INTROGEN THERAPEUTICS INC
Form 10-Q
February 14, 2001

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

FORM 10-Q

(Mark One)

X --- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2000.

OR

--- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 000-21291

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

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

301 CONGRESS AVENUE, SUITE 1850, AUSTIN, TEXAS 78701
(Address of Principal Executive Offices) (Zip Code)

(512) 708-9310
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes X No
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At December 31, 2000, 21,224,616 shares of common stock of the Registrant were outstanding.

INTROGEN THERAPEUTICS, INC.

INDEX

PART I - FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	JUNE 30, 2000
ASSETS	
Current Assets:	
Cash	$ 1,788,612
Short-term investments	9,976,469
Accounts receivable	--
Inventory	1,734,329
Other current assets	4,808
Total current assets	13,504,218
Property and equipment, net of accumulated depreciation of $2,988,387 and $4,054,074, respectively	10,152,572
Long-term investments	--
Other assets	1,197,733
Total assets	$ 24,854,523
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current Liabilities:	
Accounts payable	$ 262,977
Accrued liabilities	1,026,330
Deferred revenues from affiliate	1,205,655
Current portions of capital lease obligations and note payable	746,192
Total current liabilities	3,241,154
Capital lease obligations, net of current portion	2,149,281
Note payable, net of current portion	5,871,750
Commitments and contingencies	
Stockholders' Equity:	
Convertible preferred stock, $.001 par value; 8,308,523 shares authorized, 6,419,896 issued and outstanding at June 30, 2000	6,419
Common stock, $.001 par value; 50,000,000 shares authorized; 4,134,180 and 21,225,578 shares issued and outstanding, respectively	4,134
Additional paid-in capital	36,536,575
Deferred compensation	(4,210,412)
Accumulated deficit	(18,744,378)
Total stockholders' equity	13,592,338
Total liabilities and stockholders' equity	$ 24,854,523

The accompanying notes are an integral part of these

condensed consolidated financial statements.

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	THREE MONTHS ENDED DECEMBER 31,		SIX MONTHS END DECEMBER 31,	
	1999	2000	1999	2
Collaborative research and development revenues from affiliate	$ 2,536,597	$ 1,509,210	$ 3,915,715	$ 3
Product sales to affiliate	432,365	1,500,000	1,692,618	1
Cost of product sales	(288,243)	(2,372,204)	(1,153,056)	(2
Gross margin on product sales	144,122	(872,204)	539,562	
Other revenue	64,533	252,898	93,533	
Costs and expenses:				
Research and development	4,486,873	2,820,769	6,103,957	5
General and administrative	1,546,348	928,769	2,399,501	2
Loss from operations	(3,287,969)	(2,859,634)	(3,954,648)	(4
Interest income	182,039	609,870	359,929	
Interest expense	(147,331)	(178,797)	(151,824)	
Net loss	$ (3,253,261)	$ (2,428,561)	$ (3,746,543)	$ (4
Net loss per share, basic and diluted	$ (0.82)	$ (0.13)	$ (0.95)	$
Shares used in computing basic and diluted net loss per share	3,972,630	18,092,257	3,964,078	11

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

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited)

	SIX MONTHS ENDED DECEMBER 31,	
	1999	2000
Cash flows from operating activities:		
Net loss	$ (3,746,543)	$ (4,371,14
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	536,399	1,065,68
Compensation related to issuance of stock options	937,691	745,61
Changes in assets and liabilities		
Decrease (increase) in receivable from affiliate	(787,416)	(709,26
Decrease (increase) in inventory	1,211,051	984,32
Decrease (increase) in other assets	(129,348)	(370,56
Increase (decrease) in accounts payable	(1,585,930)	582,48
Increase (decrease) in accrued liabilities	386,392	479,04
Increase (decrease) in deferred revenue from affiliate	(573,186)	(154,65
Net cash used in operating activities	(3,750,890)	(1,748,46
Cash flows from investing activities:		
Purchases of property and equipment	(1,237,034)	(2,954,29
Purchases of investments	(11,135,761)	(47,076,26
Maturities of investments	13,567,831	20,075,10
Net cash provided by (used in) investing activities	1,195,036	(29,955,45
Cash flows from financing activities:		
Proceeds from stock option exercises	46,867	68,82
Proceeds from initial public offering, net of offering costs paid during period	--	33,001,23
Proceeds from issuance of note payable	2,814,007	1,931,60
Principal payments under capital lease obligations and note payable	(51,485)	(386,68
Net cash provided by financing activities	2,809,389	34,614,97
Net increase in cash	253,535	2,911,05
Cash, beginning of period	2,145,676	1,788,61
Cash, end of period	$ 2,399,211	$ 4,699,66
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 247,213	$ 280,17
Supplemental disclosure of noncash investing and financing activity:		
Offering costs paid during prior period netted against initial public offering proceeds	$ 775,811	$ 775,81

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

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

UNAUDITED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. FORMATION AND BUSINESS:

Introgen Therapeutics, Inc., a Delaware corporation, and its subsidiaries (Introgen) develop and manufacture gene-based drugs for the treatment of cancer and other diseases. Introgen's lead product candidate, INGN 201, combines the naturally occurring p53 tumor suppressor gene with its extensively tested adenoviral delivery system. Introgen is developing additional gene-based drugs, including INGN 241 based on the mda-7 gene, as well as other drugs based on genes such as PTEN.

