INTROGEN THERAPEUTICS INC
Form 10-Q
November 06, 2006

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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2006.

or

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

For the transition period from to .

Commission file number 000-21291

Introgen Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

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

301 Congress Avenue, Suite 1850
Austin, Texas 78701
(Address of principal executive offices, including zip code)
(512) 708-9310
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

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

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

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

As of November 1, 2006, the registrant had 37,256,728 shares of its common stock, $0.001 par value per share, issued and outstanding.

INTROGEN THERAPEUTICS, INC.
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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except per share amounts)

	December 31, 2005	September 30, 2006 (Unaudited)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 28,090	$ 13,480
Short term investments	5,032	3,022
Total cash, cash equivalents and short term investments	33,122	16,502
Marketable securities	2,892	2,379
Prepaid expense and other current assets	297	303
Total current assets	36,311	19,184
Property and equipment, net of accumulated depreciation of $12,588 and $13,686, respectively	6,181	5,379
Grant rights acquired	163	
Other assets	326	297
Total assets	$ 42,981	$ 24,860
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,258	$ 2,253
Accrued liabilities	3,296	3,049
Deferred revenue and other	472	640
Current portion of notes payable	756	743
Total current liabilities	6,782	6,685
Notes payable, net of current portion	7,784	7,550
Deferred revenue and other, long-term	1,404	758
Total liabilities	15,970	14,993
Commitments and Contingencies (Note 8)		
Stockholders Equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized; 4,900 shares issuable; zero Series A shares issued and outstanding in 2005 and 2006, respectively		

Common stock, $.001 par value per share; 100,000 shares authorized; 37,147 and 37,257 shares issued and outstanding in 2005 and 2006, respectively	37	37
Additional paid-in capital	170,675	175,609
Deferred compensation	(68)	
Accumulated deficit	(143,459)	(165,107)
Accumulated other comprehensive loss	(174)	(672)
Total stockholders equity	27,011	9,867
Total liabilities and stockholders equity	$ 42,981	$ 24,860

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
(Amounts in thousands, except per share amounts)
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Contract services, grant and other revenue	$ 398	$ 733	$ 1,243	$ 1,056
Operating costs and expense:				
Research and development, including share-based compensation of zero and $267 for the three months ended September 30, 2005 and 2006, respectively, and $396 and $737 for the nine months ended September 30, 2005 and 2006, respectively	5,090	4,256	16,029	14,198
General and administrative, including share-based compensation of zero and $928 for the three months ended September 30, 2005 and 2006, respectively, and $403 and $4,256 for the nine months ended September 30, 2005 and 2006, respectively	1,657	2,546	5,473	9,615
Total operating costs and expense	6,747	6,802	21,502	23,813
Loss from operations	(6,349)	(6,069)	(20,259)	(22,757)
Interest income	161	226	538	792
Interest expense	(153)	(176)	(461)	(507)
Other income	277	281	826	824
Net loss	$ (6,064)	$ (5,738)	$ (19,356)	$ (21,648)
Net loss per share, basic and diluted	$ (0.18)	$ (0.15)	$ (0.61)	$ (0.58)
Shares used in computing basic and diluted net loss per share	33,394	37,245	31,782	37,213

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)
(UNAUDITED)

	Nine Months Ended September 30,	
	2005	**2006**
Cash flows from operating activities:		
Net loss	$ (19,356)	$ (21,648)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,218	1,098
Share-based compensation	550	4,995
Amortization of grant rights acquired	712	133
Other	10	
Changes in assets and liabilities:		
(Increase) decrease in other assets	346	23
Increase (decrease) in accounts payable	(460)	(5)
Increase (decrease) in accrued liabilities	(194)	(247)
Increase (decrease) in deferred revenue and other	432	(672)
Net cash used in operating activities	(16,742)	(16,323)
Cash flows from investing activities:		
Purchases of property and equipment	(506)	(102)
Purchases of short-term investments	(26,908)	(25,070)
Maturities of short-term investments	26,916	27,080
Purchase of marketable securities	(3,041)	
Net cash provided by (used in) investing activities	(3,539)	1,908
Cash flows from financing activities:		
Proceeds from exercise of stock options	601	37
Proceeds from notes payable	655	377
Principal payments under notes payable	(518)	(624)
Net cash provided by (used in) financing activities	738	(210)
Effect of exchange rate changes on cash	(23)	15
Net decrease in cash and cash equivalents	(19,566)	(14,610)
Cash and cash equivalents, beginning of period	30,187	28,090
Cash and cash equivalents, end of period	$ 10,621	$ 13,480
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 424	$ 474
Construction allowance for leasehold improvements	$	$ 194

Non-cash unrealized gain (loss) on marketable securities	$ 992	$ (513)

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 of the Company

See Management s Discussion and Analysis of Financial Condition and Results of Operations (Part I, Item 2) below for a discussion of our business.

We have not yet generated any significant revenue from unaffiliated third parties, nor is there any assurance of future product revenue. We have earned minimal revenue from contract services activities, grants and interest income, as well as rent from the lease of a portion of our facilities to The University of Texas M. D. Anderson Cancer Center. We do not expect to generate revenue from the commercial sale of our products in the near future. We may never generate revenue from the commercial sale of our products.

Our research and development activities involve a high degree of risk and uncertainty. Our ability to successfully develop, manufacture and market our proprietary products is dependent upon many factors. These factors include, but are not limited to, the need for and the ability to obtain 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 these factors and the related uncertainties, there can be no assurance of our future success.

2. Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). These financial statements do not include all of the information and footnotes required under GAAP for complete financial statements. In management s opinion, all accounting entries considered necessary for a fair presentation have been made in preparing these financial statements, and such entries are normal in nature. Operating results for the three and nine month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for the entire fiscal year.

3. Significant Accounting Policies

Our significant accounting policies are described in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006. Those accounting policies remain in effect except to the extent described in the following notes.

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123R (SFAS No. 123R), Accounting For Share-Based Compensation. From that date forward, we record share-based compensation expense for all stock options issued to all persons to the extent such options vest on January 1, 2006 or later. That expense is determined under the fair value method using the Black-Scholes option pricing model. We record that expense ratably over the period the stock options vest.

Prior to January 1, 2006, we applied Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees and related interpretations for determining compensation expense related to our stock option grants. Under that principle, we measured compensation expense for stock options issued to our directors and employees using the intrinsic value of the stock option at date of grant, which generally resulted in us recording no compensation expense since the intrinsic value of those stock options was typically zero at the date of grant due to the exercise price of those stock options being equal to the fair value of our shares on the date of grant. Compensation expense for stock options issued to all other persons was measured using the fair value of the stock option at the date of grant determined under the Black-Scholes option pricing model, which generally resulted in us recording a compensation expense.

The Black-Scholes option pricing model we use to compute share-based compensation expense requires extensive use of accounting judgment and financial estimates. Items requiring estimation include the expected term optionholders will retain their vested stock options before exercising them, the estimated volatility of our common stock price over the expected term of a stock option and the number of stock options that will be forfeited prior to the completion of their vesting requirements. Application of alternative assumptions could result in significantly different

share-based compensation amounts being recorded in our financial statements.

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We implemented SFAS No. 123R using the modified prospective transition method. Under this method, prior periods are not restated.

4. Stock Options

The 2000 Stock Option Plan (Stock Option Plan) was initiated in October 2000. All stock option grants since that time have been under this plan. The Stock Option Plan provides for the granting of options, either incentive or non-statutory, or stock purchase rights to our employees, directors and consultants to purchase shares of our common stock. Option awards are generally granted with an exercise price equal to the fair value of the Company s stock at the date of grant. The awards generally cliff vest 25% per year over a four year period and have contractual terms of ten years. The Stock Option Plan provides for annual increases each January 1 in the number of shares available for issuance in an amount equal to the lesser of 1.6 million shares, 5% of the outstanding shares on the date of the annual increase, or a lesser amount as may be determined by the Board of Directors. At September 30, 2006, there were approximately 1.4 million shares of common stock reserved for future grants under this plan. In the event of a merger, reorganization or change in our controlling ownership, options granted under the Stock Option Plan (1) may be assumed or substituted with substantially equivalent options by the successor corporation and (2) become fully vested and immediately exercisable regardless of whether or not they are assumed or substituted by the successor corporation. The Stock Option Plan terminates in 2010 and may be amended or terminated by the Board of Directors.

Prior to October 2000, stock options were granted under our 1995 Stock Plan. We no longer issue options under this plan. In the event of a merger or the sale of all or substantially all of our assets, all options outstanding under this plan become fully vested and immediately exercisable unless the successor corporation assumes or substitutes other options in their place. No shares of common stock were reserved for future grants under this plan at September 30, 2006.

Our accounting policy for stock options is described in Note 3. Had we recognized share-based compensation expense in our financial statements for the three and nine months ended September 30, 2005 determined using the fair value method for all stock options (as allowed by SFAS No. 123), our net loss would have been increased to the following pro forma amounts (in thousands, except per share information):

		Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss, as reported		$ (6,064)	$ (19,356)
Add: Share-based employee compensation expense included in reported net loss			415
Deduct: Total share-based employee compensation expense determined under fair value based method for all awards		(1,260)	(3,205)
Pro forma net loss		$ (7,324)	$ (22,146)
Loss per share:			
Basic and Diluted	as reported	$ (0.18)	$ (0.61)
Basic and Diluted	pro forma	$ (0.22)	$ (0.70)

These pro forma disclosures are not applicable to the three and nine months ended September 30, 2006, because share-based compensation expense for all stock options vesting during that period is recognized in our financial statements for that period. Our adoption of SFAS No. 123R increased research and development expense by $267,000, or $0.01 per share, and $737,000, or $0.02 per share, for the three and nine months ended September 30, 2006 and general and administrative expense by $0.9 million, or $0.02 per share, and $4.3 million, or $0.12 per share, for the three and nine months ended September 30, 2006.

