene therapy technologies. Since inception, Introgen's only significant revenues have been payments from Aventis Pharma (Aventis) under collaborative research and development agreements for Introgen's early-stage development work on ADVEXIN gene therapy and Aventis' purchases of ADVEXIN gene therapy product Introgen manufactured for Aventis' use in the later-stage clinical trials it previously performed. Introgen has also earned revenue from federal research grants, contract manufacturing and process development activities and interest income on cash placed in short-term investments.

Until June 30, 2001, Introgen developed therapeutics based on p53 and on K-ras pathway inhibition under two collaboration agreements with Aventis Pharmaceuticals, Inc., a wholly-owned subsidiary of Aventis. In June 2001, Introgen and Aventis restructured this collaborative relationship. Under this restructuring, Introgen assumed responsibility for the worldwide development of all p53- and K-ras-based products, and acquired additional marketing and commercialization rights with respect to those products. Introgen assumed the control and performance of ongoing clinical trials for p53- and K-ras-based products and is now fully responsible for all pre-clinical research and development and clinical trials for new gene therapy products. As of March 31, 2002, Introgen had an accrued liability of approximately $1.0 million for amounts Introgen may have to pay Aventis for costs Aventis incurred with third parties in completing the transition of these clinical trials from Aventis to Introgen.

In accordance with the restructured p53 and K-ras collaboration agreement, Aventis licensed to Introgen all patents covering the manufacture, sale, offering for sale, importation or use of ADVEXIN gene therapy, all K-ras patents and delivery patents and all proprietary Aventis targeting technologies. Aventis agreed not to conduct any activities directed to the development or

commercialization of any gene therapy products using the p53 or K-ras genes for a period of seven years. Introgen now has the exclusive, worldwide right to market and manufacture the products developed under each of the prior collaboration agreements, as well as any new p53- or K-ras-based gene therapy products. Aventis transferred to Introgen all trademarks and goodwill associated with the developed p53-based gene therapy products.

2. BASIS OF PRESENTATION:

The accompanying condensed, consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and, accordingly, do not include all of the information and footnotes required under generally accepted accounting principles in the United States for complete financial statements. In the opinion of management, all accounting entries considered necessary for a fair presentation have been made in preparing these financial statements. Operating results for the three month period ended March 31, 2002, are not necessarily indicative of the results that may be expected for the entire fiscal year. For further information, refer to the consolidated financial statements and footnotes thereto as of December 31, 2001, and for the six months then ended, included in Introgen's Transition Report on Form 10-K, as filed with the SEC on March 20, 2002.

On March 12, 2002, Introgen filed a report with the SEC on Form 8-K reporting its dismissal of Arthur Andersen LLP and concurrent engagement of Ernst & Young LLP as its independent auditors for the fiscal year ending December 31, 2002.

3. NET LOSS PER SHARE:

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Due to losses incurred in all periods presented, the shares associated with stock options, warrants and non-voting convertible preferred stock are not included because they are anti-dilutive.

4. INVESTMENT IN VIRRX, INC.:

During the quarter ended March 31, 2002, Introgen entered into an agreement with VirRx, Inc. (VirRx) to purchase shares of its Series A Preferred Stock. In accordance with the agreement, Introgen purchased $75,000 of VirRx Series A Preferred Stock for cash during that period. Introgen has agreed to purchase an additional $150,000 of this stock for cash on the first day of each quarter beginning April 1, 2002, and continuing through January 1, 2006. Introgen has made the April 1, 2002 purchase. VirRx is required to use the proceeds from these stock sales in accordance with the terms of a collaboration and license agreement between Introgen and VirRx for the development of VirRx's technologies. Introgen may unilaterally terminate this collaboration and license agreement with 90 days prior notice at any time after March 7, 2003, which would also terminate the requirement for Introgen to make any additional stock purchases. Provided the collaboration and license agreement remains in place, Introgen will make additional milestone stock purchases, either for cash or through the issuance of Introgen common stock, upon the completion of Phase I, Phase II and Phase III clinical trials involving technologies licensed under this agreement and will make a $5.0 million cash milestone payment to VirRx, for which Introgen receives no VirRx stock, upon approval by the United States Food

and Drug Administration (FDA) of a biologics license application involving these technologies. To the extent Introgen has already made cash milestone payments, it may receive a credit of 50% of the Phase II clinical trial milestone payments and 25% of the Phase III 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. Introgen has an option to purchase all outstanding shares of VirRx at any time until March 2007.

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

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes thereto included in this Report on Form 10-Q. The discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are based on our current expectations and entail various risks and uncertainties. Our actual results could differ materially from those projected in the forward-looking statements as a result of various factors, including those set forth below under "Factors Affecting Future Operating Results."

