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INTROGEN THERAPEUTICS INC  
Form 10-Q  
November 13, 2002

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UNITED STATES SECURITIES AND EXCHANGE  
COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002

OR

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_.

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COMMISSION FILE NUMBER: 000-21291

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

|   |  |
|---|--|
| DELAWARE  | 74-2704230                                 |
| (State or other jurisdiction<br>of incorporation or organization) | (I.R.S. Employer<br>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  No

As of September 30, 2002, the Registrant had 21,464,748 shares of its common stock, \$0.001 par value per share, issued and outstanding.

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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  
(in thousands, except share and per share amounts)

DECEMBER 31,  
2001  
-----

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### ASSETS

|   |           |
|---|-----------|
| Current Assets:   |           |
| Cash and cash equivalents .....                               | \$ 37,397 |
| Short-term investments .....                                  | 11,428    |
|   | -----     |
| Total cash, cash equivalents and short-term investments ..... | 48,825    |
| Accounts receivable .....                                     | 137       |
| Other current assets .....                                    | 674       |
|   | -----     |
| Total current assets .....                                    | 49,636    |
| Property and equipment, net of accumulated depreciation       |           |
| of \$6,406 and \$7,829, respectively .....                    | 10,443    |
| Other assets .....  | 345       |
|   | -----     |
| Total assets .....  | \$ 60,424 |
|   | =====     |

### LIABILITIES AND STOCKHOLDERS' EQUITY

|   |           |
|---|-----------|
| Current Liabilities:  |           |
| Accounts payable and accrued liabilities .....  | \$ 4,974  |
| Deferred revenue .....  | --        |
| Current portion of capital lease obligations and notes payable .....  | 1,487     |
|   | -----     |
| Total current liabilities .....   | 6,461     |
| Capital lease obligations, net of current portion .....   | 957       |
| Notes payable, net of current portion .....   | 8,079     |
| Deferred revenue, long-term .....   | 362       |
|   | -----     |
| Total liabilities .....   | 15,859    |
|   | -----     |
| Commitments and contingencies   |           |
| Stockholders' Equity:   |           |
| Series A non-voting convertible preferred stock, \$.001 par value,<br>100,000 shares authorized, 100,000<br>shares issued and outstanding ..... | --        |
| Common stock, \$.001 par value; 50,000,000 shares<br>authorized, 21,446,363 and 21,464,748 shares issued<br>and outstanding, respectively ..... | 21        |
| Additional paid-in capital .....  | 94,544    |
| Deferred compensation .....   | (2,485)   |
| Accumulated deficit .....   | (47,515)  |
|   | -----     |
| Total stockholders' equity .....  | 44,565    |
|   | -----     |
| Total liabilities and stockholders' equity .....  | \$ 60,424 |
|   | =====     |

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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(UNAUDITED)

(in thousands, except share and per share amounts)

|  | THREE MONTHS ENDED SEPTEMBER 30, |            |
|--|----------------------------------|------------|
|  | 2001                             | 2002       |
|  | -----                            | -----      |
| Contract services, grant and other revenue .....                       | \$ 15                            | \$ 453     |
| Costs and expenses:  |                                  |            |
| Research and development .....   | 5,045                            | 4,633      |
| General and administrative .....                                       | 1,685                            | 1,729      |
|  | -----                            | -----      |
| Loss from operations .....   | (6,715)                          | (5,909)    |
| Interest income .....  | 611                              | 136        |
| Interest expense .....   | (236)                            | (181)      |
| Other income .....   | 237                              | 261        |
|  | -----                            | -----      |
| Net loss .....   | \$ (6,103)                       | \$ (5,693) |
|  | =====                            | =====      |
| Net loss per share, basic and diluted .....                            | \$ (0.28)                        | \$ (0.27)  |
|  | =====                            | =====      |
| Shares used in computing basic and diluted net<br>loss per share ..... | 21,435,044                       | 21,464,748 |
|  | =====                            | =====      |

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(in thousands)

|  | NINE MONTHS END |
|--|-----------------|
|  | -----           |
|  | 2001            |
|  | -----           |
| Cash flows from operating activities:  |                 |
| Net loss .....   | \$ (18,174)     |
| Adjustments to reconcile net loss to net cash used in<br>operating activities: |                 |
| Depreciation .....   | 1,793           |
| Compensation related to issuance of stock options .....                        | 1,246           |
| Changes in assets and liabilities:   |                 |
| Decrease (increase) in accounts receivable .....                               | 515             |
| Decrease (increase) in inventory .....   | 750             |