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Activity under our option plans is as follows:

	Options Outstanding	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (000 s)
Balance, December 31, 2005	5,978,369	$ 4.49		n/a
Granted	1,153,350	4.83		$ 19
Exercised	(61,501)	0.61		$ 265
Cancelled	(79,600)	6.38		n/a
Balance, September 30, 2006	6,990,618	4.56	6.67	$ 5,118
Vested at September 30, 2006 and expected to vest	6,839,441	4.54	6.64	$ 5,054
Exercisable at September 30, 2006	4,597,501	4.15	5.85	$ 4,664

Additional information of note related to our stock options includes:

The weighted average fair value of options granted during the nine months ended September 30, 2006 was $3.60. There were no options granted during the three months ended September 30, 2006.

The aggregate intrinsic value of stock options at exercise, represented in the table above, was $58,000 and $265,000 for the three and nine months ended September 30, 2006.

The total unrecognized share-based compensation expense related to unvested stock options and subject to recognition in future periods was approximately $8.5 million as of September 30, 2006. This amount relates to approximately 2.4 million shares with a per share weighted average fair value of $4.52. We anticipate this expense to be recognized over a weighted average period of approximately 2.03 years.

We applied the following assumptions on a weighted average basis in computing the fair value of stock options at their date of grant using the Black-Scholes option pricing model:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Expected volatility	87.40%	(1)	89.38%	87.85%
Risk free interest rate	4.21%	(1)	4.08%	4.84%
Expected dividend yield	0.00%	(1)	0.00%	0.00%
Expected life, in years	10.00	(1)	10.00	5.78

(1) No options were issued during the three months ended September 30, 2006, hence this information is not applicable for that period.

Specifics regarding these assumptions include:

The expected volatility is calculated using the daily historical volatility of our common stock over a term that approximates the expected life of the option grants. The range of our volatility estimates for the nine months ended September 30, 2006 and 2005 was 84.8% to 90.5% and 87.4% to 91.8%, respectively.

The risk-free interest rate is based on the U.S. treasury yield curve for five to seven-year terms and the ten-year zero coupon treasury bill rate for the three and nine months ended September 30, 2006 and 2005, respectively. The range of our risk-free interest rates for the nine months ended September 30, 2006 and 2005 was 4.29% to 5.10% and 3.94% to 4.46%, respectively.

As allowed by Staff Accounting Bulletin No. 107, we have elected to apply the shortcut approach in developing our estimate of expected term for plain vanilla stock options by using the mid-point between the vesting date and contractual termination date.

We periodically evaluate and revise, as necessary, the assumptions used to calculate the fair value of our stock options in response to changing market conditions and experience.

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5. Intangible Assets

Our intangible assets with definite lives that are subject to amortization, all of which arose from our acquisition of Magnum Therapeutics Corporation (Magnum) in 2004, are as follows (in thousands):

	December 31, 2005			September 30, 2006			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Adjustment To Carrying Amount	Accumulated Amortization	Net Carrying Amount
Asset acquisition:							
Acquired grant rights (22 month amortization period)	$1,741	$(1,578)	$163	$1,741	$ (30)	$(1,711)	$
Ending balance	$1,741	$(1,578)	$163	$1,741	$ (30)	$(1,711)	$

Research and development expense includes amortization of intangibles of zero and $237,000 for the three months ended September 30, 2006 and September 30, 2005, respectively, and $133,000 and $712,000 for the nine months ended September 30, 2006 and September 30, 2005, respectively. During the three months ended March 31, 2006, the acquired grant rights were reduced by $30,000 as a result of the final contractual settlement of the purchase of Magnum. During the three months ended December 31, 2005, we changed our estimate of the useful life of the acquired grant rights from 22 months to 17 months. The effect of this change was to increase amortization expense for the year ended December 31, 2005 and decrease amortization expense for the year ending December 31, 2006 by $470,000. Estimated annual amortization expense for the year ending December 31, 2006 is $133,000, all of which has been recorded as of September 30, 2006, and zero thereafter.

6. Investment in VirRx, Inc.

Under an agreement with VirRx, Inc. (VirRx), we purchased zero and $150,000 of their Series A Preferred Stock in the three and nine month periods ended September 30, 2006, respectively. We purchased $150,000 and $450,000 of that stock during the three and nine month periods ended September 30, 2005, respectively, and are not obligated to make any additional such purchases at this time. We record these purchases as research and development expense. We may be required to make additional stock purchases in the event VirRx reaches certain specified milestones. For additional discussion of our agreements with VirRx, see Business-Business and Collaborative Agreements-VirRx, Inc. in, and Note 9 to our consolidated financial statements included in, our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006.

7. Investment in SR Pharma plc

In July 2005, we purchased approximately 8.3% of the issued share capital of SR Pharma plc (SR Pharma) for approximately $3.0 million. SR Pharma is a European biotechnology company publicly traded on the Alternative Investment Market of the London Stock Exchange (LSE) that is developing oncology and other products. This investment is classified as marketable securities on our balance sheet. Marketable securities are classified as available-for-sale and are presented at fair value with any unrealized gains or losses included in accumulated other comprehensive loss in the stockholders equity section of our balance sheet.

8. Mortgage Note Payable

We have a mortgage note payable to a bank related to our facilities that had an outstanding principal balance of $7.3 million and $7.5 million at September 30, 2006 and December 31, 2005, respectively. In April 2006, we exercised our option to extend the note payable to a November 2009 maturity date, at which time the remaining outstanding principal balance, estimated to be approximately $6.6 million, is payable in full. As a result, the interest rate changed from 6.25% to 7.35% and our monthly installments of principal and interest changed from approximately $56,000 per month to approximately $61,000 per month. Our facilities are pledged as security for the mortgage note payable.

9. Stockholders Equity

Stock Sales

In November 2005, we sold approximately 3.6 million shares of our common stock in a direct equity sale to Colgate-Palmolive pursuant to a shelf registration statement for an aggregate purchase price of approximately $20.0 million. Our net proceeds from this transaction, after related fees and expense, were approximately $19.6 million. For additional discussion of our agreements with Colgate-Palmolive, see Note 9 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006.

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Conversion of Preferred Stock to Common Stock

In 2001, we sold 100,000 shares of $0.001 par value, Series A Non-Voting Convertible Preferred Stock to Aventis Pharmaceutical Products, Inc. (Aventis), which is now Sanofi-Aventis, for $25.0 million. In June 2005, these 100,000 issued and outstanding shares of our Series A non-voting convertible preferred stock were converted into 2,343,721 shares of our common stock. Following the conversion, these shares of preferred stock were cancelled and are no longer issuable. We received no cash or other consideration in connection with this conversion.

Under a voting agreement related to these shares, Aventis must vote all of the shares of ours it holds in the same manner as the shares voted by a majority of the other stockholders on any corporate action put to a vote of our stockholders. This voting requirement terminates at the earliest of June 2011 or the sale of these shares pursuant to an effective registration statement on the open market or to an Aventis non-affiliate, as defined in the voting agreement.

Pursuant to a demand registration made by Aventis in accordance with the terms of a registration rights agreement related to these shares, in November 2005 we filed a Registration Statement on Form S-3 (File No. 333-129687) to facilitate the public resale of up to 4,322,369 shares of our common stock held by Aventis, which includes the converted shares. This registration statement has been declared effective by the SEC and Aventis may resell these shares from time to time in the open market pursuant to the registration statement. We will not receive any of the proceeds from the sale of the shares held by Aventis. As of September 30, 2006, Aventis held approximately 3.7 million shares of our common stock subject to the voting agreement.

After this conversion, we have 5.0 million shares of authorized and unissued preferred shares, of which 100,000 shares have been cancelled and 4.9 million shares are undesignated and issuable.

10. Accumulated Other Comprehensive Income or Loss

Accumulated other comprehensive income or loss is included as a component of stockholders equity and is composed of (1) foreign currency translation adjustments and (2) unrealized gains and losses on investments designated as available-for-sale securities. Accumulated other comprehensive income (loss) is calculated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Net loss	$ (6,064)	$ (5,738)	$ (19,356)	$ (21,648)
Foreign currency translation adjustments	(23)	1	(23)	15
Unrealized gain (loss) on marketable securities	992	478	992	(513)
Total comprehensive loss	$ (5,095)	$ (5,259)	$ (18,387)	$ (22,146)

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes thereto included in this Quarterly Report on Form 10-Q and the other documents we have filed with the Securities and Exchange Commission. In addition to historical information, this report and the following 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 address our future operations, financial condition, business strategies and other prospective items and include, among other subjects, matters concerning our expectations regarding:

The growth of our operations, business and revenues and the growth rate of our costs and expenses;

Future increases in our research and development, sales and marketing and general and administrative expenses;

The sufficiency of our existing cash, cash equivalents, marketable securities and cash generated from operations;

Our expectations regarding various regulatory applications, procedures and approvals relating to our product candidates, including but not limited to our expectations regarding the timing of such applications, procedures and approvals ;

Better efficacy of our product candidates through the use of biomarkers ; and

Application of our research and development expertise to other diseases that result from cellular dysfunction and uncontrolled cell growth;

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as well as other statements regarding our future operations, financial condition and business strategies. These forward-looking statements are based on our current expectations and entail various risks and uncertainties. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report, and in particular, the risks discussed under the heading Risk Factors in Part II, Item 1A of this report and those discussed in other documents we file with the Securities and Exchange Commission.