OVERVIEW

We are a leading developer of gene therapy products for the treatment of cancer. Our drug discovery and development programs have resulted in innovative approaches by which physicians use genes to treat cancer and other diseases. Our lead product candidate, ADVEXIN(R) gene therapy, combines the p53 gene, one of the most potent members of a group of naturally occurring genes, the tumor suppressor genes, which act to protect cells from becoming cancerous, with a gene delivery system that we have developed and extensively tested. We are conducting pivotal Phase III clinical trials of ADVEXIN gene therapy in head and neck cancer. Pivotal

Phase III trials are typically the final trials required for FDA approval. We have completed a Phase II clinical trial in non-small cell lung cancer, a category that includes approximately 80% of the various types of lung cancer. Phase II trials are efficacy trials. We are conducting a Phase I/II trial of ADVEXIN gene therapy in breast cancer. We are also conducting several Phase I clinical trials, or safety trials, of ADVEXIN gene therapy in other types of cancer. To date, doctors at clinical sites in North America, Europe and Japan have treated hundreds of patients with ADVEXIN gene therapy, establishing a large safety database.

We are developing additional gene therapy product candidates that we believe may be effective in treating certain cancers, notably those based on the mda-7 and PTEN genes, as well as associated vector technologies for delivering the gene-based products into target cells. Our INGN 241 product candidate, which combines the mda-7 gene with our gene delivery system, is undergoing safety testing in a Phase I clinical trial.

Since our inception in 1993, we have used our resources primarily to conduct research and development activities for ADVEXIN gene therapy and, to a lesser extent, for other product candidates. At March 31, 2002, we had an accumulated deficit of approximately $55.5 million. We anticipate that we will incur losses in the future that are likely to be greater than cumulative losses incurred in prior years. At March 31, 2002, we had cash, cash equivalents and short-term

investments of $41.7 million. During the three months ended March 31, 2002, we used $6.7 million of cash for operating activities. This cash usage rate may increase in future periods as we continue our ADVEXIN gene therapy Phase III clinical trials and our research and development of various other gene therapy technologies. Since our inception, our only significant revenues have been payments from Aventis under collaborative research and development agreements for our early-stage development work on ADVEXIN gene therapy and Aventis' purchases of ADVEXIN gene therapy product we manufactured for use in the later-stage clinical trials it previously performed. As a result of the June 2001 restructuring of our collaborative relationship with Aventis, we no longer receive these revenues from Aventis. We have also earned interest income on cash placed in short-term investments. We may 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.

Until June 30, 2001, we developed therapeutics based on p53 and on K-ras pathway inhibition under two collaboration agreements with Aventis Pharmaceuticals, Inc., a wholly-owned subsidiary of Aventis. In June 2001, we restructured this collaborative relationship. Under this restructuring, we assumed responsibility for the worldwide pre-clinical and clinical development of all p53- and K-ras-based gene therapy products, acquired all marketing and commercialization rights with respect to those products, sold $25.0 million of non-voting preferred stock to Aventis (for which we received payment in July 2001), and made a one-time payment in August 2001 of $2.0 million to Aventis in consideration for internal costs it incurred in facilitating the transition of control and performance of these clinical trials to us. We no longer receive collaborative research and development or product sales revenue from Aventis, which, over the life of the collaboration, totaled $57.2 million and $7.5 million, respectively. As of March 31, 2002, we had an accrued liability of approximately $1.0 million for amounts we may have to pay Aventis for costs Aventis incurred with third parties in completing the transition of these clinical trials from Aventis.

In accordance with the restructured p53 and K-ras collaboration agreement, Aventis licensed to us all of its patents covering the manufacture, sale, offering for sale, importation or use of ADVEXIN gene therapy and other K-ras patents, delivery patents and targeting technologies. Aventis also agreed, for a period of seven years, not to conduct any activities directed to the development or commercialization of any gene therapy products using the p53 or K-ras genes. We now have the exclusive, worldwide right to market and manufacture the products developed under each of the prior collaboration agreements, as well as any new p53- or K-ras-based gene therapy products. Aventis transferred to us all trademarks and goodwill associated with ADVEXIN gene therapy.

CRITICAL ACCOUNTING POLICIES

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted 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.

Short-Term Investments. Short-term investments consist of investments in short-term, investment grade securities, which consist primarily of federal and state government obligations, commercial paper and/or corporate bonds with various maturity dates not exceeding one year. All short-term investments have been 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. Additionally, we could incur future losses on investments if the investment issuer becomes impaired or the investment is downgraded.

Research and Development Costs. In conducting our pivotal Phase III clinical trials of ADVEXIN gene therapy, 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 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.

RESULTS OF OPERATIONS

REVENUES

Contract Manufacturing, Grant and Other Revenue. We earn contract manufacturing revenues from third parties under agreements to provide manufacturing process development services and to produce products for them. We earn grant revenue under research grants from U.S. Government agencies. Contract manufacturing, grant and other revenue was $228,782 for the quarter ended March 31, 2002, compared to $24,442 for the quarter ended March 31, 2001. This increase was due to our having multiple contract manufacturing agreements in place in 2002 with Biogen, Inc. and other companies, compared to limited activity in 2001, and having in place a larger number of Federal grants in 2002 compared to 2001.