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|  |           |
|--|-----------|
| Decrease (increase) in other assets .....                                  | 392       |
| Increase (decrease) in accounts payable and accrued liabilities .....      | 1,673     |
| Increase (decrease) in deferred revenue .....                              | (698)     |
|  | -----     |
| Net cash used in operating activities .....                                | (12,503)  |
|  | -----     |
| Cash flows from investing activities:                                      |           |
| Purchases of property and equipment .....                                  | (725)     |
| Purchases of short-term investments .....                                  | (42,453)  |
| Maturities of short-term investments .....                                 | 75,968    |
|  | -----     |
| Net cash provided by (used in) investing activities .....                  | 32,790    |
|  | -----     |
| Cash flows from financing activities:                                      |           |
| Proceeds from sale of common stock .....                                   | 57        |
| Collection of preferred stock subscription .....                           | 25,000    |
| Proceeds from issuance of notes payable .....                              | 1,332     |
| Principal payments under capital lease obligations and notes payable ..... | (772)     |
|  | -----     |
| Net cash provided by (used in) financing activities .....                  | 25,617    |
|  | -----     |
| Net increase (decrease) in cash .....                                      | 45,904    |
| Cash, beginning of period .....  | 4,699     |
|  | -----     |
| Cash, end of period .....  | \$ 50,603 |
|  | =====     |
| Supplemental disclosure of cash flow information:                          |           |
| Cash paid for interest .....   | \$ 870    |
|  | =====     |
| Total cash, cash equivalents and short term investments .....              | \$ 48,825 |
|  | =====     |

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

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### INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

#### UNAUDITED NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

##### 1. BUSINESS

See the "Overview" section below in "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our business.

We have not generated any significant revenues from unaffiliated third parties, nor is there any assurance of future product revenues. Our research and development activities involve a high degree of risk and uncertainty. Our ability to successfully develop, manufacture and market our 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

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product liability exposure, as well as those factors set forth below under "Factors Affecting Future Operating Results." As a result of the aforementioned factors and the related uncertainties, there can be no assurance of our future success.

### 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 and nine month periods ended September 30, 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 our Transition Report on Form 10-K, as filed with the SEC on March 20, 2002; to the condensed, consolidated financial statements as of March 31, 2002, and for the three months then ended included in our Quarterly Report on Form 10-Q, as filed with the SEC on May 15, 2002; and to the condensed, consolidated financial statements as of June 30, 2002, and for the three and six months then ended, included in our Quarterly Report on Form 10-Q, as filed with the SEC on August 14, 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.

We have an ongoing agreement with VirRx, Inc. (VirRx) to purchase shares of VirRx Series A Preferred Stock. We purchased \$150,000 and \$375,000 of this stock for cash during the quarter and nine months ended September 30, 2002, respectively. 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 us and VirRx for the development of VirRx's technologies. We 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 us 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 will make a \$5.0 million cash milestone payment to VirRx, for which we receive no VirRx stock, upon approval by the United States Food and Drug Administration 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 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.

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 Quarterly 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 and other diseases. Our drug discovery and development programs have resulted in innovative approaches by which physicians may 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 tumor suppressor genes, which act to protect cells from becoming cancerous, with an adenoviral 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 of ADVEXIN gene therapy in non-small cell lung cancer, a category that includes approximately 80% of the various types of lung cancer. We are also conducting a Phase II trial of ADVEXIN gene therapy in breast cancer. Phase II trials are efficacy trials. We are conducting 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 hold the worldwide rights for pre-clinical and clinical development, manufacturing, marketing and commercialization of ADVEXIN gene therapy.

We are developing additional gene therapy product candidates that we believe may be effective in treating certain cancers, notably those product candidates based on the mda-7 and PTEN genes. Our INGN 241 product candidate, which combines the mda-7 gene with our gene delivery system, is undergoing safety and efficacy testing in a clinical trial, with one of the objectives also being to determine if this technology displays anti-tumor activity.

