INTROGEN THERAPEUTICS INC
Form 10-Q
May 14, 2001

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

FORM 10-Q

(Mark One)

X ----- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2001.

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 __

At March 31, 2001, 21,285,292 shares of common stock of the Registrant were outstanding.

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INTROGEN THERAPEUTICS, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1: CONSOLIDATED FINANCIAL STATEMENTS

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	JUNE 30, 2000	MARCH 200
		(unaudited)
Current Assets:		
Cash and cash equivalents	$ 1,788,612	$ 7,09
Short-term investments	9,976,469	23,50
Accounts receivable	--	
Inventory	1,734,329	
Other current assets	4,808	32
Total current assets	13,504,218	30,93
Property and equipment, net of accumulated depreciation of $2,988,387 and $4,596,274, respectively	10,152,572	11,95
Long-term investments	--	7,960
Other assets	1,197,733	41
Total assets	$24,854,523	$51,27
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 262,977	$ 44
Accrued liabilities	1,026,330	1,60
Deferred revenues from affiliate	1,205,655	
Current portions of capital lease obligations and notes payable	746,192	1,26
Total current liabilities	3,241,154	3,32
Capital lease obligations, net of current portion	2,149,281	1,56
Notes payable, net of current portion	5,871,750	8,61
Commitments and contingencies		
Stockholders' Equity:		
Preferred Stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	--	
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 21,285,292 shares issued and outstanding, respectively	4,134	2
Additional paid-in capital	36,536,575	69,52
Deferred compensation	(4,210,412)	(3,75
Accumulated deficit	(18,744,378)	(28,03
Total stockholders' equity	13,592,338	37,75
Total liabilities and stockholders' equity	$ 24,854,523	$ 51,27

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

(Unaudited)

	THREE MONTHS ENDED MARCH 31,		
	2000	2001	
Collaborative research and development revenues from affiliate	$ 1,298,995	$ --	$
Product sales to affiliate	12,267	--	
Cost of product sales	--	--	(
Gross margin on product sales	12,267	--	
Other revenue	--	24,442	
Costs and expenses:			
Research and development	2,305,742	3,784,509	
General and administrative	1,292,115	1,204,479	
Loss from operations	(2,286,595)	(4,964,546)	(
Interest income	187,410	106,230	
Interest expense	(222,653)	(221,805)	
Other income	--	162,411	
Net loss	$(2,321,838)	$ (4,917,710)	$(
Net loss per share, basic and diluted	$ (0.57)	$ (0.23)	$
Shares used in computing basic and diluted net loss per share	4,060,586	21,268,187	

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited)

	NINE MONTHS ENDED MARC	
	2000	20
Cash flows from operating activities:		
Net loss	$ (6,068,381)	$ (9,2
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	1,089,664	1,6
Compensation related to issuance of stock options	1,578,690	1,1
Adjustment to investments	--	5
Changes in assets and liabilities		
Decrease (increase) in receivable from affiliate	(400,917)	
Decrease (increase) in inventory	516,055	1,7
Decrease (increase) in other assets	(446,496)	(3
Increase (decrease) in accounts payable	(1,722,626)	1
Increase (decrease) in accrued liabilities	353,661	5
Increase (decrease) in deferred revenue from affiliate	99,819	(1,2
Net cash used in operating activities	(5,000,531)	(5,0
Cash flows from investing activities:		
Purchases of property and equipment	(590,977)	(3,4
Purchases of investments	(12,855,671)	(70,4
Maturities of investments	15,139,500	48,4
Net cash provided by (used in) investing activities	1,692,852	(25,4
Cash flows from financing activities:		
Proceeds from stock option exercises	56,385	
Proceeds from initial public offering, net of offering costs paid during period	(268,570)	33,0
Proceeds from issuance of notes payable	2,814,007	3,2
Principal payments under capital lease obligations and notes payable	(137,615)	(5
Net cash provided by financing activities	2,464,207	35,7
Net increase (decrease) in cash	(843,472)	5,3
Cash, beginning of period	2,145,676	1,7
Cash, end of period	$ 1,302,204	$ 7,0
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 465,875	$ 6
Supplemental disclosure of noncash investing and financing activity:		
Offering costs paid during prior period netted against initial public offering proceeds	$ --	$ 7

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. 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, which is based on the mda-7 gene.