INGN 201, developed in collaboration with Aventis Pharma AG, formerly Rhone-Poulenc Rorer Pharmaceuticals, Inc. (Aventis or the affiliate), is currently in Phase III clinical trials for the treatment of head and neck cancer. Introgen is also conducting a Phase II clinical trial in non-small cell lung cancer and several Phase I clinical trials in additional cancer indications. INGN 241 is currently undergoing safety testing in a Phase I clinical trial, which Introgen is conducting without a collaborative partner. Introgen's product candidates are intended to engage molecular targets to produce a highly specific therapeutic effect. By selectively killing cancer cells and harnessing natural protection mechanisms, Introgen's product candidates may be less toxic than conventional treatments. Introgen specializes in combining appropriate gene delivery systems and therapeutics genes to make its gene-based drugs, which have been used in numerous clinical trials worldwide either alone or in combination with conventional treatments such as chemotherapy and radiotherapy.

Introgen has research collaboration agreements with Aventis. Introgen is also manufacturing and selling INGN 201 to Aventis for use in clinical trials. Introgen has not yet generated any significant revenues from unaffiliated third parties, nor is there any assurance of future product revenues. Introgen's research and development activities involve a high degree of risk and uncertainty, and its ability to successfully develop, manufacture and market its proprietary products is dependent upon many factors. These factors include, but are not limited to, the need for additional financing, the reliance on collaborative research and development arrangements with corporate and academic affiliates, and the ability to develop manufacturing, sales and marketing experience. Additional factors include uncertainties as to patents and proprietary technologies, competitive technologies, technological change and risk of obsolescence, development of products, competition, government regulations and regulatory approval, and product liability exposure. As a result of the aforementioned factors and the related uncertainties, there can be no assurance of Introgen's future success.

2. BASIS OF PRESENTATION:

The accompanying condensed, consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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 adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three- and six-month periods ended December 31, 2000, are not necessarily indicative of the results that may be expected for the fiscal year ending June 30, 2001. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended June 30, 2000, included in Introgen's prospectus dated October 12, 2000, as filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act of 1933.

3. NET LOSS PER SHARE:

Net loss per share is computed using the weighted average number of shares of common stock outstanding and reflects the conversion of each outstanding share of preferred stock into 1.92 shares of Introgen's

common stock effective upon the closing of Introgen's initial public offering (see Note 5). Basic earnings per share (EPS) excludes dilution and is determined by dividing loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS reflects the potential dilution that could occur if securities and other contracts to issue common stock were exercised or converted into common stock. There are no differences between basic EPS and diluted EPS for all periods presented.

4. STOCK:

Common Stock Split

In August 2000, Introgen's board of directors approved a stock dividend to effect a stock split of 1.6 shares for every one share of common stock outstanding. An amount equal to the increased par value of the common shares has been reflected as a transfer from additional paid-in capital to common stock. Retroactive effect has been given to the stock split in stockholders' equity and in all share and per share data as of the earliest date presented in the accompanying consolidated financial statements.

Initial Public Offering and Conversion of Preferred Stock

In October 2000, Introgen completed an initial public offering (IPO) of 4,600,000 newly-issued shares of its common stock at a price of $8.00 per share. Introgen received $33.2 million in cash proceeds from the IPO, net of underwriting discounts, commissions and other offering costs.

Simultaneous with the closing of the IPO, 3,011,423 shares of Series A Convertible Preferred Stock, 1,757,063 shares of Series B Convertible Preferred Stock, 551,410 shares of Series C Convertible Preferred Stock and 1,100,000 shares of Series D Convertible Preferred Stock then outstanding were automatically converted into 12,326,173 shares of common stock.

Stock Option Grant

Introgen has an employment agreement with its president and chief executive officer that obligates Introgen to grant the officer 80,000 fully vested options as a result of the closing of its IPO, and on August 1, 2001 and August 1, 2002. Such options will be exercisable at a price determined by the Compensation Committee of the Company's Board of Directors. To date, the exercise price of the options that will be granted in connection with the IPO has not yet been determined and, accordingly, the options have not been granted. Upon the determination of the exercise price, Introgen will record compensation expense if and to the extent the then-current fair market value of Introgen's common stock exceeds the exercise price of the options.

5. SUBSEQUENT EVENTS:

Sublease and Loan Agreement

Introgen is negotiating with The University of Texas M.D. Anderson Cancer Center to sublease to them approximately 11,000 square feet of space in its Houston research and administration facility at prevailing market rates. To finance finish-out of the space to be subleased, Introgen entered into a $3.5 million loan agreement with a commercial bank. The loan bears interest at prime and is payable in equal monthly installments over five years. As of December 31, 2000, $1,931,602 has been drawn under this agreement. In accordance with the sublease agreement, in addition to rent paid at market rates, the tenant will pay Introgen monthly an amount equal to Introgen's debt service payment on this loan. Introgen will own the finish-out improvements both during the term of this sublease and after the sublease has expired.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes thereto included in this report on Form 10-Q. The discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which include the statements in paragraphs seven and fifteen under "Results of Operations" regarding amortization of deferred compensation and the statements below under "Factors Affecting Future Operating Results." 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-based drugs for the treatment of cancer and other diseases. Our lead product candidate, INGN 201, combines the p53 gene, one of the most potent members of a group of naturally-occurring genes, the tumor suppressor genes, that act to protect cells from becoming cancerous, with a gene delivery system that we have developed and extensively tested in collaboration with Aventis. We and Aventis are conducting pivotal Phase III clinical studies of INGN 201 in head and neck cancer. Pivotal Phase III trials are typically the final phase required for FDA approval. We are also conducting

a Phase II clinical trial in non-small cell lung cancer, a category that includes approximately 80% of the various kinds of lung cancer. Phase II trials are efficacy studies. We are also conducting several Phase I clinical trials, or safety studies, in additional cancer types, or indications.

Another of our product candidates, INGN 241, combines the mda-7 gene with our gene delivery system. We are conducting safety testing of INGN 241 in a Phase I clinical study. We have identified and are developing additional gene therapy product candidates, notably those base on the PTEN gene, as well as associated technologies for delivering the gene-based products into target cells, which we refer to as vectors.