We are investigating other vector technologies for delivering gene-based products into targeted cells. Through our strategic collaboration with VirRx, Inc., we are developing replication-competent viral therapies in which viruses bind directly to cancer cells, replicate in those cells, and cause those cancer cells to die. We anticipate pursuing clinical confirmation as to whether this self-amplifying delivery system can complement our existing adenoviral gene delivery system, which is replication disabled, in selected therapeutic scenarios.

Introgen places substantial emphasis on developing and maintaining a strong intellectual property program. We own or exclusively control numerous patents and pending patent applications in the United States and elsewhere that cover ADVEXIN gene therapy in particular, adenoviral p53 in general, clinical applications of adenoviral and other forms of p53, and adenoviral production. Certain of our patents are licensed from The University of Texas System and from

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Aventis Pharmaceuticals, Inc. The patents directed to clinical applications of p53 broadly cover the use of p53 in combination with standard chemotherapy and clinical therapy with adenoviral p53 in general. Our adenoviral production patent position is of particular potential commercial importance in that it covers most methods currently in use by Introgen and others for commercial scale adenoviral production and purification processes. We have recently been successful in having certain European patents held by our competitors revoked by the European patent office, subject to appeal by the patent holder, and we are pursuing similar proceedings with respect to an additional European patent. In addition to our p53 intellectual property position, we also own or have exclusively licensed rights in a number of other patents and applications directed to the clinical application of various other tumor suppressor genes.

We own and operate a manufacturing facility that we believe complies with the FDA's current Good Manufacturing Practices requirements, commonly known as CGMP requirements. We produce ADVEXIN gene therapy in this facility for use in our Phase I, II and III clinical studies and INGN 241 for use in our Phase I clinical studies. The designs of the facility and the processes operated therein have been reviewed with the FDA. Our work to validate our manufacturing processes in accordance with FDA regulations is ongoing. We plan to use this facility for our market launch of ADVEXIN gene therapy. We have produced over 20 batches of ADVEXIN gene therapy clinical material, including all clinical material used in the Phase II and Phase III studies for this product candidate. In addition, we have entered into agreements with third parties under which we have provided process development and manufacturing services related to products they are developing.

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The FDA recently placed a clinical hold on clinical trials of gene therapy for the X-linked form of severe combined immune deficiency disease (SCID), a disease for which we are not developing products, after a participant in such a trial being conducted in Europe developed what appeared to be a leukemia-like illness about three years after receiving the gene therapy procedure. This clinical hold is restricted to the use of a retroviral vector in these trials. We do not use retroviral vectors in our ongoing clinical trials. Our products do not use the gene used in the clinical trials placed on hold. We have received no communications from the FDA to indicate this clinical hold will affect our clinical trials, and we anticipate no future negative effects on us from this event. Our pharmacovigilance department monitors every patient in our clinical studies for safety and reports all side effects to the FDA and the National Institutes of Health according to applicable regulations. We have witnessed no adverse effects in our clinical trials that even remotely resemble what occurred in the SCID study. Due to the basic differences between retrovirus vectors and the adenovirus vector employed in ADVEXIN gene therapy, we believe the likelihood of our encountering an event such as that experienced in the SCID study is remote.

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 September 30, 2002, we had an accumulated deficit of approximately \$68.0 million. We anticipate that we will incur losses in the future that may be greater than losses incurred in prior periods. At September 30, 2002, we had cash, cash equivalents and short-term investments of \$30.9 million. During the nine months ended September 30, 2002, we used \$16.7 million of cash for operating activities. While this cash usage rate could increase in future periods as we continue our ADVEXIN gene therapy Phase III clinical trials and our research and development of various other gene



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therapy technologies, we are taking measures to reduce the amount of cash used in our operating activities. Currently, we earn revenue 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 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.

### SUMMARY OF 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.

**Short-Term Investments.** Our short-term investments are 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.

**Research and Development Costs.** In conducting our clinical trials of ADVEXIN gene 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 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.