COSTS AND EXPENSES

Research and Development. Research and development expenses, excluding amortization of deferred stock compensation of $107,000 in 2002 and $111,000 in 2001, were $6.6 million for the quarter ended March 31, 2002, compared to $3.7 million for the quarter ended March 31, 2001. As a result of the June 2001 restructuring of our collaborative relationship with Aventis, we assumed responsibility for conducting and funding the Phase II and Phase III clinical trials for ADVEXIN gene therapy subsequent to that date. The 78% increase in research and development expenses in 2002 compared to 2001 is a result of our being responsible for all expenses of those trials in 2002, whereas we incurred no such expenses in 2001 since Aventis paid the costs of those trials during that time.

General and Administrative. General and administrative expenses, excluding amortization of deferred stock compensation of $282,000 in 2002 and $281,000 in 2001, were $1.5 million for the quarter ended March 31, 2002, compared to $924,000 for the quarter ended March 31, 2001. This 62% increase was primarily due to the additional administrative costs associated with conducting the Phase

II and Phase III clinical trials for ADVEXIN gene therapy as a result of restructuring our collaboration with Aventis.

Amortization of Deferred Compensation. Amortization of deferred stock compensation was $390,000 for the quarter ended March 31, 2002, compared with $392,000 for the quarter ended March 31, 2001. This expense was relatively constant between these periods since substantially all options to purchase common stock issued subsequent to March 31, 2001 have had an option price equal to the market price of our common stock on the date of issuance, such that no additional deferred compensation has arisen since March 31, 2001. Also, there have been no options of significance for which deferred compensation arising prior to March 31, 2001, became fully amortized subsequent to that date. The amount of deferred 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 and 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 $192,000 for the quarter ended March 31, 2002, compared with $106,000 for the quarter ended March 31, 2001, which is an increase of 81%. Interest income for 2001 is net of a $500,000 reduction of interest income to recognize the decline in the market value of certain commercial paper held as an investment. After considering the effects of this reduction, our interest income declined in 2002 compared to 2001 due to a general decrease in interest rates between periods and our more conservative investment philosophy subsequent to the events of September 11, 2001.

Interest expense was $219,000 for the quarter ended March 31, 2002, compared with $222,000 for the quarter ended March 31, 2001. This expense was relatively constant between these periods as there were no new borrowings of significance subsequent to March 31, 2001, and principal reductions as a result of debt service payments since March 31, 2001 were minimal since most of our significant debt is still in the early stages of principal amortization.

Other income was $316,000 for the quarter ended March 31, 2002, compared to $162,000 for the quarter ended March 31, 2001. This 95% increase in other income was due to our sublease of space to M. D. Anderson Cancer Center that was in place for all of the 2002 period but for only a portion of the 2001 period.

LIQUIDITY AND CAPITAL RESOURCES

We have incurred annual operating losses since our inception, and at March 31, 2002, we had an accumulated deficit of $55.5 million. From inception through March 31, 2002, we have financed our operations using $49.7 million of collaborative research and development payments from Aventis, $32.2 million of net proceeds from our initial public offering in October 2000, $39.4 million of private equity sales to Aventis, $14.6 million of private equity sales, net of offering costs, to others, $7.5 million of sales of ADVEXIN gene therapy product to Aventis for use in later-stage clinical trials, $9.2 million in mortgage financing from banks for our facilities, $4.3 million in leases from commercial leasing companies to acquire equipment pledged as collateral for those leases and $5.3 million from interest income earned on cash and short- and long-term investments.

At March 31, 2002, we had cash and short-term investments of $41.7 million,

compared with $48.8 million at December 31, 2001. This decrease was primarily a result of the use of cash to fund our operations. For at least the next two years, we expect to focus our activities primarily on conducting Phase III clinical trials, conducting data analysis, preparing regulatory documentation including FDA submissions and conducting pre-marketing activities for ADVEXIN gene therapy. We also expect to continue our research and development of various other gene therapy technologies. The majority of our expenditures over this period will most likely relate to the clinical trials of ADVEXIN gene 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 three months ended March 31, 2002. We believe our existing working capital can fund our operations for the next eighteen to twenty-four months, although 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. We may 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 $6.7 million for the quarter ended March 31, 2002, and $3.3 for the quarter ended March 31, 2001. The increase in cash used was primarily the result of (1) a higher net loss in 2002 compared to 2001, (2) a smaller decrease in receivables and inventory attributable to Aventis collaboration activities in 2002 compared to 2001 due to the restructuring of the Aventis collaboration in 2001, and (3) an increase in other assets in 2002 compared to a decrease in other assets in 2001 due to a higher level of clinical trial activity requiring an increase in the prepayment of certain expenses. These increases were offset by (1) a smaller decrease in accounts payable and an increase in accrued liabilities in 2002 compared to 2001 due to the increase in operating expenses in 2002 resulting from Advexin clinical trials activity and (2) an increase in deferred revenue in 2002 compared to a decrease in 2001. The decrease in deferred revenue in 2001 was related to the earning of revenue on sales of inventory to Aventis, an activity that no longer exists as a result of the Aventis collaboration restructuing in 2001. The increase in deferred revenue in 2002 was related to the deferral of the recognition of income under the sublease of space to M. D. Anderson Cancer Center, which was in place for all of the 2002 period but for only a portion of the 2001 period.