Since our inception in 1993, we have used our resources primarily to conduct research and development activities, primarily for INGN 201 and, to a lesser extent, for other product candidates. At December 31, 2000, we had an accumulated deficit of approximately $23.1 million. We anticipate that we will incur losses in the future that are likely to be greater than losses incurred in prior years. We expect that cash needed for operating activities will increase as we continue our research and development of various gene therapy technologies. Since inception, our only significant revenues have been payments from Aventis under collaborative research and development agreements for our early stage development work on INGN 201 and Aventis' purchases of INGN 201 product we manufactured for their use in later stage clinical trials. We have also earned interest income on cash placed in short-term investments.

We have two collaboration agreements with Rhone-Poulenc Rorer Pharmaceuticals Inc. to develop therapeutics based on p53 and on K-ras pathway inhibition. In December 1999, Rhone-Poulenc S.A., the ultimate parent company of Rhone-Poulenc Rorer Pharmaceuticals Inc., combined with Hoechst AG, and the parties then combined Hoechst Marion Roussel, the pharmaceutical business of Hoechst AG, with that of Rhone-Poulenc Rorer to form Aventis Pharma AG. Rhone-Poulenc Rorer Pharmaceuticals Inc. is now known as Aventis Pharmaceuticals Products Inc. From inception of these agreements in 1994 through December 31, 2000, we have earned a total of $49.7 million in collaborative research and development revenues from Aventis pursuant to the agreement relating to the p53 gene. Historically, we have generally received payments from Aventis for early stage development activities quarterly in advance. We record these payments as revenue as we perform the collaboration work and incur the related expenses. We record as deferred revenue collaborative research and development payments which we receive but for which the related expenses have not yet been incurred. Continued funding of early stage development programs under the collaboration agreements is subject to an annual, mutually agreed-upon budget.

Under the terms of the collaboration agreements, we also manufacture and sell INGN 201 to Aventis for use in later stage clinical trials. We record revenue from these product sales upon completion of production and delivery and Aventis' acceptance of the product. From inception of these agreements through December 31, 2000, we have recorded $7.5 million in revenues from these product sales.

RESULTS OF OPERATIONS

COMPARISON OF QUARTERS ENDED DECEMBER 31, 2000 AND 1999

Revenues

Revenue from Collaborations. Collaborative research and development revenues from Aventis were $1.5 million for the quarter ended December 31, 2000,

compared to $2.5 million for the quarter ended December 31, 1999. This 40% decrease was primarily due to a decreased level of early stage research and development relative to products based on the p53 gene as such products evolve into later stage development. We earn revenue from Aventis for early stage research and development we perform under our collaboration agreements with them. Aventis performs later stage development work.

Revenue from Product Sales to Affiliate. Revenues from product sales to Aventis were $1.5 million for the quarter ended December 31, 2000, compared to $432,000 for the quarter ended December 31, 1999. This 247% increase was due to our manufacturing facility being fully operational in 2000 whereas in 1999 we had recently completed construction of the facility and were in the process of validating it for operation for a significant part of that period.

Other Revenue. Other revenue was $253,000 for the quarter ended December 31, 2000, compared to $65,000 for the quarter ended December 31, 1999. This 289% increase was due to a higher level of funding received under research grants from U. S. Government agencies and increased contract manufacturing work for third parties.

Costs and Expenses

Cost of Product Sales. Cost of product sales was $2.4 million for the quarter ended December 31, 2000, compared to $288,000 for the quarter ended December 31, 1999. This 733% increase was due to a reduction in the number of batches of clinical material in production during the 2000 period, which resulted in an increase in the amount of the costs of our manufacturing operations that were expensed as incurred instead of capitalized as part of inventory. This reduction in clinical materials production was a result of our successful production and shipment in previous periods of INGN 201 to Aventis in the amounts and timeframes they requested, which has allowed them to accumulate an adequate supply of clinical materials to support INGN 201 Phase II and Phase III clinical trials in the near term.

Research and Development. Research and development expenses, excluding amortization of deferred stock compensation of $111,000 in 2000 and zero in 1999, were $2.7 million for the quarter ended December 31, 2000, compared to $4.5 million for the quarter ended December 31, 1999. This 62% decrease was primarily due to a decreased level of early stage research and development relative to products based on the p53 gene, which we conduct, as such products evolve into later stage development, which Aventis conducts.

General and Administrative. General and administrative expenses, excluding amortization of deferred stock compensation of $263,000 in 2000 and $753,000 in 1999, were $665,000 for the quarter ended December 31, 2000, compared to $793,000 for the quarter ended December 31, 1999. This 19% increase was due to the additional, ongoing administrative costs associated with operating as a public company beginning in 2000.

Amortization of Deferred Compensation. Amortization of deferred stock compensation was $375,000 for the quarter ended December 31, 2000, compared with $753,000 for the quarter ended December 31, 1999. This 50% decrease was primarily due to the 1999 amount including a one-time charge to compensation

expense arising from the acceleration of vesting of options held by a former member of the board of directors in recognition of his service to us.

The amount of deferred compensation expense to be recorded in future periods may decrease if unvested options for which deferred compensation has been recorded are subsequently forfeited or may increase if additional options are issued at a price below the deemed fair value of common stock at the date of grant.

Interest Income and Expense

Interest income was $610,000 for the quarter ended December 31, 2000, compared with $182,000 for the quarter ended December 31, 1999. This 235% increase was due to higher cash and short- and long-term investment balances on which interest is earned as a result of our receiving the proceeds from our IPO in October 2000. Interest expense was $179,000 for the quarter ended December 31, 2000, compared with $147,000 for the quarter ended December 31, 1999. This increase was the result of our additional borrowings to finance new facilities and equipment placed in service in 1999.