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### RESULTS OF OPERATIONS

COMPARISON OF THE QUARTERS ENDED SEPTEMBER 30, 2002 AND 2001

#### REVENUES

**Contract Services, Grant and Other Revenue.** We earn contract services revenues from third parties under agreements to provide manufacturing process

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development services and to produce products for them. We earn contract research services revenue from Aventis, an Introgen stockholder, under an agreement through which Aventis provides funding for the conduct of a Phase II clinical trial of ADVEXIN gene therapy in breast cancer. We earn grant revenue under research grants from U.S. Government agencies. Total contract services, grant and other revenue was \$453,000 for the quarter ended September 30, 2002, compared to \$15,000 for the quarter ended September 30, 2001, an increase of 2920%. This increase was primarily due to (1) our having multiple contract manufacturing services agreements in place with Biogen, Inc. and other companies during the quarter ended September 30, 2002, compared to there being substantially no similar activity during the quarter ended September 30, 2001, and (2) the quarter ended September 30, 2002 being the first quarter in which we earned contract research services revenue from Aventis under their agreement to provide funding for the conduct of a Phase II clinical trial of ADVEXIN gene therapy in breast cancer.

### COSTS AND EXPENSES

**Research and Development.** Research and development expenses, excluding compensation related to the issuance of stock options of \$98,000 in 2002 and \$115,000 in 2001, were \$4.5 million for the quarter ended September 30, 2002, compared to \$4.9 million for the quarter ended September 30, 2001, a decrease of 8%. These expenses in 2001 included a one-time charge of approximately \$1.0 million related to the restructuring of our collaborative relationship with Aventis in June 2001, resulting in our assuming responsibility for conducting and funding the Phase II and Phase III clinical trials for ADVEXIN gene therapy subsequent to that date. Excluding this one-time charge, these expenses increased 15% in the quarter ended September 30, 2002, compared to the quarter ended September 30, 2001. This increase was a result of us being fully engaged in our responsibility for the conduct and funding of the Phase II and Phase III clinical trials of ADVEXIN gene therapy in the 2002 period, whereas we were transitioning into this responsibility in the 2001 period as a result of restructuring the Aventis collaboration agreements at that time.

**General and Administrative.** General and administrative expenses, excluding compensation related to the issuance of stock options of \$228,000 in 2002 and \$288,000 in 2001, were \$1.5 million for the quarter ended September 30, 2002, compared to \$1.4 million for the quarter ended September 30, 2001, an increase of 7%. This increase was primarily due to the higher level of administrative support necessary to conduct the Phase II and Phase III clinical trials for ADVEXIN gene therapy during the 2002 period.

**Compensation Related to the Issuance of Stock Options.** Compensation related to the issuance of stock options was \$326,000 for the quarter ended September 30, 2002, compared with \$403,000 for the quarter ended September 30, 2001, a decrease of 24%. This decrease was due to deferred compensation arising from the issuance of certain stock options becoming fully amortized subsequent to September 30, 2001. The amount of 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 or are issued to individuals or entities other than employees or directors 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 \$136,000 for the quarter ended September 30, 2002, compared with \$611,000 for the quarter ended September 30, 2001, a decrease of 78%. This decrease was due to a decrease in interest rates between periods, lower average cash and investment balances and our more conservative investment philosophy subsequent to the events of September 11, 2001.

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Interest expense was \$181,000 for the quarter ended September 30, 2002, compared with \$236,000 for the quarter ended September 30, 2001, a decrease of 23%. This decrease was due to lower principal amounts upon which interest was incurred in 2002 compared to 2001 as a result of continuing debt service payments on notes payable and capital lease obligations.

Other income was \$261,000 for the quarter ended September 30, 2002, compared to \$237,000 for the quarter ended September 30, 2001, an increase of 10%. This increase was due to an increase in amounts paid to us by M. D. Anderson Cancer Center for common area maintenance charges under its agreement to lease space from us.

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### COMPARISON OF THE NINE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001