Net cash provided by investing activities was $421,000 for the quarter ended March 31, 2002, and $4.5 million for the quarter ended March 31, 2001. This decrease is primarily due to investing activity in 2002 being focused within cash and cash equivalents while in 2001 there was a higher level of investment activity that resulted in the movement of funds between cash and cash equivalents, short-term and long-term investments. This change in the nature of investment activity was due to a more conservative investment philosophy subsequent to the events of September 11, 2001. The costs associated with purchases of property and equipment declined in 2002 compared to 2001 because the 2001 period included costs related to the completion of tenant improvements to the space subleased to M. D. Anderson Cancer Center, for which there were no similar costs in 2002. While we have no obligations at this time to purchase significant amounts of additional property or equipment, 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, cash equivalents and short-term investments available to fund operating activities.

Net cash used by financing activities was $354,000 for the quarter ended March 31, 2002, and net cash provided by financing activities was $1.2 million for the quarter ended March 31, 2001. This change between periods is due to the 2001 period including the receipt of proceeds from a note payable used to finance tenant improvements for the sublease of space to M. D. Anderson Cancer Center, which were completed in 2001. Meanwhile, principal payments under capital lease obligations and notes payable were higher in 2002 compared to 2001 due to debt service requirements commencing on this note payable subsequent to March 31, 2001.

During the quarter ended March 31, 2002, we entered into an agreement with VirRx, Inc. (VirRx) to purchase shares of its Series A Preferred Stock. In accordance with the agreement, we purchased $75,000 of VirRx Series A Preferred Stock for cash during that period. We have agreed to purchase an additional $150,000 of this stock for cash on the first day of each quarter beginning April 1, 2002, and continuing through January 1, 2006. We have made the April 1, 2002 purchase. VirRx is required to use the proceeds from these stock sales in accordance with the terms of a collaboration and license agreement between Introgen and VirRx for the development of VirRx's technologies. We may unilaterally terminate this collaboration and license agreement with 90 days prior notice after March 7, 2003, which would also terminate our requirement to make any additional stock purchases. Provided the collaboration and license agreement remains in place, we will make additional milestone stock purchases, either for cash or through the issuance of our common stock, upon the completion of Phase I, Phase II and Phase III clinical trials involving technologies licensed under this agreement and we will make a $5.0 million cash milestone payment to VirRx, for which we receive no VirRx stock, upon FDA approval of a biologics license application involving these technologies. To the extent we have already made cash milestone payments, we may receive a credit of 50% of the Phase II clinical trial milestone payments and 25% of the Phase III clinical trial milestone payments against this $5.0 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 and lease payment obligations under notes payable and capital leases for which the liability is reflected on our balance sheet. We used the proceeds from these notes payable and leases to finance facilities and equipment. Aggregate payments due under these obligations are as follows:

TOTAL DEBT SERVICE AND CAPITAL LEASE PAYMENTS DUE DURING THE YEAR ENDING DECEMBER 31,	
2002	$ 2,292,602
2003	2,218,278
2004	1,440,121
2005	1,312,536
2006	860,280
Thereafter	9,670,332
Total debt service and capital lease payments	17,794,149
Less portion representing interest	(7,271,185)
Total principal balance at December 31, 2001	$ 10,522,964
PRINCIPAL BALANCE PRESENTED ON THE DECEMBER 31, 2001 BALANCE SHEET AS LIABILITIES IN THESE CATEGORIES:	

Current portion of obligations under capital leases and notes payable	$ 1,486,376
Capital lease obligations, net of current portion	957,467
Notes payable, net of current portion	8,079,121
Total principal balance at December 31, 2001	$ 10,522,964

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 principals. We make total annual rent payments of $136,188 under this lease which will continue until the expiration of the initial term of this lease in September 2026. We have other operating leases expiring in 2002 with significantly smaller rent payments that we also account for as operating leases. Future annual rental payments due under all operating leases are as follows:

YEAR ENDING DECEMBER 31,	
2002	$ 198,230
2003	136,188
2004	136,188
2005	136,188
2006	136,188
Thereafter	2,689,713
Total minimum lease payments under operating leases	$ 3,432,695

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.

We pay consulting fees of approximately $175,000 per annum to a company owned by the Chairman of our Board of Directors and which formerly employed one of our directors. 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 an individual primarily responsible for the creation of one of our technologies, who is also one of our stockholders. This agreement provides for payments to such individual of $165,000 per annum until September 30, 2002, $181,500 per annum from October 1, 2002 through September 30, 2003, and $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, 2002, we would have been obligated to make final payments to this individual totaling $173,250.