COMPARISON OF SIX MONTHS ENDED DECEMBER 31, 2000 AND 1999

Revenues

Revenue from Collaborations. Collaborative research and development revenues from Aventis were $3.0 million for the six months ended December 31, 2000, compared to $3.9 million for the six months ended December 31, 1999. This 30% decrease was primarily due to a decreased level of early stage research and development relative to products based on the p53 gene as such products evolve into later stage development. We earn revenue from Aventis for the early stage research and development we perform under our collaboration agreements with them. Aventis performs later stage development work.

Revenue from Product Sales to Affiliate. Revenues from product sales to Aventis were $1.5 million for the six months ended December 31, 2000, compared to $1.7 for the six months ended December 31, 1999. This 12% decrease occurred because, during the first half of the six months ended December 31, 1999, a higher number of batches of clinical material were produced and shipped to Aventis to ensure a steady supply of materials to support clinical trials during subsequent periods when our production volumes were temporarily lower while we were in the pre-production and validation phase of our new manufacturing facility.

Other Revenue. Other revenue was $391,000 for the six months ended December 31, 2000, compared to $94,000 for the six months ended December 31, 1999. This 316% increase was due to a higher level of funding received under research grants from U.S. Government agencies and increased contract manufacturing work for third parties.

Costs and Expenses

Cost of Product Sales. Cost of product sales was $2.5 million for the six months ended December 31, 2000, compared to $1.2 million for the six months ended December 31, 1999. This 108% increase was due to a reduction in the number of batches of clinical material in production during the second half of the 2000 period, which resulted in an increase in the amount of the costs of our manufacturing operations that were expensed as incurred instead of capitalized as part of inventory. This reduction in clinical materials production was a result of our successful production and shipment in previous periods of INGN 201 to Aventis in the amounts and timeframes they requested, which has allowed them to accumulate an adequate supply of clinical materials to support INGN 201 Phase II and Phase III clinical trials in the near term.

Research and Development. Research and development expenses, excluding amortization of deferred stock compensation of $209,000 in 2000 and zero in

1999, were $4.9 million for the six months ended December 31, 2000, compared to $6.1 million for the six months ended December 31, 1999. This 20% decrease was primarily due to a decreased level of early stage research and development relative to products based on the p53 gene, which we conduct, as such products evolve into later stage development, which Aventis conducts.

General and Administrative. General and administrative expenses, excluding amortization of deferred stock compensation of $537,000 in 2000 and $938,000 in 1999, were $1.5 million in each of the six months ended December 31, 2000 and December 31, 1999.

Amortization of Deferred Compensation. Amortization of deferred stock compensation was $746,000 for the six months ended December 31, 2000, compared with $938,000 for the six months ended December 31, 1999. This 20% decrease was primarily due to the 1999 amount including a one-time charge to compensation expense arising from the acceleration of vesting of options held by a former member of the board of directors in recognition of his service to us. The amount of deferred compensation expense to be recorded in future periods may decrease if unvested options for which deferred compensation has been recorded are subsequently forfeited or may increase if additional options are issued at a price below the deemed fair value of common stock at the date of grant.

Interest Income and Expense

Interest income was $783,000 for the six months ended December 31, 2000, compared with $360,000 for the six months ended December 31, 1999. This 105% increase was due to higher cash and short- and long-term investment balances on which interest is earned as a result of our receiving proceeds from our IPO in October 2000. Interest expense was $380,000 for the quarter ended December 31, 2000, compared with $152,000 for the quarter ended December 31, 1999. This 150% increase was the result of our additional borrowings to finance new facilities and equipment placed in service in 1999.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2000, we had cash and short term investments of $36.4 million and long-term investments of $5.2 million, compared with cash and short-term investments of $11.8 million and long-term investments of zero at June 30, 2000. We completed our IPO in October 2000 for net proceeds of $32.2 million.

Net cash used in operating activities was $1.7 million and $3.8 million for the six months ended December 31, 2000 and 1999, respectively. The decrease in cash used during the six months ended December 31, 2000, compared to the six months ended December 31, 1999, was primarily the result of a higher net loss in 2000 compared to 1999 offset by (1) a smaller increase in inventory in 2000 compared to 1999 as a result of our lower production levels arising from our successful production and shipment in previous periods of INGN 201 to Aventis in the amounts and timeframes they requested, which allowed them to accumulate an adequate supply of clinical materials to support INGN 201 Phase II and Phase III clinical trials in the near term and (2) an increase in accounts payable in 2000 compared to a decrease in 1999 due to (a) certain costs related to our IPO not being paid until 2001 resulting in those costs being in accounts payable at December 31, 2000, and (b) the payment in 1999 of costs related to the construction of our new facilities, which were in accounts payable at June 30, 1999.

Net cash used in investing activities was $30.0 million for the six months ended December 31, 2000, and net cash provided by investing activities was $1.2 million for the six months ended December 31, 1999. The change in the six months ended December 31, 2000, compared to the six months ended December 31, 1999 was primarily due to (1) higher payments for purchases of property and equipment in 2000 compared to 1999 as a result of costs incurred for finish-out work on our facilities in 2000 related to the sublease of space to The University of Texas M.D. Anderson Cancer Center and (2) higher purchases of investments net of maturities of investments in 2000 compared to 1999 due to investment activities involving the proceeds from our IPO in 2000.

Net cash provided by financing activities was $34.6 million for the six months ended December 31, 2000 and $2.8 million for the six months ended December 31, 1999. The increase in the six months ended December 31, 2000, compared to the six months ended December 31, 1999 was primarily due to the receipt of proceeds from our IPO during in 2000 offset by (1) higher proceeds being received in 1999 compared to 2000 from the mortgage note payable for our new facilities and (2) higher payments on debt obligations in 2000 compared to 1999. As of December 31, 2000, we had $7.8 million outstanding under notes payable for our facilities and $2.5 million outstanding under capital lease obligations to finance purchases of equipment.