#### REVENUES

Contract Services, Grant and Other Revenue. We earn contract services revenues from third parties under agreements to provide manufacturing process development services and to produce products for them. We earn contract research services revenue from Aventis under an agreement through which Aventis provides funding for the conduct of a Phase II clinical trial of ADVEXIN gene therapy in breast cancer. We earn grant revenue under research grants from U.S. Government agencies. Contract services, grant and other revenue was \$1.0 million for the nine months ended September 30, 2002, compared to \$308,000 for the nine months ended September 30, 2001, an increase of 225%. This increase was primarily due to (1) our having multiple contract manufacturing services agreements in place with Biogen, Inc. and other companies in 2002, compared to limited activity in 2001, (2) the quarter ended September 30, 2002, being the first quarter in which we earned contract research services revenue from Aventis under their agreement to provide funding for the conduct of a Phase II clinical trial of ADVEXIN gene therapy in breast cancer and (3) 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 compensation related to the issuance of stock options of \$313,000 in 2002 and \$348,000 in 2001, were \$16.8 million for the nine months ended September 30, 2002, compared to \$14.6 million for the nine months ended September 30, 2001, an increase of 15%. These expenses in 2001 included a one-time charge of approximately \$3.0 million related to the restructuring of our collaborative relationship with Aventis in June 2001. Excluding this one-time charge, these expenses increased 45% for the nine months ended September 30, 2002 compared to the nine months period September 30, 2001. The increase in this expense was a result of our being responsible for all expenses of the ADVEXIN clinical trials throughout 2002, whereas we had this responsibility for only the portion of 2001 subsequent to the restructuring of the collaborative relationship with Aventis.

General and Administrative. General and administrative expenses, excluding compensation related to the issuance of stock options of \$754,000 in 2002 and \$863,000 in 2001, were \$4.9 million for the nine months ended September 30, 2002, compared to \$3.7 million for the nine months ended September 30, 2001, an increase of 32%. This increase was 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 the restructuring of our collaborative relationship with Aventis.

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Compensation Related to the Issuance of Stock Options. Compensation related to the issuance of stock options was \$1.1 million for the nine months ended September 30, 2002, compared with \$1.2 million for the nine months ended September 30, 2001, a decrease of 8%. This decrease was due to deferred compensation arising from the issuance of certain stock options becoming fully amortized subsequent to June 30, 2001. The amount of 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 or are issued to individuals or entities other than employees or directors 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 \$493,000 for the nine months ended September 30, 2002, compared with \$1.1 million for the nine months ended September 30, 2001, a decrease of 55%. Interest income for 2001 is net of a \$500,000 reduction to recognize the decline in the market value of certain commercial paper held as an investment. Excluding the effects of this reduction, our interest income declined due to a decrease in interest rates between periods, lower average cash and investment balances and our more conservative investment philosophy subsequent to the events of September 11, 2001.

Interest expense was \$604,000 for the nine months ended September 30, 2002, compared with \$705,000 for the nine months ended September 30, 2001, a decrease of 14%. This decrease was a result of lower principal amounts upon which interest was incurred in 2002 compared to 2001 as a result of continuing debt service payments on notes payable and capital lease obligations.

Other income was \$911,000 for the nine months ended September 30, 2002, compared to \$590,000 for the nine months ended September 30, 2001, an increase of 54%. This increase in other income was due to our lease 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.

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### LIQUIDITY AND CAPITAL RESOURCES

We have incurred annual operating losses since our inception, and at September 30, 2002, we had an accumulated deficit of \$68.0 million. From inception through September 30, 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 \$6.2 million from contract services, grants, interest and other income.

At September 30, 2002, we had cash and short-term investments of \$30.9 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

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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 two-year 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 nine months ended September 30, 2002. We believe our existing working capital can fund our operations for the next fifteen to eighteen months, although unforeseen events could shorten that time period. We are taking measures to reduce the amount of cash used in our operating activities. 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 \$16.7 million for the nine months ended September 30, 2002, compared with \$12.5 million for the nine months ended September 30, 2001. In general, this increase in cash used was due to our having responsibility for conducting the Phase II and Phase III clinical trials for ADVEXIN gene therapy throughout 2002 whereas we did not have this responsibility in 2001 until June of that year. Specifically, the increase in cash used was primarily the result of a higher net loss in 2002 compared to 2001, after considering adjustments for depreciation and compensation related to the issuance of stock options, offset primarily by (1) a decrease in receivables and inventory that was smaller in 2002 than in 2001 due to the primary activity in these accounts in 2001 being related to the restructuring of the Aventis collaboration in 2001, (2) an increase in accounts payable and accrued liabilities that was smaller in 2002 than in 2001 because the 2001 increase included \$2.0 million related to expenses we agreed to pay Aventis in connection with the restructuring of the Aventis collaboration in 2001, and (3) an increase in deferred revenue in 2002 compared to a decrease in this amount in 2001 due to (a) the deferral of the recognition of income under the lease of space to M. D. Anderson Cancer Center, which was in effect for the entire 2002 period but for only a portion of the 2001 period and (b) a decrease in deferred revenue in 2001 relating to the earning of revenue on sales of inventory to Aventis, an activity that no longer exists due to the restructuring of the Aventis collaboration in June 2001.