FACTORS AFFECTING FUTURE OPERATING RESULTS

WE MAY ENCOUNTER DELAYS OR DIFFICULTIES IN CLINICAL TRIALS FOR OUR PRODUCT CANDIDATES, WHICH MAY DELAY OR PRECLUDE REGULATORY APPROVAL OF SOME OR ALL OF OUR PRODUCT CANDIDATES.

In order to commercialize our product candidates, we must obtain 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 that our product candidates are safe and effective for a particular cancer type or other disease.

We are conducting Phase III clinical trials of our lead product candidate, ADVEXIN(R) gene therapy, for the treatment of head and neck cancer, and are conducting numerous Phase I and Phase II clinical trials of ADVEXIN gene therapy for other cancer types. Current or future clinical trials may demonstrate that ADVEXIN gene therapy is neither safe nor effective.

While we are conducting a Phase I clinical trial with INGN 241, a product candidate based on the mda-7 gene, our most significant clinical trial activity and experience has been with ADVEXIN gene 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 gene therapy 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 trials may demonstrate that INGN 241 or 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 III clinical trials of ADVEXIN gene 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 gene 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 failure of the product candidate to be more effective than current therapies;
- the presence of unforeseen adverse side effects of a product candidate, including its delivery system;

- the longer than expected time required to determine whether or not a product candidate is effective;
- the death of patients during a clinical trial, even though the product candidate may not have caused those deaths;
- the failure to enroll a sufficient number of patients in our clinical trials; or

- the our inability to produce sufficient quantities of a product candidate to complete the trials.

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. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us.

Outside the United States, our ability to market a product is contingent upon receiving clearances from the appropriate regulatory authorities. This foreign regulatory approval process includes all of the risks associated with FDA clearance described above.

WE HAVE A HISTORY OF OPERATING LOSSES AND EXPECT TO INCUR SIGNIFICANT ADDITIONAL OPERATING LOSSES.

We have generated operating losses since we began operations in June 1993. As of March 31, 2002, we had an accumulated deficit of approximately $55.5 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. We have no products that have generated any commercial revenue. Presently, we earn minimal revenue from contract manufacturing activities, grants, interest income and rent from the sublease to others of a portion of our facilities. In the past, we earned revenue from Aventis under collaborative agreements for research and development and sales of ADVEXIN gene therapy for use in Aventis' clinical trials, neither of which revenues we will receive in the future under our restructured agreements with Aventis. We do not expect to generate revenues from the commercial sale of products in the foreseeable future, and we may never generate revenues from the 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 for multiple disease indications is expensive. We expect that we will fund our operations over the next eighteen to twenty-four months with our current working capital, resulting primarily from the net proceeds from our initial public offering in October 2000, the sale of Series A Non-Voting Convertible Preferred Stock to Aventis in June 2001, income from contract manufacturing and research grants, debt financing of equipment acquisitions and interest on invested funds. We may raise additional capital sooner, however, due to a number of factors, including:

- an acceleration of the number, size or complexity of our clinical trials;
- slower than expected progress in developing ADVEXIN gene 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 our manufacturing capability; and

- higher than expected costs to develop our sales and marketing capability.

We do not know whether additional financing will be available when needed, or on terms favorable to us or our stockholders. We may 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 that 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 that are not favorable to us.

AS A RESULT OF THE RESTRUCTURING OF OUR COLLABORATIVE RELATIONSHIP WITH AVENTIS, OUR PRODUCT DEVELOPMENT MAY BE DELAYED.

In the past, we relied to a significant extent on Aventis to fund and support the development of products based on the p53 and K-ras genes, including ADVEXIN gene therapy. In June 2001, we restructured our collaborative relationship with Aventis. Under this restructuring, we assumed responsibility for the worldwide development of all p53- and K-ras-based products. Our development and commercialization efforts for these products could be delayed if we are unable to commit the necessary resources to fund the development of the p53 and K-ras programs.

Historically, Aventis agreed on an annual basis whether, and to what extent, it would continue to fund our early-stage development in North America of products based on the p53 or K-ras genes, which includes pre-clinical research and development and Phase I clinical trials. Since we assumed responsibility for the development of all p53 and K-ras products under the terms of the restructuring, if we decide to continue this development, we would have to fund this development ourselves or obtain funding from other sources. If we are unable to commit the necessary resources to fund this development, then our development and commercialization effort would be delayed.

Under the terms of the prior collaboration agreements with Aventis, once we had completed Phase I clinical trials of a product candidate based on the p53 and K-ras genes, Aventis could have elected to pursue later-stage clinical development of that product candidate, which includes conducting Phase II and Phase III clinical trials, commercializing the product, making all further submissions to existing IND, applications and preparing all product license applications. However, under the terms of the restructuring, we are responsible for later-stage clinical development. If we are unable to commit the necessary resources to fund this development, then our development and commercialization effort would be delayed.

IF WE CANNOT MAINTAIN OUR OTHER CORPORATE AND ACADEMIC ARRANGEMENTS AND ENTER INTO NEW ARRANGEMENTS, PRODUCT DEVELOPMENT COULD BE DELAYED.