Short-term investments at December 31, 2001 include $2.0 million of commercial paper issued by Southern California Edison Electric with a maturity date of February 28, 2001. We intend to hold this investment until maturity.

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 indication or other disease.

We and Aventis have commenced the first of our planned Phase III clinical trials of INGN 201, our lead product candidate, for the treatment of head and neck cancer, and are conducting a Phase II clinical trial of INGN 201 for the treatment of non-small cell lung cancer and six Phase I clinical trials of INGN 201 for other cancer indications. We have also commenced a Phase I clinical trial of INGN 241, our product candidate based on the mda-7 gene. We do not have significant clinical trial experience with other product candidates. Current or future clinical trials may demonstrate that INGN 201, INGN 241 and our other product candidates are neither safe nor effective.

Any delays or difficulties we encounter in our clinical trials, in particular the Phase III clinical trial of INGN 201 for the treatment of head and neck cancer, may delay or preclude regulatory approval. Any delay or preclusion could also delay or preclude the commercialization of INGN 201 or any other product candidates. In addition, we or the United States Food and Drug Administration, or FDA, might delay or halt any of our clinical trials of a product candidate at any time for various reasons, including:

- failure of the product candidate to be more effective than current therapies;
- presence of unforeseen adverse side effects of a product candidate, including its delivery system;
- longer than expected time required to determine whether or not a product candidate is effective;
- death of patients during a clinical trial, even though the product candidate may not have caused those deaths;
- failure to enroll a sufficient numbers of patients in our clinical trials; or
- our inability to produce sufficient quantities of a product candidate to complete the trials.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us.

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

WE MAY ENCOUNTER FAILURES OR DELAYS IN PERFORMING CLINICAL TRIALS FOR INGN 241 AND OUR OTHER NON-INGN 201 PRODUCT CANDIDATES, WHICH WOULD INCREASE OUR PRODUCT DEVELOPMENT COSTS.

While we have begun a Phase I clinical trial with INGN 241, a product candidate based on the mda-7 gene, our most significant clinical trial activity and experience has been with INGN 201. We will need to continue conducting significant research and animal testing, referred to as preclinical testing, to support performing clinical trials for INGN 241 and our other non-INGN 201 product candidates. It will take us many years to complete preclinical testing and clinical trials, and failure could occur at any stage of testing. Acceptable results in early testing or trials may not be repeated later. Moreover, not all product candidates in preclinical testing or early stage clinical trials will receive timely, or any, 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. If the delays are significant, the increased development costs will negatively affect our financial results, and these delays could delay our commercialization efforts.

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, that occur in the field of gene therapy may result in greater governmental regulation of our product candidates

and potential regulatory delays relating to the testing or approval of our product candidates. The death in 1999 of a patient undergoing gene therapy using an adenoviral vector to deliver a gene for disease treatment in a clinical trial which was unrelated to our clinical trials, was widely publicized. As a result of this death, the United States Senate held hearings concerning the adequacy of regulatory oversight of gene therapy clinical trials and to determine whether additional legislation is required to protect volunteers and patients who participate in such clinical trials. The Recombinant DNA Advisory Committee, or RAC, which acts as an advisory body to the National Institutes of Health, or NIH, evaluated and continues to evaluate the use of adenoviral vectors in gene therapy clinical trials. The RAC has made recommendations to the NIH director concerning prospective review of study designs and adverse event reporting procedures, and the FDA has requested that sponsors of clinical trials provide detailed procedures for supervising clinical investigators and clinical study conduct. In addition, the FDA has recently begun to conduct more frequent inspections at clinical trial sites. Implementation of any additional review and reporting procedures or other additional regulatory measures could increase the costs of or prolong our product development efforts or clinical trials.

Following routine procedure, we report to the FDA and the NIH serious adverse events, whether treatment-related or not, that occur in our clinical trials, including deaths. In one of our Phase I studies conducted from 1995 to 1997, we reported two deaths for which the clinical investigator involved could not unequivocally rule out the possibility that the deaths were related to our gene therapy treatment; however, there was no evidence that our gene therapy was responsible for the deaths. We have not received any correspondence from any regulatory body or experienced any increased scrutiny of our clinical or other activities as a result of these deaths. However, reporting of serious adverse events that are determined to be treatment-related in gene therapy clinical trials conducted by us or by others could result in 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.

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

We have generated operating losses since we began operations in June 1993. As of December 31, 2000, we had an accumulated deficit of approximately $23.1 million. We expect to incur substantial additional

operating expenses and losses over the next several years as our research, development, preclinical testing and clinical trial activities increase. We have no products that have generated any commercial revenue, and our only revenues to date have been payments from Aventis under collaborative agreements for research and development and sales to Aventis of INGN 201 for use in clinical trials. We do not expect to generate revenues from the commercial sale of products in the foreseeable future, and we may never generate revenues from the sale of products.

IF WE CONTINUE TO INCUR OPERATING LOSSES FOR A PERIOD LONGER THAN WE ANTICIPATE AND FAIL TO OBTAIN THE CAPITAL NECESSARY TO FUND OUR OPERATIONS, WE WILL BE UNABLE TO ADVANCE OUR DEVELOPMENT PROGRAM AND COMPLETE OUR CLINICAL TRIALS.