Product Development Overview

Introgen Therapeutics, Inc. was incorporated in Delaware in 1993. We are a biopharmaceutical company focused on the discovery, development and commercialization of targeted molecular therapies for the treatment of cancer and other diseases. We are developing product candidates to treat a wide range of cancers using tumor suppressors, cytokines and other targeted molecular therapies. These agents are designed to increase production of normal cancer-fighting proteins that act to overpower cancerous cells, stimulate immune activity and enhance conventional cancer therapies.

Our primary approach to the treatment of cancers is to deliver targeted molecular therapies that increase production of normal cancer-fighting proteins to induce apoptosis, cell cycle control, cell growth control and gene regulation, including the regulation of angiogenic and immune factors. Our products work by acting as templates for the transient *in vivo* production of proteins that have pharmacological properties. The resultant proteins engage disease-related molecular targets or receptors to produce specific therapeutic effects.

We believe the use of targeted molecular therapies to induce the production of biopharmaceutical proteins represents a new approach for treating many cancers while avoiding the toxic side effects common to traditional therapies. We have developed significant expertise in developing targeted therapies that may be used to treat disease and in using what we believe are safe and effective delivery systems to transport these agents to the cancer cells. We believe we are able to treat a number of cancers in a way that kills cancer cells without harming normal cells.

The Introgen Strategy

Our objective is to be a leader in the development of targeted molecular tumor suppressor therapies and other products for the treatment of cancer and other diseases that, like cancer, result from cellular dysfunction and uncontrolled cell growth. To accomplish this objective, we are pursuing the following strategies:

Develop and Commercialize ADVEXIN Therapy and INGN 241 for Multiple Cancer Indications. We plan to continue our development programs to commercialize our ADVEXIN therapy using the p53 tumor suppressor and our INGN 241 product using the mda-7 tumor suppressor, also know as interleukin 24 (IL-24), in multiple cancer indications.

Develop Our Portfolio of Targeted Molecular Therapies and Other Drug Products. Utilizing our significant research, clinical, regulatory and manufacturing expertise, we are evaluating development of additional molecular therapies for various cancers, such as INGN 225, a highly specific cancer immunotherapy, INGN 234, an oral rinse or mouthwash formulation containing the p53 tumor suppressor, INGN 401, using the FUS-1 tumor suppressor, and INGN 007, a replication-competent viral therapy. We have established an efficient process for evaluating new drug candidates and advancing them from pre-clinical to clinical development. We have identified and licensed multiple technologies, which we intend to combine with our adenoviral and non-viral vector systems and which we believe are attractive development targets for the treatment of various cancers. We are also evaluating the development of mebendazole (INGN 601), our first small molecule product candidate. We intend to evaluate additional opportunities to in-license or acquire new technologies.

Develop a Nanoparticle Systemic Administration Platform. Early pre-clinical and clinical studies with these new nanoparticle drugs have demonstrated a good safety profile and promising anti-cancer activity. In addition to FUS-1, we incorporate the p53 tumor suppressor and the mda-7 tumor suppressor in these

nanoparticle formulations.

Develop the Topical Use of Tumor Suppressors. We plan to continue developing topical product candidates for the treatment or prevention of oral and dermal cancers. We believe these treatments are a logical extension of our loco-regional delivery of

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cancer therapies and represent attractive product candidates since pre-malignant and malignant cells can be exposed to natural, biological tumor suppressors and DNA repairing agents.

Establish Targeted Sales and Marketing Capabilities. The oncology market can be effectively addressed by a small, focused sales force because it is characterized by a concentration of specialists in relatively few major cancer centers. We believe we can address this market by a combination of building a direct sales force as part of the ADVEXIN therapy commercialization process and pursuing marketing and distribution agreements with corporate partners for ADVEXIN therapy as well as additional products.

Expand Our Market Focus to Non-Cancer Indications. We plan to leverage our scientific, research and process competencies in molecular therapy and vector development to pursue targeted molecular therapies for a variety of other diseases and conditions. We believe these therapies could hold promise for diseases such as cardiovascular disease and rheumatoid arthritis, which, like cancer, result from cellular dysfunction or uncontrolled cell growth.

ADVEXIN® Therapy (p53)

ADVEXIN Therapy Overview and Regulatory Status

Our lead product candidate, ADVEXIN® therapy, combines the p53 tumor suppressor with a non-replicating, non-integrating adenoviral delivery system we have developed and extensively tested. The p53 molecule is one of the most potent members of a group of naturally-occurring tumor suppressors, which act to kill cancer cells, arrest cancer cell growth and protect cells from becoming cancerous. ADVEXIN therapy has been studied in a variety of cancers including phase 2 trials for non-small lung cancer, breast cancer and esophageal cancers .

ADVEXIN therapy for head and neck cancer has been designated an Orphan Drug under the Orphan Drug Act. This designation may give us up to seven years of marketing exclusivity for ADVEXIN therapy for this indication if approved by the U.S. Food and Drug Administration (FDA). The European Medicines Agency (EMEA) Committee for Orphan Medicinal Products has granted ADVEXIN therapy an Orphan Medicinal Product Designation in Europe for the treatment of Li-Fraumeni Syndrome (LFS). This designation has been ratified by the European Commission. LFS is an inherited cancer characterized by inherited mutations in the p53 tumor suppressor gene. The Orphan Medicinal Product Designation in Europe confers a number of regulatory benefits to ADVEXIN therapy, including access to protocol assistance, reduced regulatory fees and a 10-year period of marketing exclusivity from the date of approval.

We have an agreement with EMEA to file for marketing approval for ADVEXIN therapy under the EMEA s Exceptional Circumstances (EC) provisions. The application will be for the use of ADVEXIN p53 therapy for the treatment of LFS. Exceptional circumstances provisions are designed to facilitate access to needed treatments for certain Orphan Medicinal Products. A Marketing Authorization Application filed with the EMEA under these provisions can be reviewed on an expedited basis. This EC registration approach is designed by EMEA to be more streamlined than EMEA s Conditional Approval procedures, which are similar to the FDA s Accelerated Approval regulations.

We have two ongoing Phase 3 clinical trials of ADVEXIN therapy in patients with advanced recurrent squamous cell carcinoma of the head and neck (recurrent head and neck cancer). These trials involve administration of ADVEXIN therapy, both independently and in combination with chemotherapy, in recurrent head and neck cancer.

We received Fast Track designation for ADVEXIN therapy from the FDA under its protocol assessment program as a result of the FDA s agreement with the design of our two ongoing Phase 3 clinical trials of ADVEXIN therapy. Under this Fast Track designation, the FDA will take actions to expedite the evaluation and review of the Biologics License Application (BLA) for ADVEXIN therapy. We plan to pursue with the FDA an Accelerated Approval of ADVEXIN therapy, which is one alternative provided under a Fast Track designation.

We reviewed historically successful FDA registration strategies for numerous cancer drugs, noting that during the past seven years, approximately 14 cancer drugs were initially approved based upon submissions of Phase 2 clinical data. A number of the Phase 2 trials supporting these approvals employed single-arm studies involving relatively small patient populations. Virtually all of those drugs relied on surrogate endpoints for approval and a substantial number of the products were for orphan drug indications.

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We conducted a series of meetings with the FDA to develop and implement the filing strategy for the BLA for ADVEXIN therapy, which is the application for approval to market and sell ADVEXIN therapy in the United States. As a result of these meetings, we are developing and pursuing an initial rolling BLA filing strategy based primarily on data from our Phase 2 clinical trials of ADVEXIN therapy for treatment of recurrent head and neck cancer. The FDA has concurred that preliminary evaluation of this data suggests a level of efficacy consistent with the standard for the initiation of a rolling BLA (a submission process also known as Submission Of a Partial Application or SOPA). The FDA has also concluded that ADVEXIN therapy continues to show promise with respect to an unmet medical need since there are limited treatment alternatives in the United States for recurrent head and neck cancer. The FDA has also concluded that the clinical development program for ADVEXIN therapy for recurrent head and neck cancer continues to meet the criteria for Fast Track designation. In conjunction with the new data, the new analyses, and other newly employed biological techniques, we are hopeful of more specifically targeting recurrent head and neck cancer in patients using indicators known as biomarkers , as discussed further below, resulting in even better efficacy than has already been demonstrated.

We submitted a SOPA Request to the FDA Division of Cell and Gene Therapy proposing a rolling BLA for ADVEXIN therapy for the treatment of recurrent head and neck cancer, based primarily on data from our Phase 2 clinical trials. We have proposed to the FDA that, since the basis of the proposed rolling BLA is Phase 2 clinical data utilizing surrogate endpoints, the rolling BLA could be evaluated under the provisions of Subpart H for Accelerated Approval. In order to fully explore all of the review and approval possibilities for ADVEXIN therapy, the FDA has requested we submit new data and analyses from the Phase 2 ADVEXIN therapy clinical trials for recurrent head and neck cancer and consider conducting interim efficacy analyses on one or both of our ongoing Phase 3 trials. Given that we have two ongoing Phase 3 clinical trials in recurrent head and neck cancer as discussed further below, we and the FDA are evaluating the most effective use of the data from these Phase 2 and 3 clinical trials in the review and approval of ADVEXIN therapy. Regulatory approval approaches may allow Accelerated Approval on the basis of Phase 2 clinical data with subsequent confirmatory data being provided by the Phase 3 clinical studies or, alternatively, a full approval based on data from Phase 2 and certain Phase 3 clinical trials. We will also be exploring with the FDA whether its recently announced Critical Path Initiative, which permits new product evaluation on the basis of specifically targeted (i.e., by prognostic or biologic parameters) clinical trials and/or patient populations, can be used in the ADVEXIN therapy approval process. This initiative also encouraged sponsors to examine novel approaches to define tumor responses that correlate with clinical benefit. We have employed several response criteria to evaluate ADVEXIN efficiency as described below.