Net cash used in investing activities was \$10.6 million for the nine months ended September 30, 2002, compared to net cash provided by investing activities of \$32.8 million for the nine months ended September 30, 2001. The change in the amounts of purchases and maturities of short-term investments for the nine months ended September 30, 2002, as compared to the nine months ended September 30, 2001, was due to a significant portion of our investment activity in the 2001 period being in short-term investments, followed by a period subsequent to September 11, 2001, during which we concentrated our investments in cash and cash equivalents, which was then followed in the 2002 period by more investments in short-term securities. 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 leased 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.

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Net cash used in financing activities was \$1.1 million for the nine months ended September 30, 2002, and net cash provided by financing activities was \$25.6 million for the nine months ended September 30, 2001. This change between periods is due to the 2001 period including the receipt of proceeds from (1) the purchase of preferred stock by Aventis in connection with the restructuring of our collaboration agreement with them and (2) a note payable used to finance tenant improvements for the lease of space to M. D. Anderson Cancer Center, whereas there were no similar events in 2002. Offsetting these items were higher principal payments under

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notes payable and capital lease obligations in 2002 compared to 2001 due to debt service payments on the note payable for tenant improvements being made for all of 2002, but for only a portion of 2001, and a larger portion of debt service payments on all mortgage notes and capital lease obligations applying to principal as the principal balances under these obligations continue to be amortized.

We have an ongoing agreement with VirRx, Inc. (VirRx) to purchase shares of VirRx Series A Preferred Stock. We purchased \$150,000 and \$375,000 of this stock for cash during the three and nine months ended September 30, 2002, respectively. 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 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 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 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 payments and capital lease payments for the three months ending |           |
| December 31, 2002 .....  | .....     |
| Total debt service and capital lease payments for the year ending December 31,     |           |
| 2003 .....   | .....     |
| 2004 .....   | .....     |
| 2005 .....   | .....     |
| 2006 .....   | .....     |
| Thereafter .....   | .....     |
| <br>Total debt service and capital lease payments .....                            | <br>..... |

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|  |  |
|--|--|
| Less portion representing interest .....   |  |
| Total principal balance at September 30, 2002 .....                                |  |
| Categories in which the principal balances are presented as of September 30, 2002: |  |
| Current portion of obligations under capital leases<br>and notes payable .....     |  |
| Capital lease obligations, net of current portion .....                            |  |
| Notes payable, net of current portion .....  |  |
| Total principal balance at September 30, 2002 .....                                |  |

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 approximately \$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:

|  |    |           |
|--|----|-----------|
| Three months ending December 31, 2002 .....                  | \$ | 78,589    |
| Year ending December 31,                                     |    |           |
| 2003 .....   |    | 289,352   |
| 2004 .....   |    | 294,152   |
| 2005 .....   |    | 212,952   |
| 2006 .....   |    | 152,952   |
| Thereafter .....   |    | 2,898,050 |
|  |    | -----     |
| Total minimum lease payments under operating<br>Leases ..... | \$ | 3,926,047 |
|  |    | =====     |

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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 EJ Financial Enterprises, Inc., a company owned by the Chairman of our Board of Directors and which formerly employed one of our 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

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at The University of Texas M. D. Anderson Cancer Center. Dr. Roth was the primary inventor of the technology upon which our ADVEXIN gene 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 totaling \$181,500 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 September 30, 2002, we would have been obligated to make final payments totaling \$181,500. Dr. Roth is one of our stockholders.