INGN 201 is currently in Phase III clinical trials for the treatment of head and neck cancer, 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. 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 developed INGN 201 in collaboration with Aventis Pharma AG, formerly Rhone-Poulenc Rorer Pharmaceuticals, Inc. (Aventis or the affiliate). In April 2001, Introgen and Aventis signed a letter of intent to restructure this collaboration. Under this proposed restructuring, which is subject to definitive documentation, certain due diligence and board approvals, Introgen will assume responsibility for the worldwide development of all p53 programs under the existing collaboration between the two companies and will obtain exclusive, worldwide commercial rights to p53 based gene therapy products, including INGN 201. Aventis will increase its equity interest in Introgen by investing a minimum of $20 million and a maximum of $22.7 million in non-voting, preferred stock of Introgen, convertible into Introgen common stock at a premium to the market price at the date of conversion. Introgen and Aventis will also exchange certain intellectual property, which will include Introgen granting Aventis a license under certain of its intellectual property relating to adenoviral technology and transferring to Aventis certain intellectual property rights held by Introgen's wholly-owned European subsidiary, Gendux AB. Aventis has announced it intends to restructure its Gencell gene therapy division into a separate operating company. As part of the proposed restructuring with Aventis, Introgen will receive a five-percent equity interest in Gencell when it is formed. As a result of the proposed restructuring of the Aventis collaboration, Introgen recorded a charge of $408,000 in the quarter ended March 31, 2001 related to the write-off of accounts receivable, inventory and deferred revenue.

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 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 March 31, 2001, 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, as amended.

3. INVESTMENTS:

Short-term investments at March 31, 2001 include $2.0 million of commercial paper issued by Southern California Edison Electric with a maturity date of February 28, 2001. This commercial paper was not redeemed by the issuer on its maturity date. Accordingly, Introgen has reduced the carrying value of this investment by $500,000 in order to state this commercial paper at its estimated fair market value.

4. 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 6). 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.

5. 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.

6. 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 $32.2 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.

7. SUBLEASE AND LOAN AGREEMENT:

Introgen is finalizing an agreement with The University of Texas M.D. Anderson Cancer Center (UTMDACC) to sublease UTMDACC approximately 11,000 square feet of space in Introgen's 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 March 31, 2001, borrowings of $3.2 million had been made 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. UTMDACC is currently occupying this space and paying Introgen an access and use fee of approximately $76,000 per month until the lease is finalized.

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

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes thereto included in this report on Form 10-Q. The discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include 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, to date, we have developed and extensively tested

in collaboration with Aventis. We 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 based on the PTEN gene, as well as associated technologies for delivering the gene-based products into target cells, which technologies are referred 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 March 31, 2001, we had an accumulated deficit of approximately $28.0 million. We anticipate that we will incur losses in the future that are likely to be greater than cumulative losses incurred in prior years. We expect that cash needed for operating activities will increase as we continue to expand 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 currently 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 March 31, 2001, 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. In April 2001, we signed a letter of intent with Aventis to restructure the collaboration agreements for the p53 and K-ras genes. Under this proposed restructuring, which is subject to definitive documentation, certain due diligence and board approvals, we will assume responsibility for the worldwide development of all p53 and K-ras products under the existing collaboration between the two companies and will obtain exclusive worldwide commercial rights to p53- and K-ras-based gene therapy products, including INGN 201. Aventis will increase its equity interest in Introgen by investing a minimum of $20.0 million and a maximum of $22.7 million in our non-voting preferred stock, which preferred stock will be convertible into our common stock at a premium to the market price at the date

of conversion. We and Aventis will also exchange certain intellectual property, which will include our granting Aventis a license under certain of our intellectual property relating to adenoviral technology and transferring to Aventis of certain intellectual property rights held by our wholly-owned European subsidiary, Gendux AB. Aventis has announced it intends to restructure its Gencell gene therapy division into a separate operating company. As part of the proposed restructuring with Aventis, we will receive a five-percent equity interest in Gencell if and when it is formed.

Under the existing collaboration agreements, we have generally received payments from Aventis for early stage development activities quarterly in advance. We recorded these payments as revenue as we performed the collaboration work and incurred the related expenses. We recorded as deferred revenue collaborative research and development payments which we received but for which the related expenses had not yet been incurred. Under the proposed restructuring, Aventis will no longer fund any of our research and development.