Our strategy for the research, development and commercialization of our product candidates may require us to enter into contractual arrangements with corporate collaborators, academic institutions and others. We have entered into sponsored research and/or collaborative arrangements with several entities, including M. D. Anderson Cancer Center, Imperial Cancer Research Technology Limited, the National Cancer Institute and Corixa Corporation. Our success depends upon our collaborative partners performing their responsibilities under

these arrangements. We cannot control the amount and timing of resources our collaborative partners devote to our research and testing programs or product candidates, 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 GENE 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 successfully sell, market and distribute our products. To the extent that 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 successfully commercialize our products.

SERIOUS UNWANTED SIDE EFFECTS ATTRIBUTABLE TO GENE THERAPY MAY RESULT IN GOVERNMENTAL AUTHORITIES IMPOSING ADDITIONAL REGULATORY REQUIREMENTS OR A NEGATIVE PUBLIC PERCEPTION OF OUR PRODUCTS.

Serious unwanted side effects attributable to treatment, which physicians classify as treatment-related adverse events, occurring in the field of gene therapy may result in greater governmental regulation of our product candidates and potential regulatory delays relating to the testing or approval of our product candidates. The death in 1999 of a patient undergoing gene therapy using an

adenoviral vector to deliver a gene for disease treatment in a clinical trial that was unrelated to our clinical trials, was widely publicized. As a result of this death, the United States Senate held hearings concerning the adequacy of regulatory oversight of gene therapy clinical trials 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, or NIH, evaluated and continues to evaluate the use of adenoviral vectors in gene therapy clinical trials. The RAC has made recommendations to the NIH director concerning prospective review of study designs and adverse event reporting procedures, and the FDA has requested that sponsors of clinical trials provide detailed procedures for supervising clinical investigators and clinical trial conduct. In addition, the FDA has recently begun to conduct more frequent inspections at clinical trial sites. 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.

Following routine procedure, we report to the FDA and other regulatory agencies serious adverse events that we believe may be reasonably related to our

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

To date no governmental authority has approved any gene therapy product for sale in the United States or internationally. The commercial success of our products will depend in part on public acceptance of the use of gene therapies, 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 is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy could also result in greater government regulation and stricter clinical trial oversight.

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 that the United States Patent and Trademark Office, or PTO, or the courts, may deny or significantly narrow claims made under patents or patent applications. 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 that any patents that may be issued or licensed to us may not provide any competitive advantage to us and they 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 therapy, viruses for delivering the genes to cells, formulations, gene therapy delivery systems that do not involve 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 that patent applications concerning biotechnology-related inventions 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 that cover 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 are currently seeking patent protection for adenoviral p53, including ADVEXIN gene therapy, and its use in cancer therapy. Further, in February 2001, we were issued a United States patent for our adenovirus production technology. We also control, through licensing arrangements, two issued United States patents for combination therapy involving the p53 gene and conventional chemotherapy or radiation, and one issued United States patent covering the use of adenoviral p53 in cancer therapy. Our competitors may challenge the validity of one or more of our combination therapy, our adenoviral process technology or our adenoviral p53 therapy patents in the courts or through an administrative procedure known as an interference. 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.

The PTO has notified us that one of our patent applications, which involves the use of retrovirus, not adenovirus (which retroviral technologies do not relate to any of our current product candidates) has been allowed, but that its issuance is being suspended for the possible institution of interference proceedings. An interference proceeding is instituted by the PTO to determine, as between two or more parties claiming the same patentable invention, which party has the right to the patent. If any of these or other patent applications becomes involved in an interference proceeding, there is a likelihood that it will take many years to resolve. Resolution of any such interference will require that we expend time, effort and money. Only the application directed to the adenoviral p53 technology is relevant to our current potential products. If an interference is declared with respect to the adenoviral p53 application, and if the opponent ultimately prevails in the interference, the opponent will have a patent that could cover our potential ADVEXIN gene therapy product or its clinical use. The patent application that is currently involved in an ongoing interference proceeding does not relate to any of our product candidates. While the resolution of this interference will require that we expend time, effort and money, its outcome is not expected to affect any of our current commercialization efforts.

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 that relate 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 patent applications and a European patent and applications, some of which are directed to therapy using the p53 gene, and others to adenoviruses that contain the p53 gene, or adenoviral p53, and to methods for carrying out therapy using adenoviral p53. In addition, Canji controls an issued United States patent and its international counterparts, including a European patent, involving a method of treating mammalian cancer cells lacking normal p53 protein by introducing a p53 gene into the cancer cell.

While we believe that our potential products do not infringe any valid claim of the Canji p53 patents, Canji or Schering-Plough could assert a claim against us. 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 Canji p53 issued United States patent, our business could be materially harmed.