We proposed to the FDA and received an acceleration of the initiation of the planned interim safety analysis relative to one of our two ongoing Phase 3 clinical trials of ADVEXIN therapy in patients with recurrent head and neck cancer. This analysis was performed by a Data Safety Monitoring Board and did not result in any changes in the study conduct. We believe such safety information will be useful to the FDA as part of our ongoing BLA submission process. We plan to avail ourselves of suggestions by the FDA that we consider proposing to them an interim efficacy analysis of one or both of the ongoing Phase 3 clinical trials. As with the acceleration of the interim safety analysis, we believe that the interim efficacy results from one or both Phase 3 studies will be useful to the FDA in its review of our BLA. With regard to these interactions, the FDA has requested that we submit a proposal for the Phase 3 interim efficacy analyses, which we anticipate providing to the FDA by December 31, 2006. In addition, the FDA has agreed that we may utilize our biomarkers indicating the molecular mechanism of ADVEXIN therapy for the analyses of Phase 2 and Phase 3 clinical data.

With respect to the activities described above, we anticipate that the FDA will agree with our interim efficacy analysis plans for our Phase 3 head and neck cancer studies before the end of 2006. We also anticipate achieving the following additional regulatory milestones during 2007:

Completion and submission to the FDA of the Phase 3 interim efficacy analysis data for head and neck cancer;

Conditional Approval approach for head and neck cancer application agreed to by the EMEA;

Completion of Exceptional Circumstance Approval Application filing for Li-Fraumeni Syndrome with the EMEA; and

Completion of the necessary filings for head and neck cancer at the FDA and EMEA to support review and advisory committee review meetings, if required, by those agencies.

We cannot assure you that we will be able to achieve these regulatory milestones during the time period that we currently anticipate. We may encounter delays in the regulatory process relating to these milestones due to additional information requirements from regulatory authorities, unintentional omissions in our applications, additional government regulation or other delays in the review process. We may update our expectations regarding these regulatory milestones from time to time to reflect new information as it becomes available to us.

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ADVEXIN Therapy as a Targeted Molecular Therapy

We identified a set of predictive indicators, commonly referred to as biomarkers, associated with high response rates and increased survival in Phase 2 clinical trials of ADVEXIN therapy in patients with recurrent head and neck cancer. These trials are discussed in more detail below under Other ADVEXIN Therapy Activities. These biomarkers support the use of ADVEXIN therapy as a targeted molecular therapy.

The identification of predictive indicators of ADVEXIN therapy activity complies with recent FDA biomarker initiatives to accelerate the approval of oncology products by predicting the patient populations most likely to benefit from a specific cancer therapy. The population we identified as benefiting from ADVEXIN therapy includes patients who are less likely to respond to standard therapies such as chemotherapies and radiation.

A molecular biomarker predictive of ADVEXIN therapy activity is abnormal p53 function detected in tumor tissues by a routine immunohistochemistry laboratory test. In patients with the abnormal p53 biomarker, ADVEXIN therapy caused a statistically significant increase in median survival of 11 months compared to only 3 months for patients without abnormal p53 function. Patients with abnormal p53 function are known to have a poor prognosis when treated with standard therapies. In addition to this molecular biomarker, we have identified clinical prognostic biomarkers that correlate with statistically significant increases in survival, partial and complete tumor responses and durable locoregional disease control (tumor responses or tumor growth arrest for three months or longer in duration) following treatment with ADVEXIN therapy. These clinical biomarkers include prior chemotherapy or radiotherapy consistent with ADVEXIN therapy s mechanism of action of inducing tumor death in cells, or apoptosis, with DNA damage from previous treatments.

The predictive biomarkers define target populations of patients with high tumor response rates and increased survival following treatment with ADVEXIN therapy. In our combined Phase 2 trials of recurrent head and neck cancer (trials T201 and T202 with 163 total patients), we have observed prognostic factors defining targeted subpopulations with tumor response rates up to 29% and durable locoregional disease control rates of 57%. In these studies, tumor response was defined by at least a 50% reduction in tumor size and durable locoregional disease control was defined by reduced tumor size or stable disease of at least three months duration. These tumor responses are associated with a statistically significant increase in median survival. The median survival of patients with durable locoregional disease control in this group was 12.4 months compared to 5.9 months for the entire study population.

In a separate analysis of patients treated in the T201 Phase 2 trial of recurrent head and neck cancer treated with the ADVEXIN therapy dose proposed for regulatory approval, the ADVEXIN therapy tumor response rate, defined by a 30% reduction in tumor area, was 10% for the overall population and 26% for the clinical biomarker defined population, with a progression free interval of greater than 12 months from initial treatment who had prior chemotherapy. The durations of these responses were durable with a median of 5.7 months. In this overall treatment population, tumor response was associated with a statistically significant increase in survival. The median survival of the responders was 16.9 months compared to 5.4 months for non-responders. This difference was statistically significant ($p < 0.0001$). This Phase 2 study evaluated 106 patients utilizing the ADVEXIN therapy dose that is also employed in our Phase 3 clinical trials.

The FDA, the National Cancer Institute (NCI), and the Centers for Medicare & Medicaid Services are undertaking the Oncology Biomarker Qualification Initiative to expedite the development of novel cancer treatments. These agencies define biomarkers as clinical or biological indicators of disease or therapeutic effects, which can be measured through dynamic imaging tests, laboratory tests on blood or tissue samples as well as by clinically defined parameters. This initiative was developed to employ biomarkers as a way of speeding the development and evaluation of new cancer therapies.

The targeted molecular therapy provided by ADVEXIN therapy is evidenced by its use to successfully treat a Li-Fraumeni Syndrome (LFS) cancer patient on a compassionate use basis under a protocol authorized by the FDA. Our treatment of a tumor in an LFS patient with ADVEXIN therapy led to improvement of tumor-related symptoms and resulted in a complete response in the treated lesion as determined by positron emission tomography (PET) computerized tomography (CT) scans. PET-CT scans measure the metabolic activity of tumors and are being increasingly utilized in the management of cancer patients because they provide more sensitive assessments of treatment effects compared to conventional CT and magnetic resonance imaging scans.

This LFS study defined important biomarkers to guide the administration of ADVEXIN therapy to patients with other cancers who display p53 pathway abnormalities. Our molecular analysis of biopsies of the LFS tumor before and after treatment identified key markers of p53 pathway abnormalities that are used to predict and evaluate the effects of ADVEXIN therapy. These markers included detection of abnormal levels of p53 protein that identify aberrant p53 pathways and the induction of molecular markers of tumor growth control and tumor cell death that validate ADVEXIN therapy s mechanisms of action. We believe these biomarkers can be used to identify patients most likely to benefit from ADVEXIN therapy.

The European Medicines Agency (EMEA) Committee for Orphan Medicinal Products has granted ADVEXIN therapy an Orphan Medicinal Product Designation in Europe for the treatment of Li-Fraumeni Syndrome (LFS). This designation has been ratified by the European Commission. The Orphan Medicinal Product Designation in Europe confers a number of regulatory benefits to ADVEXIN therapy, including access to protocol assistance, reduced regulatory fees and a 10-year period of marketing exclusivity from the date of approval. We received this designation through Gendux AB, our wholly-owned subsidiary.

We have an agreement with EMEA to file for marketing approval for ADVEXIN therapy under the EMEA s Exceptional Circumstances provisions. The application will be for the use of ADVEXIN therapy for the treatment of LFS. Exceptional

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circumstances provisions are designed by EMEA to facilitate access to needed treatments for certain Orphan Medicinal Products. A Marketing Authorization Application filed with the EMEA under these provisions can be reviewed on an expedited basis. This registration approach is more streamlined than EMEA s Conditional Approval procedures, which are similar to the FDA s Accelerated Approval regulations. As a result of the encouraging clinical findings in treating LFS, we have made ADVEXIN therapy available on a compassionate use basis to qualified LFS patients with tumors refractory to standard treatment.

LFS is an inherited genetic disorder that greatly increases the risk of developing several types of cancer typically with initial occurrence at a young age. The majority of LFS families have inherited mutations in the p53 tumor suppressor gene. The findings described above have been presented at the annual meetings of the American Society of Gene Therapy (ASGT) and the American Society of Clinical Oncology (ASCO).

Other ADVEXIN Therapy Activities

We performed a Phase 2 clinical trial of ADVEXIN therapy combined with neoadjuvant chemotherapy and surgery in women with locally advanced breast cancer. The results of this study were published in the journal *Cancer.* Objective clinical responses were seen following the combined therapy in 100% of the patients with a median of 80% reduction in tumor size. Following tumor shrinkage, complete tumor removal by subsequent surgery was achieved in 100% of the patients. At a median follow-up of 37 months (range, 30-41 months), four patients (30%) developed systemic recurrence and two patients died. The estimate breast cancer-specific survival rate at three years was 84%. There was no increase in systemic toxicity. Neoadjuvant treatments are administered prior to surgery and represent a novel and increasingly applied approach to making surgical tumor resections less invasive, improving outcomes and facilitating breast conservation.