We manufactured and sold INGN 201 to Aventis for use in later stage clinical trials under the terms of the collaboration agreements. We recorded revenue from these product sales upon completion of production and delivery and Aventis' acceptance of the product. From inception of these agreements through March 31, 2001, we have recorded $7.5 million in revenues from these product sales. Under the proposed restructuring, we will no longer sell INGN 201 to Aventis for use in clinical trials.

RESULTS OF OPERATIONS

COMPARISON OF QUARTERS ENDED MARCH 31, 2001 AND 2000

Revenues

Revenue from Collaborations. We had no revenues from Aventis for collaborative research and development for the quarter ended March 31, 2001, compared to $1.3 million for the quarter ended March 31, 2000. This decrease was due to the proposed restructuring of our collaboration with Aventis for the development of INGN 201 and other p53-based gene therapy products, resulting in us not receiving payments from Aventis during the 2001 quarter for early stage research and development related to the p53-based gene therapy products. Prior to this proposed restructuring, we earned revenue from Aventis for early stage research and development we performed under the collaboration agreements.

Revenue from Product Sales to Affiliate. Revenues from product sales to Aventis were minimal for the quarters ended March 31, 2001, and March 31, 2000. The absence of significant product sales during the quarter ended March 31, 2001, was due to the restructuring of our collaboration with Aventis, which eliminated our need to sell product to Aventis since we will use the product internally in the future development of INGN 201.

Other Revenue. Other revenue was minimal for the quarters ended March 31, 2001, and March 31, 2000. We generally earn other revenue under research grants from U.S. Government agencies and contract manufacturing arrangements with third parties.

Costs and Expenses

Cost of Product Sales. Cost of product sales was zero for the quarters ended March 31, 2001, and March 31, 2000. The absence of cost of product sales during the quarter ended March 31, 2001 was due to the proposed restructuring of our collaboration with Aventis, which eliminated our need to sell product to Aventis since we will use the product internally in the future development of INGN 201.

Research and Development. Research and development expenses, excluding amortization of deferred stock compensation of $111,000 in 2001 and zero in 2000, were $3.7 million for the quarter ended March 31, 2001, compared to $2.3 million for the quarter ended March 31, 2000. This 61% increase was primarily due to (1) increased activity related to the development of INGN 241, which combines the mda-7 gene with our gene delivery system, (2) expenses of $408,000 related to the write-off of accounts receivable, inventory and

deferred revenue that will not be realized as a result of the proposed Aventis collaboration restructuring and (3) no costs being capitalized as inventory as a result of the proposed Aventis collaboration restructuring, which will eliminate future inventory sales to Aventis.

General and Administrative. General and administrative expenses, excluding amortization of deferred stock compensation of $281,000 in 2001 and $641,000 in 2000, were $924,000 for the quarter ended March 31, 2001, compared to $651,000 for the quarter ended March 31, 2000. This 42% increase was due to the additional, ongoing administrative costs associated with operating as a public company subsequent to our IPO in October 2000.

Amortization of Deferred Compensation. Amortization of deferred stock compensation was $392,000 for the quarter ended March 31, 2001, compared with $641,000 for the quarter ended March 31, 2000. This 39% decrease was primarily due to the 2000 amount including compensation expense arising from the vesting of options held by a non-employee officer. 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 $106,000 for the quarter ended March 31, 2001, compared with $187,000 for the quarter ended March 31, 2000. This 43% decrease was due to higher cash and short- and long-term investment balances arising as a result of our receiving the proceeds from our IPO in October 2000, offset by a $500,000 reduction of interest income to recognize the decline in the market value of certain commercial paper held as an investment. Interest expense was $222,000 for the quarter ended March 31, 2001, compared with $223,000 for the quarter ended March 31, 2000. Even though our notes payable amount was higher in 2001 compared to 2000, interest expense did not increase proportionally because the interest incurred related to the additional borrowings in 2001 was capitalized as a cost of finishing the space to be subleased to UTMDACC.