Developing a new drug and conducting clinical trials for multiple disease indications is expensive. We expect that we will fund our capital expenditures and operations over at least the next two years with our current working capital, the net proceeds from our IPO in October 2000 and future payments, if any, under our collaborative agreements with Aventis. We may need to raise additional capital sooner, however, due to a number of factors, including:

- an acceleration of the number, size or complexity of our clinical trials;
- slower than expected progress in developing INGN 201, INGN 241 and other product candidates;
- higher than expected costs to obtain regulatory approvals;
- higher than expected costs to pursue our intellectual property strategy;
- higher than expected costs to further develop our manufacturing capability; and
- higher than expected costs to develop our sales and marketing capability, particularly if we choose to form a joint marketing operation with Aventis for the sale of INGN 201.

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

IF WE CANNOT MAINTAIN OUR CURRENT COLLABORATIVE RELATIONSHIP WITH AVENTIS, OUR PRODUCT DEVELOPMENT WOULD BE DELAYED.

We rely to a significant extent on Aventis to fund and support the development of products based on the p53 gene, including INGN 201, which are part of our collaboration with Aventis. Under our collaboration agreements, Aventis agrees on an annual basis whether and to what extent it will continue to fund our early stage development in North America of products based on the p53 gene, which includes preclinical research and development and Phase I clinical trials. If Aventis does not agree to continue to fund this early stage development, and we decide to continue this development, we would have to fund this development ourselves or obtain funding from other sources.

Once we have completed Phase I clinical trials of a product candidate based on the p53 gene, Aventis may elect to pursue later stage clinical development of that product candidate, which includes conducting Phase II and III clinical trials, commercializing the product, making all further submissions to existing Investigational New Drug, or IND, applications and preparing all product license applications. Aventis has elected to pursue later stage development of INGN 201. However, if Aventis does not make this election with respect to other product candidates based on the p53 that may emerge in the future, neither we nor

Aventis may develop or

commercialize such product candidates before October 2004 without the other's approval. Consequently, our development or commercialization efforts for the product could be delayed if Aventis fails to consent to our further development and commercialization. We are currently in negotiations with Aventis regarding the possible restructuring of our collaborative relationship. We are uncertain whether we can restructure the relationship on terms that are favorable to us. Aventis may terminate its collaboration agreements with us, in whole or in part with respect to individual products, at any time upon six months' notice. If Aventis were to breach or terminate its collaboration agreements with us or otherwise fail to conduct the collaborative activities successfully and in a timely manner, the research, development or commercialization of the affected products or research programs could be delayed or terminated.

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

Our strategy for the research, development and commercialization of our product candidates may require us to enter into contractual arrangements with corporate collaborators in addition to Aventis, academic institutions and others. We have entered into sponsored research and/or collaborative arrangements with several entities, including The University of Texas M.D. Anderson Cancer Center, 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 or enter into new arrangements or negotiate current or new arrangements on acceptable terms, if at all. Some of our collaborative partners may also be researching competing technologies independently from us to treat the diseases targeted by our collaborative programs.

IF WE ARE NOT ABLE TO CREATE AND CONTINUE EFFECTIVE COLLABORATIVE MARKETING RELATIONSHIPS WITH AVENTIS AND OTHERS, WE MAY BE UNABLE TO MARKET INGN 201 SUCCESSFULLY.

If we elect to form a joint commercial operation with Aventis to market the products developed under our collaboration with Aventis in North America, we may be required 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 additional 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.

In markets where Aventis has exclusive marketing rights to INGN 201, including North America should we elect not to form a joint commercial

operation, Aventis will pay us royalties on product sales. Further, any royalties we receive from product sales in the markets where Aventis has exclusive marketing rights will depend entirely on the efforts of Aventis. In those markets where we and Aventis have co-marketing rights, there is the potential that we will compete with Aventis in those markets. Aventis is a large, global pharmaceutical company with far greater financial and other resources than we have, and therefore, our ability to compete with Aventis will be limited.

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 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 The University of Texas M. D. Anderson Cancer Center, we are currently seeking patent protection for adenoviral p53, including INGN 201, and its use in cancer therapy. We are also seeking patent protection for our adenovirus production technology. While we have received a notice of allowance from the PTO that it will issue to us a patent for our adenovirus production technology, it is possible that the patents may not issue. We also control, through licensing arrangements, two issued United States patents for combination therapy involving the p53 gene and conventional chemotherapy or radiation and one issued United States patent covering the use of adenoviral p53 in cancer

therapy. Our competitors may challenge the validity of one or more of our combination therapy or adenoviral p53 therapy patents, or the potential patents relating to adenovirus production, 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 an interference proceedings regarding our patents and none of our patents may give us a competitive advantage.

The PTO has notified us that one of our patent applications directed to our adenoviral p53 technology, and one other patent application directed to specific retroviral technologies directed to vectors based on a different type of virus that uses RNA instead of DNA as its genetic material, and that do not relate to any of our current product candidates, have been allowed, but that their issuance is being suspended for the possible institution of interference proceedings. Another patent application directed to another adenoviral technology that also does not relate to any of our current product candidates is currently involved in an interference proceeding. An interference proceeding is instituted by the PTO to determine, as between two or more parties claiming the same patentable invention, which party has the right to the patent. If any of these or other patent applications become involved in an interference proceeding, there is a likelihood that it will take many years to resolve. Resolution of any such interference will require that we expend time, effort and money. Of the two suspended applications, only the application directed to the adenoviral p53 technology is relevant to our current potential products. If an interference is declared with respect to the adenoviral p53 application, and if the opponent ultimately prevails in the interference, the opponent will have a patent that could cover our potential INGN 201 product or its clinical use. The patent application that is currently involved in an ongoing interference proceeding does not relate to any of our product candidates. While the resolution of this interference will require that we expend time, effort and money, its outcome is not expected to affect any of our current commercialization efforts.