### 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, have completed a Phase II clinical trial of ADVEXIN gene therapy for the treatment of non-small cell lung cancer, are conducting a Phase II clinical trial of ADVEXIN gene therapy for the treatment of breast cancer and are conducting several Phase I 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/II 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:

- o the failure of the product candidate to be more effective than current therapies;



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

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- o the longer than expected time required to determine whether or not a product candidate is effective;
- o the death of patients during a clinical trial, even though the product candidate may not have caused those deaths;
- o the failure to enroll a sufficient number of patients in our clinical trials;
- o the inability to produce sufficient quantities of a product candidate to complete the trials; or
- o the inability to commit the necessary resources to fund the clinical 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 1993. As of September 30, 2002, we had an accumulated deficit of approximately \$68.0 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 services activities, grants, interest income and rent from the lease of a portion of our facilities to M. D. Anderson Cancer Center. Prior to December 31, 2000, we earned revenue from Aventis under collaborative agreements for research and development and sales of ADVEXIN gene therapy for use in Aventis' clinical trials, which are revenues we no longer receive. 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 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 for multiple disease indications is expensive. We expect that we will fund our operations over the next fifteen to eighteen months with our current working capital, resulting

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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 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, due to a number of factors, including:

- o an acceleration of the number, size or complexity of our clinical trials;
- o slower than expected progress in developing ADVEXIN gene therapy, INGN 241 or other product candidates;
- o higher than expected costs to obtain regulatory approvals;
- o higher than expected costs to pursue our intellectual property strategy;
- o higher than expected costs to further develop our manufacturing capability;
- o higher than expected costs to develop our sales and marketing capability; and
- o slower than expected progress in reducing our operating costs.

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

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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.

IF WE CANNOT MAINTAIN OUR 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.

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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 and negative public perception of our product candidates, as well as potential regulatory delays relating to the testing or approval of our product candidates. The FDA recently placed a clinical hold on clinical trials of gene therapy for the X-linked form of severe combined immune deficiency disease (SCID), a disease for which we are not developing products, after a participant in such a trial being conducted in Europe developed what appeared to be a leukemia-like illness about three years after receiving the gene therapy procedure. This clinical hold is restricted to the use of a retroviral vector in these trials. We do not use retroviral vectors in our ongoing clinical trials. Our products do not use the gene used in the clinical trials placed on hold. We have received no communications from the FDA to indicate this clinical hold will affect our clinical trials, and we anticipate no future negative effects on us from this event. Our pharmacovigilance department monitors every patient in our clinical studies for safety and reports all side effects to the FDA and the National Institutes of Health according to applicable regulations. We have witnessed no adverse effects in our clinical trials that even remotely resemble what occurred in the SCID study. Due to the basic differences between retrovirus vectors and the adenovirus vector employed in ADVEXIN gene therapy, we believe the likelihood of our encountering an event such as that experienced in the SCID study is remote.

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 healthy 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, 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.

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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 require 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 have obtained and are currently seeking further patent protection for adenoviral p53, including ADVEXIN gene therapy, and its use in cancer therapy. Further, the PTO issued us a United States patent for our adenovirus production technology. We also control, through licensing arrangements, three issued United States patents for combination therapy involving the p53 gene and conventional chemotherapy or radiation, one issued United States patent covering the use of adenoviral p53 in cancer therapy and one issued United States patent covering adenoviral p53 as a product. Our competitors may challenge the validity of one or more of our combination therapy, our adenoviral process technology or our adenoviral p53

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therapy and product 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.

We have been notified by the European Patent Office, or EPO, that Schering-Plough has filed an opposition against the issuance of 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. We expect that the EPO will hold an initial oral proceeding to determine whether the patent should be maintained in late 2003. Resolution of this opposition will require that we expend time, effort and money. If the party opposing the patent ultimately prevails in having our European patent revoked in whole or in part 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 impact on our commercialization efforts in Europe.

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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

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United States patent, our business could be materially harmed.

We are currently involved in opposing three European patents in proceedings before the 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 a European patent directed to the use of a tumor suppressor gene, the EPO revoked the European patent in its entirety. Canji has appealed this revocation. In the second opposition, involving a patent directed to therapeutic and other applications of the p53 gene that is owned by Johns Hopkins and, we understand, controlled by Schering-Plough, the European Patent Office recently revoked the patent in its entirety. The patent owner will have an opportunity to appeal this decision. In a third case 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. 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 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, Inc., Genvec, Inc., Vical Incorporated 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 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 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.

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The commercial success of our product candidates will depend on whether:

- o they are more effective than alternative treatments;
- o their side effects are acceptable to patients and doctors;
- o we produce and sell them at a profit; and

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- o 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, INGN 241 and other product candidates for currently planned clinical trials. This facility will be used for the initial commercial launch of ADVEXIN gene therapy. 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 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 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 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 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 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

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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 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

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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™ 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:

- o decreased demand for our product candidates;
- o injury to our reputation and significant media attention;
- o withdrawal of clinical trial volunteers;
- o costs of litigation; and
- o substantial monetary awards to plaintiffs.