COMPARISON OF NINE MONTHS ENDED MARCH 31, 2001 AND 2000

Revenues

Revenue from Collaborations. Collaborative research and development revenues from Aventis were $3.0 million for the nine months ended March 31, 2001, compared to $5.2 million for the nine months ended March 31, 2000. This 42% decrease was primarily due to the proposed restructuring of our collaboration with Aventis, resulting in us not receiving payments from Aventis during the quarter ended March 31, 2001, for early stage research and development related to p53-based gene therapy based products. Prior to this proposed restructuring, we earned revenue from Aventis for the early stage research and development we performed under our collaboration agreements with them.

Revenue from Product Sales to Affiliate. Revenues from product sales to Aventis were $1.5 million for the nine months ended March 31, 2001, compared to $1.8 for the nine months ended March 31, 2000. This 17% decrease occurred because there were no product sales during the quarter ended March 31, 2001, due to the proposed restructuring of our collaboration with Aventis, which eliminated our need to sell product to Aventis during that period since we will

use the product internally for the future development of INGN 201.

Other Revenue. Other revenue was $415,000 for the nine months ended March 31, 2001, compared to zero for the nine months ended March 31, 2000. This 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 nine months ended March 31, 2001, compared to $1.2 million for the nine months ended March 31, 2000. This 116% increase was due to a reduction in the number of batches of clinical material in production during the quarter ended December 31, 2000, 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 situation did not continue into the quarter ended March 31, 2001, since the proposed restructuring of the Aventis collaboration eliminated future sales of clinical materials to Aventis resulting in there being no cost of product sales during that quarter.

Research and Development. Research and development expenses, excluding amortization of deferred stock compensation of $320,000 in 2001 and zero in 2000, were $8.6 million for the nine months ended March 31, 2001, compared to $7.9 million for the nine months ended March 31, 2000. This 9% increase was primarily due to (1) increased activity related to the development of INGN 241, which combines the mda-7 gene with our gene delivery system, (2) expenses of $408,000 related to the write-off of accounts receivable, inventory and deferred revenue that will not be realized as a result of the proposed restructuring of the Aventis collaboration and (3) no costs being capitalized as inventory during the quarter ended March 31, 2001 as a result of the proposed restructuring of the Aventis collaboration eliminating future inventory sales to Aventis. These increases were offset by a decreased level of early stage research and development performed by us relative to products based on the p53 gene, as such products evolved into later stage development, which Aventis performed prior to the proposed restructuring of our collaboration agreement.

General and Administrative. General and administrative expenses, excluding amortization of deferred stock compensation of $817,000 in 2001 and $1.6 million in 2000, were $2.4 million for the nine months ended March 31, 2001 and $2.9 million for the nine months ended March 31, 2000. This 17% decrease was due primarily to non-recurring costs incurred during the nine months ended March 31, 2000 related to the organization and formation of Gendux AB, which was partially offset by the additional, ongoing costs associated with operating as a public company subsequent to our IPO in October 2000.

Amortization of Deferred Compensation. Amortization of deferred stock compensation was $1.1 million for the nine months ended March 31, 2001, compared with $1.6 million for the nine months ended March 31, 2000. This 31% decrease was primarily due to the 2000 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 and compensation expense arising from the vesting of options held by a non-employee officer. 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 $889,000 for the nine months ended March 31, 2001, compared with $546,000 for the nine months ended March 31, 2000. This 63% 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, offset by a $500,000 reduction of interest income in 2001 to recognize the decline in the market value of certain commercial paper held as an investment. Interest expense was $602,000 for the nine months ended March 31, 2001, compared with $133,000 for the nine months ended March 31, 2000. This 353% increase was the result of our borrowings to finance new facilities and equipment placed in service during the last six months of the 2000 period, which were outstanding for only a portion of that period as compared to being outstanding for all of the 2001 period.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2001, we had cash and short term investments of $30.6 million and long-term investments of $8.0 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 $5.1 million and $5.0 million for the nine months ended March 31, 2001 and 2000, respectively. The increase in cash used during the nine months ended March 31, 2001, compared to the nine months ended March 31, 2000, was primarily the result of a higher net loss in 2001 compared to 2000 offset by (1) a smaller increase in receivables from affiliate in 2001 compared to 2000 as a result of lower product sales to affiliate, (2) an increase in accounts payable in 2001 compared to a decrease in 2000 due to the 2000 period including the final payment of accounts payable related to the construction of our new facilities and (3) various other changes in working capital accounts.