We completed a Phase 2 clinical trial of ADVEXIN therapy administered as a complement to radiation therapy in non-small cell lung cancer. In the 19 patients who participated in the trial, combined ADVEXIN therapy and radiation treatment resulted in 63% biopsy-proven complete responses at three months, which is approximately four times the expected rate using radiotherapy alone. The results of this study were published in *Clinical Cancer Research.*

We performed a Phase 1/early Phase 2 clinical trial of ADVEXIN therapy for the treatment of advanced, unresectable, squamous cell esophageal cancer. Results of this trial in patients with esophageal cancer refractory to chemotherapy and radiation indicate three of the ten patients treated, or 30%, had negative biopsies after receiving ADVEXIN therapy. The median survival of the patients treated with ADVEXIN therapy was approximately twelve months, which compared favorably to historical controls in which a median survival of less than ten months was observed for patients who did not respond to standard treatments. Six patients, or 60%, were still alive one year after beginning ADVEXIN therapy. This clinical trial was performed at Chiba University in Japan.

We are currently conducting additional Phase 1/2 clinical trials of ADVEXIN therapy by itself and in combination with chemotherapy or radiation therapy in a variety of cancers. These additional clinical trials include:

A Phase 2 clinical trial of ADVEXIN therapy in squamous cell carcinoma of the oral cavity, or oropharynx, that can be removed surgically, to assess the feasibility, efficacy and safety of administering ADVEXIN therapy at the time of surgery for suppression of remaining tumor cells, followed by a combination of chemotherapy and radiation therapy.

A Phase 1/early Phase 2 clinical trial in which a mouthwash or oral rinse formulation of ADVEXIN therapy, which has been designated as INGN 234, is administered to prevent precancerous oral lesions from developing into cancerous lesions.

We have completed other clinical trials of ADVEXIN therapy, including Phase 1 studies in prostate cancer and bronchoalveolar carcinoma. To date, clinical investigators at sites in North America, Europe and Japan have treated over 600 patients with ADVEXIN therapy, establishing a large safety database. Findings from several of our clinical trials have been published in *Clinical Cancer Research* and *Proceedings of the American Society for Clinical Oncology* as well as presented at numerous conferences, including the San Antonio Breast Cancer Conference and various meetings of the ASCO, ASGT and the American Association for Cancer Research.

A growing body of data suggests ADVEXIN therapy demonstrates clinical activity in a variety of cancer indications. Safety data from our clinical trials suggest this activity may be achieved without the treatment-limiting

side effects frequently associated with many other cancer therapies.

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Our clinical trials indicate ADVEXIN therapy is well tolerated as a monotherapy. The addition of ADVEXIN therapy to standard chemotherapy, surgery or radiation does not appear to increase the frequency or severity of side effects normally associated with these treatment regimens.

Recent studies provide new insight into the molecular pathways by which the p53 tumor suppressor, the active component of ADVEXIN therapy, kills tumor cells. These studies were undertaken to provide additional molecular data supporting the activity observed during the clinical development of ADVEXIN therapy and to provide additional information regarding the specific pathways that mediate the observed clinical effects of ADVEXIN therapy. The studies were conducted by our collaborators at Okayama University in Japan and at The University of Texas M. D. Anderson Cancer Center and were published in *Molecular Cancer Therapeutics*. Other data suggest the enhanced therapeutic effects of a combination of ADVEXIN and Erbitux® therapies in an animal model of human non-small cell lung cancer. Other pre-clinical studies conducted by our collaborators at Wayne State University, the Karmanos Cancer Institute located in Detroit, Michigan and the University of California-Irvine, as published in *The Laryngoscope*, show that the combination of ADVEXIN therapy and docetaxel resulted in increased levels of programmed cell death in head and neck tumor cells. Two lung cancer patients who were part of our ADVEXIN therapy studies program were featured in the Summer 2004 issue of *Conquest* magazine, a publication of M. D. Anderson Cancer Center, in connection with reaching their five-year survival anniversary. In addition, a patient with recurrent head and neck cancer who achieved a complete tumor remission on ADVEXIN therapy continues to be disease-free over eight years later while receiving repeated treatments of ADVEXIN therapy.

We hold a worldwide, exclusive license to a family of patent applications directed to combination therapy using ADVEXIN therapy with inhibitors of epidermal growth factor receptors (EGFr inhibitors) such as Erbitux®, Vectibix®, Tarceva® and Iressa®. We licenced this family of patents from M. D. Anderson Cancer Center. This important technology is based on the discovery by scientists at M.D. Anderson Cancer Center that p53 therapies (which is the basis for our ADVEXIN therapy) and mda7 therapies (which is the basis for our INGN 241 product candidate discussed below) can work synergistically with inhibitors of epidermal growth factor receptors to arrest tumor growth. Preclinical studies have shown that this therapeutic approach results in a greater level of cancer cell death than when either therapy is used alone.

We hold the worldwide rights for pre-clinical and clinical development, manufacturing, marketing and commercialization of ADVEXIN therapy.

INGN 241 (mda-7)

INGN 241 uses mda-7, a promising tumor suppressor, that we believe, like p53, has broad potential to induce apoptosis or cell death in many types of cancer. We have combined the mda-7 tumor suppressor with our adenoviral delivery system to form INGN 241. Our pre-clinical trials have shown the protein produced by INGN 241 suppresses the growth of many cancer cells, including those of the breast, lung, ovaries, colon, prostate and the central nervous system, while not affecting the growth of normal cells. Because INGN 241 kills cancer cells even if other tumor suppressors, including p53, are not functioning properly, it appears mda-7 functions via a novel mechanism of tumor suppression.

We have conducted pre-clinical work indicating that in addition to its known activity as a tumor suppressor, the protein produced by mda-7 may also stimulate the body s immune system to kill metastatic tumor cells and to protect the body against cancer, thereby offering the potential of providing an added advantage in treating various cancers because it may attack cancer using two different mechanisms. Because the mda-7 tumor suppressor may act as a cytokine, or immune system modulator, it is also known as interleukin 24, or IL-24. The mda-7 molecule may also work as a radiation sensitizer to make several types of human cancer cells more susceptible to radiation therapy. We have seen evidence of this effect in pre-clinical and clinical settings.

We have identified the molecular pathways by which mda-7, the active component of INGN 241, induces growth arrest and programmed cell death or apoptosis in cancer cells. Pre-clinical studies using lung cancer cells have demonstrated the mda-7 protein binds to a critical cellular enzyme known as PKR. The binding of mda-7 to PKR is essential for the anti-cancer activity of INGN 241. The identification of this binding partner demonstrates a significant advancement in understanding how this therapeutic can be effective against cancer. Additional studies have identified bystander killing of pancreatic cancer cells by the mda-7 protein. Bystander killing involves the killing of neighboring

tumor cells by the mda-7 protein released from adjacent INGN 241-treated tumor cells.

Pre-clinical data indicate INGN 241 works synergistically with celecoxib, marketed by Pfizer as Celebrex®, to inhibit the growth and increase killing of breast cancer cells. The combination of celecoxib and INGN 241 showed greater than additive increases in cell death compared with either therapy alone and also resulted in the suppression of tumor cell growth.

Pre-clinical data indicate INGN 241 and bevacizumab, marketed by Roche Holding AG and Genentech, Inc. (Genentech) as Avastin®, each inhibit tumor angiogenesis through distinct mechanisms in models of lung cancer. Study results demonstrate that the combination of INGN 241 and Avastin® significantly increases anti-tumor activity compared with either agent used separately.

Pre-clinical data indicate the combination of INGN 241 and Tarceva®, marketed by Genentech, more significantly inhibits tumor cell growth than Tarceva® administered alone. The preclinical data suggest the two agents work in concert to inhibit activity of the epidermal growth factor receptor, a potent driver for cell growth in many types of cancer.

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Our pre-clinical work indicates INGN 241 effectively kills cancer cells that are resistant to cisplatin, one of the most commonly used chemotherapeutic agents. These pre-clinical studies also identified a novel defect in a protein degradation pathway in the cisplatin-resistant cells. This defect enhances the activity of INGN 241, suggesting that INGN 241 may have particular utility in treating cancers that do not respond to cisplatin.

In pre-clinical studies, we have observed the expression of mda-7 in ovarian cancer cells potently activates a cell death or apoptotic pathway regulated by the Fas signaling system. This activation resulted in significant increases in apoptosis and inhibition of cancer cell proliferation that were specific to cancer cells. These effects were not observed in normal ovarian tissue, supporting previous data showing a cancer-selective effect of INGN 241.

We have published the results of a pre-clinical study indicating INGN 241 may suppress the growth *in vivo* of non-small cell lung cancer through apoptosis in combination with anti-angiogenesis. The data demonstrate INGN 241 can inhibit production of the VEGF protein, a potent inducer of angiogenesis, within lung cancer cells, which in turn inhibits tumor angiogenesis, a key requirement for tumor growth.