We currently maintain product liability insurance with coverage of \$5.0 million per occurrence with a \$15.0 million 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 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.



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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:

- o the announcement of new products or services by us or our competitors;
- o quarterly variations in our or our competitors' results of operations;
- o failure to achieve operating results projected by securities analysts;
- o changes in earnings estimates or recommendations by securities analysts;
- o developments in our industry; and
- o general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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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:

- o results of our pre-clinical and clinical trials;
- o announcement of technological innovations or new commercial products by us or our competitors;
- o developments concerning proprietary rights, including patent and litigation matters;
- o publicity regarding actual or potential results with respect to products under development by us or by our competitors;
- o regulatory developments; and
- o 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:

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- o potential exposure to unknown liabilities of acquired companies;
- o the difficulty and expense of assimilating the operations and personnel of acquired businesses;
- o diversion of management time and attention and other resources;
- o loss of key employees and customers as a result of changes in management;
- o the incurrence of amortization expenses; and
- o 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 currently consist primarily of United States federal government obligations. 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 September 30, 2002, the fair value of our fixed-rate debt approximated its carrying value based upon discounted future cash flows using current market prices.

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## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS.

We are involved from time to time in legal proceedings in the ordinary course of business. We do not believe the results of any of our present litigation 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.

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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 September 30, 2002, and for the nine months ended September 30, 2002, we used approximately \$26.3 million and \$17.9 million, respectively, of these net proceeds for operating, investing and financing activities. Pending these uses, the remaining \$5.9 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.

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 approval of non-audit services approved by the audit committee of our board of directors (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 that are 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 for the non-audit services of preparation of state and federal tax returns.

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

#### (a) EXHIBITS

99.1 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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#### (b) REPORTS ON FORM 8-K

In connection with the resignation of Elise T. Wang from our Board of Directors, we filed a Current Report on Form 8-K on August 23, 2002.

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## 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: November 13, 2002

By: /s/ JAMES W. ALBRECHT, JR.

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James W. Albrecht, Jr.  
On behalf of the Registrant and as Chief  
Financial Officer (Principal Financial  
and Accounting Officer)

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## CERTIFICATIONS

I, David G. Nance, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Introgen Therapeutics, Inc.;
2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of Introgen as of, and for, the periods presented in this Quarterly Report;
4. Introgen's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for Introgen and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to Introgen, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;
  - b) evaluated the effectiveness of Introgen's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Quarterly Report (the "Evaluation Date"); and
  - c) presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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5. Introgen's other certifying officer and I have disclosed, based on our most recent evaluation, to Introgen's auditors and the audit committee of Introgen's board of directors (or persons performing the equivalent function):
- a) all significant deficiencies in the design or operation of internal controls which could adversely affect Introgen's ability to record, process, summarize and report financial data and have identified for Introgen's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in Introgen's internal controls; and
6. Introgen's other certifying officer and I have indicated in this Quarterly Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

By: /s/ DAVID G. NANCE

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David G. Nance  
Chief Executive Officer

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I, James W. Albrecht, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Introgen Therapeutics, Inc.;
2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of Introgen as of, and for, the periods presented in this Quarterly Report;
4. Introgen's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for Introgen and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to Introgen, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

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- b) evaluated the effectiveness of Introgen's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Quarterly Report (the "Evaluation Date"); and
  - c) presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. Introgen's other certifying officer and I have disclosed, based on our most recent evaluation, to Introgen's auditors and the audit committee of Introgen's board of directors (or persons performing the equivalent function):
- a) all significant deficiencies in the design or operation of internal controls which could adversely affect Introgen's ability to record, process, summarize and report financial data and have identified for Introgen's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in Introgen's internal controls; and
6. Introgen's other certifying officer and I have indicated in this Quarterly Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

By: /s/ JAMES W. ALBRECHT, JR.

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James W. Albrecht, Jr.  
Chief Financial Officer

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EXHIBIT INDEX

| EXHIBIT<br>NUMBER<br>----- | DESCRIPTION<br>-----  |
|----------------------------|---|
| 99.1                       | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

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