THIRD PARTY CLAIMS OF INFRINGEMENT OF INTELLECTUAL PROPERTY COULD REQUIRE US TO SPEND TIME AND MONEY TO ADDRESS THE CLAIMS AND COULD LIMIT OUR INTELLECTUAL PROPERTY RIGHTS.

The biotechnology and pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We are aware of a number of issued patents and patent applications that relate

to gene therapy, the treatment of cancer and the use of the p53 and other tumor suppressor genes. Schering-Plough Corporation, or its subsidiary Canji, Inc., controls various United States patent applications and a European patent and applications, some of which are directed to therapy using the p53 gene, and others to adenoviruses that contain the p53 gene, or adenoviral p53, and to methods for carrying out therapy using adenoviral p53. In addition, Canji controls an issued United States patent and its international counterparts, including a European patent, involving a method of treating mammalian cancer cells lacking normal p53 protein by introducing a p53 gene into the cancer cell.

While we believe that our potential products do not infringe any valid claim of the Canji p53 patents, Canji or Schering-Plough could assert a claim against us. We may also become subject to infringement claims or litigation arising out

of other patents and pending applications of our competitors, if they issue, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO interference proceedings and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how or to determine the enforceability, scope and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes are often settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, the necessary licenses may not be available to us on satisfactory terms, if at all. In particular, if we were found to infringe a valid claim of the Canji p53 issued United States patent, our business could be materially harmed.

We and Aventis are currently involved in three opposition proceedings before the European Patent Office, or EPO, in which we are seeking to have the EPO revoke three different European patents owned or controlled by Canji. These European patents relate to the use of a p53 gene, or the use of tumor suppressor genes, in the preparation of therapeutic products. In one opposition involving the use of a p53 gene, the European patent at issue was upheld following an initial hearing. A second hearing to determine whether this patent should be revoked will be upcoming. The other two oppositions are in earlier stages and a hearing date has not been set. If we do not ultimately prevail in one or more of these oppositions, our competitors could seek to assert by means of litigation any patent surviving opposition against European commercial activities involving our potential products. If our competitors are successful in any such litigation, it could have a significant detrimental effect on our, or our collaborator's, ability to commercialize our potential commercial products in Europe.

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

We compete with pharmaceutical and biotechnology companies, including Canji and Onyx Pharmaceuticals, Inc., which are pursuing other forms of treatment for the diseases INGN 201 and our other product candidates target. We also may face competition from companies that may develop internally or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions which may prevent or limit our product commercialization efforts.

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

EVEN IF WE RECEIVE REGULATORY APPROVAL TO MARKET INGN 201, 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 INGN 201, INGN 241 and our other product candidates. The commercial success of our product candidates will depend on whether:

- they are more effective than alternative treatments;
- their side effects are acceptable to patients and doctors;
- we produce and sell them at a profit; and
- we and Aventis market INGN 201 effectively, if we choose to form a joint marketing operation with Aventis.

IF WE ARE UNABLE TO MANUFACTURE OUR PRODUCTS IN SUFFICIENT QUANTITIES OR ARE UNABLE TO OBTAIN REGULATORY APPROVALS FOR OUR MANUFACTURING FACILITY, WE MAY BE UNABLE TO MEET DEMAND FOR OUR PRODUCTS AND LOSE POTENTIAL REVENUES.

Completion of our clinical trials and commercialization of our product candidates require 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 INGN 201 for our currently planned clinical trials and eventually for the initial commercial launch of INGN 201. We manufacture INGN 241 and other product candidates in a separate, leased facility. We have no experience manufacturing INGN 201, INGN 241 or any other product candidates in the volumes that will be necessary to support commercial sales. If we are unable to manufacture our product candidates in clinical or, when necessary, commercial quantities, then we will need to rely on third party manufacturers to manufacture compounds for clinical and commercial purposes. These third party manufacturers must receive FDA approval before they can produce clinical material or commercial product. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority than ours. In addition, we may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms. There are very few contract manufacturers who currently have the capability to produce INGN 201, 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 INGN 201, INGN 241 or any other product candidate, we must obtain regulatory approval of our manufacturing facility and process. Manufacturing of our product candidates for clinical and commercial purposes must comply with the FDA's Current Good Manufacturing Practices requirements, commonly known as CGMP, and foreign regulatory requirements. The CGMP requirements govern quality control and documentation policies and procedures. In complying with CGMP and foreign regulatory requirements, we will be obligated to expend time, money and effort in production, recordkeeping and quality control to assure that the product meets applicable specifications and other requirements. We must also pass a pre-approval inspection prior to FDA approval. Our manufacturing facilities have not yet been subject to an FDA or other regulatory inspection. Failure to pass a preapproval 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 INGN 201 or any other product candidates would be significantly hampered. This, in turn, could result in delays in our

preclinical testing, clinical trials or commercialization efforts.

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 INGN 201, INGN 241 and our other product candidates. Some of these materials are available from only one supplier or vendor. Any significant problem that one of our sole source suppliers experiences could result in a delay or interruption in the supply of materials to us until that supplier cures the problem or until we locate an alternative source of supply. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations, which could negatively affect our operations.

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

IF PRODUCT LIABILITY LAWSUITS ARE SUCCESSFULLY BROUGHT AGAINST US, WE MAY INCUR SUBSTANTIAL DAMAGES AND DEMAND FOR THE PRODUCTS MAY BE REDUCED.

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

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

We currently maintain product liability insurance with coverage of $2.0 million. This coverage may not be sufficient to protect us fully against product liability claims. We intend to expand our product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or limit the commercialization of our products.

WE USE HAZARDOUS MATERIALS IN OUR BUSINESS, AND ANY CLAIMS RELATING TO IMPROPER HANDLING, STORAGE OR DISPOSAL OF THESE MATERIALS COULD HARM OUR BUSINESS.