Pre-clinical work has demonstrated administration of INGN 241 results in the development of systemic immune responses against tumor cells and suggests INGN 241 could be used as a novel cancer molecular immunotherapy. In pre-clinical studies, implantation of INGN 241-treated tumor cells into mice resulted in significant inhibition of tumor growth. Significantly, mice immunized with INGN 241-treated cells showed inhibition of tumor growth after a subsequent challenge with additional tumor cells.

We have conducted pre-clinical studies with INGN 241 in breast cancer cell lines as a single agent, as well as in combination with radiation therapy, with chemotherapy (Taxotere® or Adriamycin®), with the hormone inhibitor Tamoxifen® and with Herceptin®, a biologic cancer therapy. In all settings, INGN 241 reduced cell growth and increased programmed tumor cell death (apoptosis). This effect was enhanced when combined with drugs currently used to treat breast cancer. In animal models of breast cancer, treatment with INGN 241 alone or in combination with radiation therapy resulted in significant decreases in tumor growth. In particular, our pre-clinical studies have shown treatment with a combination of INGN 241 plus Herceptin® induces cell death in Her-2/neu positive breast cancer cells at a rate greater than that seen with either agent alone. In these studies, it was also noted while Herceptin® exhibited no activity on Her-2/neu negative cells, INGN 241 did induce cell death in these cells.

Pre-clinical studies indicate the mda-7 protein released from cells treated with INGN 241 can kill nearby, untreated breast cancer cells resulting in additional therapeutic effect. This bystander effect occurs when the therapeutic protein binds to certain receptors on nearby cancer cells. We believe this bystander effect is significant because it could indicate the number of cancer cells INGN 241 can kill is greater than the number of cells that take up this novel investigational cancer therapy.

We have completed enrollment of a Phase 1/early Phase 2 clinical trial using INGN 241 to evaluate safety, mechanism of action and efficacy in approximately 25 patients with solid tumors. This trial has indicated that in patients with solid tumors, INGN 241 was well tolerated, was biologically active and displayed minimal toxicity associated with its use. We have initiated later stage clinical trials using INGN 241 in patients with metastatic melanoma and recurrent head and neck cancer. We are studying INGN 241 in combination with radiation therapy for solid tumors in a phase 3 clinical trial.

Data from our Phase 1 trial of INGN 241 in patients with solid tumors demonstrate that direct injection of INGN 241 induced programmed cell death in 100% of the tumors treated, even in patients who had failed prior therapy with other anti-cancer drugs. Clinical responses were observed in 44% of the treated lesions, including complete and partial responses in two patients with melanoma. Patients treated with INGN 241 had increases in a subset of T-cells that help to destroy cancer cells, which is consistent with the role of the mda-7 protein as a member of the interleukin family of immune stimulating proteins.

Findings and results arising from our development of INGN 241 have been published in the *Journal of Leukocyte Biology*, *Cancer Gene Therapy*, *Cancer Research*, *Molecular Therapy*, *Oncogene*, *Surgery*, and *International Immunopharmacolgy*. Data from this work have also been presented at the annual San Antonio Breast Cancer Symposium.

We have an exclusive license to the mda-7 tumor suppressor for our therapeutic applications originally from Corixa Corporation (Corixa), which was acquired by GlaxoSmithKline. Pre-clinical studies regarding the active

component of INGN 241 have included research at The University of Texas M. D. Anderson Cancer Center and Columbia University.

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INGN 225 (p53 molecular immunotherapy)

We are developing INGN 225 using the p53 tumor suppressor in a different manner to create a molecular immunotherapy for cancer that stimulates a particular type of immune system cell known as a dendritic cell. Research published in *Current Opinion in Drug Discovery & Development* concluded that the p53 tumor suppressor can be used with a patient s isolated dendritic cells as an antigen delivery and immune enhancing therapeutic strategy. Pre-clinical testing has shown that the immune system can recognize and kill tumors after treatment with dendritic cells stimulated by the p53 tumor suppressor, which suggests a molecular immunotherapy consisting of dendritic cells stimulated by p53 could have broad utility as a treatment for progression of solid tumors.

We are conducting a Phase 1/2 clinical trial in collaboration with the Moffitt Cancer Center at the University of South Florida in patients with small cell lung cancer. We are also conducting a Phase 1/2 trial in patients with breast cancer in collaboration with the University of Nebraska. In both trials, INGN 225 is administered after the patients have been treated with standard chemotherapy.

Interim results from the Phase 1/2 trial in patients with extensive small cell lung cancer who were previously treated with chemotherapy indicate that greater than 60% of the evaluable patients in the study treated with INGN 225 had objective responses to subsequent chemotherapy. Historically, the expected objective response rate in similar patients to further chemotherapy is between approximately 5% and 30%. Similar patients with this type of lung cancer have a grave prognosis with a median survival of approximately six months, but treated patients in this study who developed an immune response to p53 had a median survival of approximately twelve months. These findings were published in *Clinical Cancer Research*.

We believe the data indicate INGN 225 may sensitize tumors to the effects of platinum and taxane chemotherapies. Of particular interest, patients with highly aggressive disease (termed platinum resistant) showed improved response rates and increased survival compared to historical controls. These findings are consistent with the results observed in lung and breast cancer patients treated with ADVEXIN therapy that increased the expected effects of cisplatin, taxane and doxorubicin chemotherapies. As platinum, taxanes and doxorubicin are among the most common types of cancer chemotherapies, these findings may have important implications for improving the efficacy of these widely utilized cancer treatments.

INGN 234 (p53 topical)

We are developing INGN 234 for the prevention of oral cancers and the treatment of oral leukoplakia. We are conducting a Phase 1/early Phase 2 clinical trial in which p53 is being administered in an oral mouthwash formulation to prevent precancerous oral lesions from developing into cancerous lesions. We are conducting pre-clinical work on other topical administrations of tumor suppressors to control or prevent oral or dermal cancers. We are investigating multiple delivery platforms, including both viral and non-viral approaches. We are also investigating combining delivery of our therapies with rinses, patches, ointments and enhancing polymers. We believe the opportunity exists to develop non-toxic treatments for pre-malignant and malignant cells that can be easily exposed to natural biological tumor suppressor and DNA repairing molecules.

We have entered into an alliance agreement with Colgate-Palmolive to develop and potentially market oral healthcare products. See Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Business and Collaborative Arrangements Alliance with Colgate-Palmolive Company below for further discussion of this alliance agreement.

INGN 401 (FUS-1)

INGN 401 uses a nanoparticle vector system to deliver the tumor suppressor FUS-1, which we exclusively license from M. D. Anderson Cancer Center. Pre-clinical studies have shown that FUS-1, delivered using an adenoviral or a non-viral delivery system through either intravenous (systemic) administration or direct intratumoral injection, significantly inhibits the growth of tumors and greatly reduces the metastatic spread of lung cancer in animals.

Pre-clinical data suggest that INGN 401 may have utility as a monotherapy in lung cancer. We have observed significant inhibition of tumor growth in lung cancer animal models following INGN 401 monotherapy treatment when compared with untreated animals.

INGN 401 has demonstrated synergistic activity with Gefitinib, a novel class of anti-cancer agents that decrease tumor growth by inhibiting growth factor receptors that promote tumor proliferation. While Gefitinib can produce dramatic responses in a small subset of lung cancer patients, most lung cancers are refractory to its effects. The data indicate nanoparticle delivery of INGN 401 can synergize with Gefitinib in killing lung tumor cells resistant to Gefitinib alone. Furthermore, in Gefitinib-sensitive tumors, INGN 401 delivery significantly enhanced anti-cancer activity.

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A Phase 1/early Phase 2 clinical trial is ongoing at M. D. Anderson Cancer Center testing INGN 401 in patients with advanced non-small cell lung cancer who have previously been treated with chemotherapy. Data and findings from our work to develop INGN 401 have been published in *Cancer Gene Therapy* and *Cancer Research*.

INGN 402 and INGN 403 (nanoparticle formulations of p53 and mda-7, respectively)

We are developing two nanoparticle formulations for systemic delivery. INGN 402 contains the p53 tumor suppressor and INGN 403 contains the mda-7 tumor suppressor, also known as interleukin 24 (IL-24). Early studies with these new nanoparticle drug candidates have demonstrated a good safety profile and promising anti-cancer activity in murine lung tumor models. Data from the mda-7 nanoparticle studies was published in *DNA and Cell Biology* and presented at the annual meetings of the ASGT and ASCO.

INGN 007 (oncolytic viral therapy)

We are developing INGN 007, a replication-competent viral therapy, which is also called an oncolytic virus, in which viruses bind directly to cancer cells, replicate in those cells, and cause those cancer cells to die. Pre-clinical testing in animal models indicates INGN 007 over-expresses a molecule that allows the vector to saturate the entire tumor. This testing has demonstrated that INGN 007 has a favorable safety profile and significantly inhibits tumor growth. Findings from this work to develop INGN 007 have been published in *Cancer Research* and were presented at a meeting of the ASCO. We are developing this replication-competent viral therapy through our strategic collaboration with VirRx.

Other Research and Development Programs

We are conducting a number of pre-clinical and research programs involving a variety of targeted therapies for the treatment of cancer. These programs involve molecules that act through diverse mechanisms to inhibit the growth of or kill cancer cells.

We license from M. D. Anderson Cancer Center a group of molecules known as the 3p21.3 family. Pre-clinical research performed on these molecules by collaborators at The University of Texas Southwestern Medical Center and M. D. Anderson Cancer Center suggests that the 3p21.3 family plays a critical role in the suppression of tumor growth in lung and other cancers. This family of molecules includes the FUS-1 tumor suppressor we are testing as INGN 401. We are working with M. D. Anderson Cancer Center to further evaluate other 3p21.3 family molecules as clinically relevant therapeutics.