We are currently involved in three opposition proceedings before the European Patent Office, or EPO, in which we are seeking to have the EPO revoke three different European patents owned or controlled by Canji. 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 the use of a p53 gene, the European patent at issue was upheld following an initial hearing. A second hearing to determine whether this patent should be revoked will be upcoming. In another opposition, involving a European patent directed to the use of a tumor suppressor gene, the European Patent Office revoked the European patent in its entirety. Canji will have the opportunity to appeal this revocation. The third opposition is in an earlier stage. If we do not ultimately prevail in one or more of these oppositions, our competitors could seek to assert by means of litigation any patent surviving opposition against 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 or our collaborators' ability to commercialize our potential commercial products in Europe.

COMPETITION AND TECHNOLOGICAL CHANGE MAY MAKE OUR PRODUCT CANDIDATES AND TECHNOLOGIES LESS ATTRACTIVE OR OBSOLETE.

We compete with pharmaceutical and biotechnology companies, including Canji and Onyx Pharmaceuticals, Inc., which are pursuing other forms of treatment for the diseases ADVEXIN gene therapy and our other product candidates target. 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 their technologies, they may develop competitive positions which may prevent or limit our product commercialization efforts.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products earlier than we do, obtaining FDA approval for products more rapidly than 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.

EVEN IF WE RECEIVE REGULATORY APPROVAL TO MARKET ADVEXIN GENE THERAPY, INGN 241 OR OTHER PRODUCT CANDIDATES, WE MAY NOT BE ABLE TO COMMERCIALIZE THEM PROFITABLY.

Our profitability will depend on the market's acceptance of ADVEXIN gene therapy, INGN 241 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;
- we produce and sell them at a profit; and

- we market ADVEXIN gene therapy, INGN 241 and other product candidates effectively.

IF WE ARE UNABLE TO MANUFACTURE OUR PRODUCTS IN SUFFICIENT QUANTITIES OR OBTAIN REGULATORY APPROVALS FOR OUR MANUFACTURING FACILITY, OR IF OUR MANUFACTURING PROCESS IS FOUND TO INFRINGE A VALID PATENTED PROCESS OF ANOTHER COMPANY, THEN WE MAY BE UNABLE TO MEET DEMAND FOR OUR PRODUCTS AND LOSE POTENTIAL REVENUES.

The completion of our clinical trials and commercialization of our product candidates requires access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We use a manufacturing facility in Houston, Texas, which we constructed and own, to manufacture ADVEXIN gene therapy for our currently planned clinical trials and eventually for the initial commercial launch of ADVEXIN gene therapy. We manufacture INGN 241 and other product candidates in a separate, leased facility. We have no experience manufacturing ADVEXIN gene therapy, INGN 241 or any other product candidates in the volumes that will be 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 manufacture compounds 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 very few contract manufacturers who currently have the capability to produce ADVEXIN gene 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 gene therapy, INGN 241 or any other product candidate, we must obtain regulatory approval of our manufacturing facility and process. Manufacturing of our product candidates for clinical and commercial purposes must comply with the FDA's current Good Manufacturing Practices requirements, commonly known as CGMP, 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 that the product meets applicable specifications and other requirements. We must also pass a pre-approval inspection prior to FDA approval.

Our 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 facility 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 gene therapy or any other product candidates would be significantly hampered, and we would incur delays in our pre-clinical testing, clinical trials and commercialization efforts.

Canji controls a United States patent and corresponding international applications, including a European counterpart, relating to the purification of viral or adenoviral compositions. While we believe that our manufacturing process does not infringe upon 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 of our competitors. 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 ONLY ONE SUPPLIER FOR SOME OF OUR MANUFACTURING MATERIALS. ANY PROBLEMS EXPERIENCED BY ANY SUCH SUPPLIER COULD NEGATIVELY AFFECT OUR OPERATIONS.

We rely on third-party suppliers for some of the materials used in the manufacturing of ADVEXIN gene therapy, INGN 241 and our other product candidates. Some of these materials are available from only one supplier or vendor. Any significant problem that one of our sole source suppliers experiences could result in a delay or interruption in the supply of materials to us until that supplier cures the problem or until we locate an alternative source of supply. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations, which could negatively affect our operations.

The CellCube(TM) Module 100 bioreactor, which Corning (Acton, MA) manufactures, and Benzonase(R), which EM Industries (Hawthorne, NY) manufactures, are currently available only from these suppliers. Any significant interruption in the supply of either of these items would require a material change in our manufacturing process. We maintain inventories of these items, but we do not have a supply agreement with either manufacturer.

IF PRODUCT LIABILITY LAWSUITS ARE SUCCESSFULLY BROUGHT AGAINST US, WE MAY INCUR SUBSTANTIAL DAMAGES AND DEMAND FOR THE PRODUCTS 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;
- 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 limit. This coverage may not be sufficient to protect us fully against product liability claims. We intend to expand our product liability insurance coverage 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 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:

- the announcement of new products or services 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, including factors unrelated to our operating performance or the operating performance of our competitors.

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. Many factors may have a significant adverse effect on the market price of our common stock, including:

- results of our pre-clinical and clinical trials;
- announcement of technological innovations or new commercial products 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; and
- quarterly fluctuations in our revenues and other financial results.