Net cash used in investing activities was $25.4 million for the nine months ended March 31, 2001, and net cash provided by investing activities was $1.7 million for the nine months ended March 31, 2000. The change in the nine months ended March 31, 2001, compared to the nine months ended March 31, 2000 was primarily due to (1) purchases of property and equipment in 2001 for finish-out work on our facilities related to the sublease of space to UTMDACC and (2) higher purchases of investments net of maturities of investments in 2001 compared to 2000 due to investment activities involving the proceeds from our IPO in October 2000.

Net cash provided by financing activities was $35.8 million for the nine months ended March 31, 2001, and $2.5 million for the nine months ended March 31, 2000. The increase in the nine months ended March 31, 2001, compared to the nine months ended March 31, 2000, was primarily due to (1) the receipt of proceeds from our IPO during the 2001 period and (2) borrowings under notes payable to finance purchases of property and equipment offset by higher payments on debt obligations in 2001 compared to 2000. As of March 31, 2001, we had $8.4 million outstanding under notes payable for our facilities and $3.1 million outstanding under capital lease obligations to finance purchases of equipment.

Short-term investments at March 31, 2001 include $2.0 million of commercial paper issued by Southern California Edison Electric with a maturity date of February 28, 2001. This commercial paper was not redeemed by the issuer on its maturity date. Accordingly, we have reduced the carrying value of this investment by $500,000 in order to state this commercial paper at its estimated fair market value.

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 have commenced 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 trials 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 number 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 March 31, 2001, we had an accumulated deficit of approximately $28.0 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 and the net proceeds from our initial public offering in October 2000. 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.

We do not know whether additional financing will be available when needed, or on terms favorable to us or our stockholders. We may raise any necessary funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. To the extent we raise additional capital by issuing equity securities, our stockholders will experience dilution. If we raise funds through debt financings, we may become

subject to restrictive covenants. To the extent that we raise additional funds

through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

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

We have relied to a significant extent on Aventis to fund and support the development of products based on the p53 and K-ras genes, including INGN 201, which are part of our existing collaboration with Aventis. We are currently restructuring our collaborative relationship with Aventis. Under this proposed restructuring, which is subject to definitive documentation, certain due diligence and board approvals, we will assume responsibility for the worldwide development of all p53 and K-ras products under the existing collaboration with Aventis. Our development or commercialization efforts for these products could be delayed if we do not complete the proposed restructuring on terms favorable to us or if we are unable to commit the necessary resources to fund the development of the p53 and K-ras programs.

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

Under the terms of the current collaboration agreements, once we have completed Phase I clinical trials of a product candidate based on the p53 and K-ras genes, 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. However, under the terms of the proposed restructuring, we are responsible for later stage clinical development. If we are unable to commit the necessary resources to fund this development, then our development and commercialization effort could be delayed.

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

Our strategy for the research, development and commercialization of our product candidates may require us to enter into contractual arrangements with corporate collaborators 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, WE MAY BE UNABLE TO MARKET INGN 201 SUCCESSFULLY.

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 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.

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 UTMDACC, we are currently seeking patent protection for adenoviral p53, including INGN 201, and its use in cancer therapy. Further, during the quarter ended March 31, 2001, we were issued a United States patent for our adenovirus production technology. We also control, through licensing arrangements, two issued United States patents for combination therapy involving the p53 gene and conventional chemotherapy or radiation and one issued United States patent covering the use of adenoviral p53 in cancer therapy. Our competitors may challenge the validity of one or more of our combination therapy, our adenoviral process technology or our adenoviral p53 therapy patents in the courts or through an administrative procedure known as an interference. The courts or the PTO may not uphold the validity of our patents, we may not prevail in such interference proceedings regarding our patents and none of our patents may give us a competitive advantage.

The PTO has notified us that one of our patent applications directed to our adenoviral p53 technology, and one other patent application, which involve the use of retrovirus, not adenovirus (which retroviral technologies 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 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:

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

o we market INGN 201, INGN 241 and other product candidates effectively.

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 an amended 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, 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 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

None.

ITEM 6: EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits - None.

(b) Reports on Form 8-K

Form 8-K filed with the Securities and Exchange Commission on April 3, 2001.

Item 5. Other Events. On April 2, 2001, Introgen issued a press release announcing the proposed restructuring of its collaboration with Aventis Pharmaceuticals Products Inc.

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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: May 14, 2001

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

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