We are evaluating additional molecules, including BAK, which hold promise as therapeutic candidates. BAK is a pro-apoptotic molecule that kills cancer cells. We are working with our collaborators at M. D. Anderson Cancer Center to identify and develop both viral and non-viral vectors containing this therapeutic molecule. We have exclusive rights to use the BAK molecule under a license with LXR Biotechnology, Inc. (LXR), with the LXR rights being subsequently sold to Tanox, Inc. (Tanox).

We are evaluating the development of mebendazole, our first small molecule candidate, which we refer to as INGN 601, for treatment of cancer and other hyperproliferative diseases. The use of the mebendazole compound is approved by the FDA for the oral treatment of parasitic diseases. Pre-clinical work suggests that mebendazole may also be an effective treatment for cancer. The results of pre-clinical investigations involving mebendazole and lung cancer were published in *Clinical Cancer Research* and *Molecular Cancer Therapeutics*.

We believe our research and development expertise gained from our molecular therapies for cancer is also applicable to other diseases that, like cancer, result from cellular dysfunction and uncontrolled cell growth. As a result, we are conducting research in collaboration with medical institutions to understand the safety and effectiveness of our molecular therapy product candidates in the treatment of other diseases.

Introgen Enabling Technologies

We have a portfolio of technologies, referred to as enabling technologies, for administering targeted molecular products to patients and for enhancing the effects of these products, which we plan to exploit to develop additional products to treat cancer and other diseases which, like cancer, result from cellular dysfunction and uncontrolled cell growth.

Nanoscale Viral Delivery Systems

We have demonstrated that ADVEXIN therapy and INGN 241, which use our adenoviral vector system, enter tumor cells and express their proteins despite the body s natural immune response to the adenoviral vector. While the

adenoviral vector system used

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appears to be appropriate for the treatment of cancer by local administration, we have developed a number of additional systems that utilize modified adenoviral vectors for delivery. These systems also may be applicable to indications where activity of the therapeutic molecule for disease treatment is required for longer periods of time or where systemic administration may be necessary.

Nanoparticle Systemic Delivery Platform

We have in-licensed and are developing a non-viral, nanoparticle delivery platform as a complementary delivery technology for certain types of cancers, or clinical indications, particularly those that require systemic administration. We are using this technology in INGN 401, INGN 402 and INGN 403.

Data published in *DNA and Cell Biology* highlight the potential utility of combining our nanoparticle delivery system with the mda-7 tumor suppressor for the treatment of lung cancer. This data demonstrate that combining this innovative delivery system with the mda-7 tumor suppressor results in potent anti-cancer effects and systemic tumor growth inhibition in an animal model of lung cancer. We believe combining potent anti-cancer tumor suppressors, such as mda-7 or p53, with our nanoparticle delivery system could allow development of clinical strategies to attack metastatic cancers.

Replicating Viral Delivery Systems

Through our strategic collaboration with VirRx, we are developing replication-competent viral therapies, also known as oncolytic viruses, in which viruses bind directly to cancer cells, replicate in those cells, and cause those cancer cells to die. This technology forms the basis for our INGN 007 product development. We anticipate pursuing clinical confirmation as to whether this self-amplifying delivery system can complement our existing adenoviral delivery system, which is replication disabled, in selected therapeutic scenarios, in applications beyond INGN 007.

Additional Enabling Technologies

Our research and licensing activities include a number of additional technologies that expand our capabilities. These activities include the following:

Multi-Molecule Vector System. This technology is designed to combine multiple therapeutic molecules with a vector. This approach has the potential for use with both viral and non-viral delivery systems to allow the activity of more than one molecular therapy at a time for disease treatment.

Pro-Apoptotic Molecule Delivery System. This technology is designed to allow the activity of pro-apoptotic, or apoptosis-inducing, molecules during treatment only, while temporarily suppressing the ability of the apoptotic molecule to kill producer cells during production. This system could facilitate higher volume production of pro-apoptotic agents.

Tissue-Specific Targeting Systems. This technology is designed to promote the activity of the therapeutic molecule in only those cells which have been affected by the disease being targeted. It is intended to be applied to both viral and non-viral vectors.

Manufacturing and Process Development

Commercialization of a targeted molecular therapy product requires process methodologies, formulations and quality release assays in order to produce high quality materials at a large scale. We believe the expertise we have developed in the areas of manufacturing and process development represents a competitive advantage. We have developed scale-up methodologies for both upstream and downstream production processes, formulations that are safe and stable, and product release assays that support product quality control.

We own and operate state-of-the-art manufacturing facilities, including a commercial-scale, validated manufacturing facility designed to comply with the FDA s Current Good Manufacturing Practice requirements, commonly known as CGMP requirements. We have produced numerous batches of ADVEXIN therapy clinical material for use in our Phase 1, 2 and 3 clinical trials. The design and processes of the facility used for ADVEXIN therapy production have been reviewed with the FDA. We plan to use our facilities for the market launch of ADVEXIN therapy. We also use our facilities to produce INGN 241 and other investigative materials for use in clinical trials of those product candidates. From time to time, as requirements for our own products allow, we also manufacture pre-clinical and clinical materials for outside parties for a fee under contract services arrangements.

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Business and Collaborative Arrangements

Alliance with Colgate-Palmolive Company

In November 2005, we entered into an alliance agreement with Colgate-Palmolive to develop and potentially market oral healthcare products. In connection with the alliance agreement and pursuant to a common stock purchase agreement, Colgate-Palmolive purchased 3,610,760 shares of our common stock at a purchase price of $5.539 per share for a total of approximately $20.0 million. These shares are subject to trading and transfer restrictions for one year from the date of purchase. Under the common stock purchase agreement, Colgate-Palmolive also agreed to vote these shares and any other shares of our capital stock owned by it in favor of corporate actions approved by our Board of Directors. This voting agreement is subject to suspension or termination upon certain events specified in the common stock purchase agreement.

Pursuant to the alliance agreement, we will conduct research and development activities involving specialized formulations of our molecular therapies (such as p53, mda-7 and FUS-1) targeted at precancerous conditions of the oral cavity and at oral cancer. The objective is to market these formulations as oral healthcare products. Excluded from the alliance agreement is our current portfolio of cancer product candidates, including ADVEXIN therapy, INGN 241, INGN 225 and INGN 401.

Under the alliance agreement, Colgate-Palmolive has a first right to negotiate development, manufacturing, marketing and distribution rights with us for specifically designed oral healthcare products for use in the human oral cavity that may result from these research and development activities. In addition, we agreed to use commercially reasonable efforts to develop one or more specialized oral formulations through completion of Phase 2 clinical trials within the seven-year term of the alliance agreement. We can terminate our development efforts earlier under certain circumstances, including if the prospects for these products do not warrant further investment, or if we expend $15.0 million in this effort. In calculating the amount of our expenditures on these efforts, we may include grant funding received by us or our collaborators for work performed by third parties (e.g., universities and other institutions) that is directly related to program activities, as specified in the alliance agreement. The term of the alliance agreement continues to November 2012, unless earlier terminated by the parties as provided in the alliance agreement.

VirRx, Inc.

We are working with VirRx to investigate other vector technologies, specifically replication-competent viral therapies, for delivering products into targeted cells. These technologies form the basis for our INGN 007 product candidate.

Under an agreement with VirRx, we purchased $2,475,000 of VirRx s Series A Preferred Stock for cash, of which we purchased zero and $150,000 in the three month periods ended September 30, 2006 and September 30, 2005, respectively, and $150,000 and $450,000 in the nine month periods ended September 30, 2006 and September 30, 2005, respectively. We are not obligated to make any additional such purchases at this time. We record these purchases as research and development expense. We are no longer required to make periodic purchases of their Series A Preferred Stock under this agreement. We may be required to make additional stock purchases in the event VirRx reaches certain specified milestones. For additional discussion of our agreements with VirRx, see Business-Business and Collaborative Agreements-VirRx, Inc. in, and Note 9 to our consolidated financial statements included in, our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006.

SR Pharma plc

In July 2005, we purchased approximately 8.3% of the issued share capital of SR Pharma for approximately $3.0 million. As of September 30, 2006, the shares we purchased had a quoted market value of $2.4 million. SR Pharma is a European biotechnology company publicly traded on the Alternative Investment Market of the LSE that is developing oncology and other products.

Academic and Other Collaborations

Academic collaboration agreements have been a cost-effective way of expanding our intellectual property portfolio, generating data necessary for regulatory submissions, accessing industry expertise and finding new technology in-license candidates, all without building a large internal scientific and administrative infrastructure.

The University of Texas M. D. Anderson Cancer Center

Many of our core technologies were developed by scientists at The University of Texas M. D. Anderson Cancer Center in Houston, Texas, one of the largest academic cancer centers in the world. We sponsor research conducted at M. D. Anderson Cancer Center to further the development of technologies that have potential commercial viability. Through these sponsored research agreements, we have access to M. D. Anderson Cancer Center s resources and expertise for the development of our technology. In

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addition, we have the right to include certain patentable inventions arising from these sponsored research agreements under our exclusive license with M. D. Anderson Cancer Center.