Our business involves the use of a broad range of hazardous chemicals and materials. Environmental laws impose stringent civil and criminal penalties for improper handling, disposal and storage of these materials. In addition, in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials, we could be subject to civil damages due to personal injury or property damage caused by the release or exposure. A failure to comply with

environmental laws could result in fines and the revocation of environmental permits, which could prevent us from conducting our business.

OUR STOCK PRICE MAY FLUCTUATE SUBSTANTIALLY.

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

- the announcement of new products or services by us or our competitors;
- quarterly variations in our or our competitors' results of operations;

- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;
- developments in our industry; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In addition, stock prices for many companies in the technology and emerging growth sectors have experienced wide fluctuations that have often been unrelated to the operating performance of such companies. Many factors may have a significant adverse effect on the market price of our common stock, including:

- results of our preclinical and clinical trials;
- announcement of technological innovations or new commercial products by us or our competitors;
- developments concerning proprietary rights, including patent and litigation matters;
- publicity regarding actual or potential results with respect to products under development by us or by our competitors;
- regulatory developments; and
- quarterly fluctuations in our revenues and other financial results.

We have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future.

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

- potential exposure to unknown liabilities of acquired companies;
- the difficulty and expense of assimilating the operations and personnel

of acquired businesses;

- diversion of management time and attention and other resources;
- loss of key employees and customers as a result of changes in management;
- the incurrence of amortization expenses; and
- possible dilution to our stockholders.

In addition, geographic distances may make the integration of businesses more difficult. We may not be successful in overcoming these risks or any other problems encountered in connection with any acquisitions. As of the date of this report, we have no present commitments or agreements for any material investment or acquisition, other than acquiring or maintaining rights to technologies in the ordinary course of our business.

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- and long-term investments in investment grade securities, which consist primarily of federal and state government obligations, commercial paper and corporate bonds. Investments are classified as held-to-maturity and are carried at amortized costs. We do not hedge interest rate exposure or invest in derivative securities.

PART II - OTHER INFORMATION

ITEM 1: LEGAL PROCEEDINGS

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

On January 12, 2001, we received notice that we had been joined as a defendant on January 11, 2001, by Canji, Inc. in a lawsuit: Canji, Inc. v. Sidney Kimmel Cancer Center, Introgen Therapeutics, Inc., and Does 2 through 25 (Case No. GIC745643, in the California Superior Court for the County of San Diego, Central District). Canji, Inc. filed its original complaint against the Sidney Kimmel Cancer Center (SKCC) on March 24, 2000. In its first amended complaint, which joins us as a defendant in the litigation, Canji alleges that certain gene therapy patents and technology relating to the treatment of cancer using gene therapy in combination with a class of chemotherapeutic agents known as DNA repair inhibitors, which patents and technology were developed by SKCC under a sponsored research agreement between SKCC and us and exclusively licensed to us from SKCC (the SKCC IP), were developed in part using materials provided by Canji to SKCC under a Material Transfer Agreement (MTA). Canji further alleges that under the MTA, Canji had the right of first refusal to a license to any patent rights arising out of the technology developed by SKCC using the Canji materials. Canji further alleges that we wrongfully obtained rights in intellectual property derived from SKCC's use of Canji's materials. As relief against us, Canji seeks: a declaratory judgment that we are not entitled to the intellectual property rights conveyed by SKCC to us, and that instead those rights belong to Canji; the imposition of a constructive trust on the patent rights granted to us; and injunctive relief to restore Canji to the position it was in prior to the SKCC's grant of intellectual property rights to

us. We believe that Canji's allegations are without merit and intend to defend the action. The SKCC IP is not material to our business.

We do not believe that the outcome of any present litigation, or all litigation in the aggregate, other than our opposition of three European patents owned by Canji discussed under "Factors Affecting Future Operating Results," will have a significant effect on our business. You can read the discussion of our opposition of the patents under "Factors Affecting Future Operating Results."

ITEM 2: CHANGES IN SECURITIES AND USE OF PROCEEDS

We closed our IPO on October 17, 2000, pursuant to a Registration Statement on Form S-1 (File No. 333-30582), which was declared effective by the Securities and Exchange Commission on October 11, 2000. In the IPO, we sold an aggregate of 4,000,000 shares of common stock at $8.00 per share (the underwriters' over-allotment option of 600,000 shares of common stock was exercised on October 18, 2000, at $8.00 per share). The sale of the shares of common stock generated aggregate net proceeds of approximately $32,225,000. We expect to use the net proceeds from our IPO to conduct research and development, including clinical trials, advance our process development and manufacturing capabilities, initiate product marketing and commercialization programs, and for general corporate purposes, including working capital. Pending these uses, the net proceeds of the offering are invested in interest bearing, investment grade securities.

ITEM 3: DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5: OTHER INFORMATION

On January 10, 2001, we announced the appointment of two new members to our board of directors: Charles E. Long and Elise T. Wang. Ms. Wang succeeds Francois Meyer, vice president of Aventis, who resigned from our board of directors effective as of January 11, 2001. Ms. Wang is a Class I director and Mr. Long is a Class II director.

ITEM 6: EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Exhibit No.	Description of Exhibit
3.2	Amended and Restated Bylaws of Introgen (supercedes and replaces Exhibits 3.2(a) and 3.2(b) filed with Introgen's Registration Statement on Form S-1 (File No. 333-30582))

(b) Reports on Form 8-K

None.

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: February 14, 2001

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

James W. Albrecht, Jr.
Chief Financial Officer (Principal Financial and Accounting Officer)

INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.2	Amended and Restated Bylaws of Introgen (supercedes and replaces Exhibits 3.2(a) and 3.2(b) filed with Introgen's Registration Statement on Form S-1 (File No. 333-30582))