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 that 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;
- 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.

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 and state government obligations, commercial paper and

corporate bonds. Investments are classified as held-to-maturity and are carried at amortized costs. We do not hedge interest rate exposure or invest in derivative securities.

At March 31, 2002, the fair value of our fixed-rate debt approximated its carrying value based upon discounted future cash flows using current market prices.

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.

On January 12, 2001, we received notice that we had been named as a defendant in a first amended complaint filed on January 11, 2001 by Canji, Inc. in an action entitled, Canji, Inc. v. Sidney Kimmel Cancer Center, Introgen Therapeutics, Inc., and Does 2 through 25 (Case No. GIC745643, in the California Superior Court for the County of San Diego, Central District). Canji filed the original complaint against the Sidney Kimmel Cancer Center, or SKCC, on March 24, 2000. On February 9, 2001, the action was removed to the United States District Court for the Southern District of California. On August 29, 2001, the case was remanded to California State Superior Court in San Diego County. The claims against us in Canji's first amended complaint arise out of SKCC's grant of an exclusive license to us to patent rights resulting from gene therapy technology developed by SKCC under a sponsored research agreement between SKCC and us. Canji contends that SKCC developed the technology using materials

provided by Canji to SKCC under a Material Transfer Agreement, or MTA. Canji also contends that under the MTA, Canji had the right of first refusal to an exclusive license to any patent rights arising out of the technology developed by SKCC using these materials and that SKCC was prohibited from disclosing to us the results of any research using Canji's materials. Canji also alleges that we wrongfully obtained rights in intellectual property derived from SKCC's use of Canji's materials and that we knew of, or consciously disregarded, the existence of the MTA.

In its answer, SKCC, who was a party to the MTA, stated that Canji's representations were false and made with the intent to defraud SKCC, and that SKCC would not have given its consent to the contract had it not been for Canji's fraudulent action. As relief against us, Canji seeks (1) a declaratory judgment that we are not entitled to the intellectual property rights conveyed by SKCC to us, and that instead, those rights belong to Canji, (2) the imposition of a constructive trust on the patent rights granted to us and (3) injunctive relief to restore Canji to the position that it was in prior to SKCC's grant of intellectual property rights to us. While Canji is not seeking an award of damages, it has requested reasonable attorney fees and costs. We believe that Canji's allegations are without merit and we intend to vigorously defend the action. The SKCC intellectual property is not material to our business.

We do not believe that the outcome of any present, or all litigation in the aggregate, other than our opposition of three European patents owned by Canji, will have a material effect on our business.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.

Pursuant to a stock purchase agreement with Aventis executed on June 30, 2001, we issued 100,000 shares of Series A Non-Voting Convertible Preferred Stock to Aventis in exchange for $25.0 million, the payment for which was received on July 2, 2001. We relied on Rule 506 promulgated under Section 4(2) of the Securities Act of 1933, as amended, as the exemption from registration, as the sale was to a single accredited investor. Under the terms of the Certificate of Designations filed in connection with the sale, the Series A Non-Voting Convertible Preferred Stock is convertible into 2,343,721 shares of our common stock at any time upon either party's election. We expect to use the proceeds from this sale for research and development, including clinical trials, the advancement of our process development and manufacturing capabilities, the initiation of product marketing and commercialization programs, and for general corporate purposes, including working capital.

We closed our initial public offering of common stock on October 17, 2000, pursuant to a Registration Statement on Form S-1, which was declared effective by the Securities and Exchange Commission on October 11, 2000. This sale of the shares of common stock generated aggregate net proceeds of approximately $32.2 million. From October 17, 2000 through March 31, 2002, and for the quarter ended March 31, 2002, we used approximately $15.5 million and $7.1 million, respectively, of these net proceeds for operating, investing and financing activities. Pending these uses, the remaining $16.7 million of net proceeds of the initial public offering are invested in interest-bearing, investment grade securities. Other than the payment of salary to our officers and the reimbursement of certain out-of-pocket expenses of our directors,

we have not made any payments out of these proceeds to our directors or officers, or any person owning ten percent or more of our equity securities.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

ITEM 5. OTHER INFORMATION.

None.

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

(a) EXHIBITS:

10.42+	Series A Preferred Stock Purchase Agreement, effective as of March 7, 2002, by and among Introgen, VirRx, Inc. and certain stockholders of VirRx, Inc.
10.43+	Collaboration and License Agreement, effective as of March 7, 2002, by and between Introgen and VirRx, Inc.

+ Confidential treatment has been requested for portions of this exhibit.

(b) REPORTS ON FORM 8-K:

In connection with the dismissal of Arthur Andersen LLP as our independent public accountants, we filed a Current Report on Form 8-K on March 12, 2002, as amended on March 18, 2002, March 20, 2002 and March 22, 2002.

SIGNATURES

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

INTROGEN THERAPEUTICS, INC.

Date: May 15, 2002

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)

EXHIBIT INDEX

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