We entered into a license agreement with The Board of Regents of the University of Texas System and M. D. Anderson Cancer Center in 1994. The license agreement terminates on July 20, 2009 (if no patent rights are applicable) or upon the last to expire of the relevant patents. The agreement is also terminable upon either party s breach, upon our notice on a patent-by-patent basis or should we become insolvent. The technologies we have licensed from M. D. Anderson Cancer Center under the exclusive license agreement relate to multiple technologies. We have agreed to pay M. D. Anderson Cancer Center royalties on sales of products utilizing these technologies. We are obligated to reimburse any of M. D. Anderson Cancer Center s costs that may be incurred in connection with obtaining patents related to the licensed technologies. Our strategy for product development is designed to take advantage of the significant multidisciplinary resources available at M. D. Anderson Cancer Center. These efforts have resulted in our becoming a significant corporate sponsor of activities at M. D. Anderson Cancer Center in recent years and have yielded to us exclusive patent and licensing rights to numerous technologies.

National Cancer Institute

We have a cooperative research and development agreement, or CRADA, with the NCI. The CRADA has a flexible duration, but is terminable upon the mutual consent of the parties or upon 30 days notice of either party. Under the CRADA, the NCI agreed to sponsor and conduct pre-clinical and human clinical trials to evaluate the effectiveness and potential superiority to other treatments of ADVEXIN therapy against a range of designated cancers, including breast cancer, ovarian cancer, bladder cancer and brain cancer. To date, the NCI has conducted numerous Phase 1 clinical trials for ADVEXIN therapy. The NCI provided most of the funding for these activities. We supplied the NCI with ADVEXIN therapy product to be administered in these trials. We have exclusive rights to all pre-clinical and clinical data accumulated under the CRADA.

Research and License Agreement for the mda-7 Tumor Suppressor

We have a research and license agreement with Corixa, pursuant to which we acquired an exclusive, worldwide license to the mda-7 tumor suppressor for the therapeutic applications we are pursuing. This agreement was originally with Corixa, which subsequently was acquired by GlaxoSmithKline. The agreement is effective until the last to expire of the subject patents. It is terminable upon the breach or insolvency of either party, or upon our notice on a patent-by-patent or product-by-product basis. Under the agreement, we paid Corixa an initial license fee and have agreed to make additional payments upon the achievement of development milestones, as well as royalty payments on product sales. We also made research payments to Corixa in connection with research it performed involving the mda-7 tumor suppressor. Corixa originally licensed the mda-7 tumor suppressor from Columbia University.

Moffitt Cancer Center

We are collaborating with the H. Lee Moffitt Cancer Center and Research Institute to advance our INGN 225 molecular cancer immunotherapy program. Moffitt Cancer Center has conducted pre-clinical research with us, and they are currently treating patients in the ongoing INGN 225 clinical study. We are designing additional studies in collaboration with Moffitt Cancer Center personnel to continue clinical research in the dendritic cell molecular immunotherapy field.

Marketing and Sales

We are focusing our current product development and commercialization efforts on the oncology market. This market is characterized by its concentration of specialists in relatively few major cancer centers, which we believe can be effectively addressed by a small, focused sales force. As regulatory approval of one or more of our product candidates for commercial sale approaches, we will address the methods of sales and marketing available to us. We will continue to evaluate the merits of building our own direct sales force, pursuing marketing and distribution arrangements with corporate partners or some combination of both.

Patents and Intellectual Property

Our Portfolio

Our success will depend in part on our ability to develop and maintain proprietary aspects of our technology. To this end, we have an intellectual property program directed at developing proprietary rights in technology that we believe may be important to our success. We also rely on a licensing program to ensure continued strong technology

development and technology transfer from

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companies and research institutions with whom we work. We have entered into a number of exclusive license agreements or options with companies and institutions, including M. D. Anderson Cancer Center, Sidney Kimmel Cancer Center, Corixa, which was acquired by GlaxoSmithKline, Aventis Pharmaceutical Products, Inc. (Aventis), which is now Sanofi-Aventis, Columbia University, VirRx and LXR, with the LXR rights being subsequently sold to Tanox. In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements.

We currently own or have an exclusive license to a large number of issued and pending United States and foreign patents and patent applications. If we do not seek a patent term extension, the currently issued United States patents that we own or have exclusively licensed will expire between the years 2010 and 2017. The exclusive licenses that give us rights on the patents, and applications that such licenses cover, will expire no earlier than the life of any patent covered under the license.

Adenoviral p53 Compositions and Therapies

In developing our patent portfolio, we have focused our efforts in part on seeking protection for our potential products and how they will be used in the clinical trials. Arising out of our work with M. D. Anderson Cancer Center, we currently have an exclusive license to a number of United States and corresponding international patents and patent applications directed to adenoviruses that contain p53, referred to as adenoviral p53, adenoviral p53 DNA, adenoviral p53 pharmaceutical compositions, the production of adenoviral p53 compositions and the use of such compositions in various cancer therapies and protocols. We have also exclusively licensed from Aventis patent applications directed to adenoviral p53 and its clinical applications. We also have an exclusive license to a United States patent application and corresponding international applications directed to the use of the p53 tumor suppressor in the treatment of cancer patients whose tumors express a normal p53 protein.

Combination Therapy with Tumor Suppressors, including p53 and mda-7/IL24

Our portfolio development includes seeking protection for clinical therapeutic strategies that combine the use of either the p53 tumor suppressor or the mda-7/IL-24 tumor suppressor with traditional cancer therapies. In this regard, also arising out of our work with M. D. Anderson Cancer Center, we have an exclusive license to a number of issued United States patents and applications with corresponding international patents and applications directed to cancer therapy using either the p53 tumor suppressor or the mda-7/IL-24 tumor suppressor in combination with conventional radiotherapy and/or other anti-cancer compounds. Such compounds include: DNA-damaging agents and conventional chemotherapies; immunotherapeutics (e.g.. Herceptin®); COX-2 inhibitors (e.g.. celecoxib); Hsp90 inhibitors; proteasome inhibitors; VEGF inhibitors (e.g.. Avastin®); and EGFR inhibitors (e.g.. Tarceva®, Iressa®). These United States patents and applications and corresponding international patents and applications concern the therapeutic application of the p53 tumor suppressor or the mda-7/IL-24 tumor suppressor before, during or after treatment with radiotherapy or other anti-cancer compounds. Additionally, in order to further extend our portfolio as it relates to combinatorial anti-cancer therapy, we have licensed from Aventis a United States patent and corresponding international patents and applications directed to therapy using the p53 tumor suppressor together with taxanes such as Taxol® or Taxotere®. Furthermore, we have exclusively licensed a United States patent application and corresponding international applications directed to the use of the p53 tumor suppressor in combination with surgical intervention in cancer therapy.

Adenovirus Production, Purification and Formulation

Another focus of our research has involved the development of procedures for the commercial-scale production of our potential adenoviral-based products, including that of ADVEXIN therapy. In this regard, we own three issued United States patents as well as a number of pending United States applications and corresponding international applications directed to highly purified adenoviral compositions, commercial-scale processes for producing adenoviral-based compositions having a high level of purity, as well as to storage-stable formulations. These patents and patent applications include procedures for preparing commercial quantities of recombinant adenovirus products and include procedures applicable to the p53 tumor suppressor, as well as any of our other potential products. We have also licensed from Aventis in the p53 field a United States patent and corresponding international applications directed to processes for the production of purified adenoviruses, which are useful for our product applications. With respect to storage-stable formulations, we were issued a United States patent directed to compositions and methods

concerning improved, storage-stable adenovirus formulations. This patent is not limited to our ADVEXIN therapy product candidate and may eventually replace formulations currently in use.

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Other Tumor Suppressors

We either own or have exclusively licensed rights in a number of other patents and applications directed to the clinical application of various tumor suppressors other than p53, including the mda-7, BAK, the 3p21.3 family (FUS-1) and anti-sense K-ras. We have exclusively licensed or optioned rights in a number of issued United States patents covering the use of the mda-7 and BAK tumor suppressors.

Other Therapeutic, Composition and Process Technologies

We own or have exclusively licensed a number of United States and international patent applications on a range of additional technologies. These include various applications and patents relating to p53, combination therapy with 2-methoxyestradiol, anti-proliferative factor technologies, retroviral delivery systems, stimulation of anti-p53, screening and product assurance technologies, as well as second-generation p53 molecules. We have exclusively licensed a number of United States and international applications directed to various improved vector applications employing more than one molecular therapy for disease treatment, as well as applications directed to the delivery of molecular therapies for disease treatment without the use of a vector, or non-viral therapy. For example, a United States patent, exclusively licensed to us, was recently issued that is directed to adenoviruses that exhibit tissue specific replication. We also have exclusive rights in an issued United States patent and corresponding international applications directed to a low toxicity analogue of IL-24, also called F42K.

Benzimidazole Small Molecule Cancer Therapy Program

We also have exclusively licensed a United States and a corresponding international patent application directed to the use of a family of known anti-helminthic benzimidazole molecules, most notably mebendazole, in the treatment of cancer. These applications are directed generally to the use of small molecules of the benzimidazole family to induce apoptosis in cancers, as well as to treat cancer patients, particularly those having p53-related cancers. Both of these therapeutic actions are based on the discovery by our scientists and their collaborators that members of the benzimidazole family will actively induce apoptosis in cancer cells, particularly in conjunction with the action of an endogenous or exogenously added p53 tumor suppressor.

Trade Secrets

We rely on trade secrets law to protect technology where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. In addition, we generally require employees, academic collaborators and consultants to enter into confidentiality agreements. Despite these measures, we may not be able to adequately protect our trade secrets or other proprietary information. We are a party to various license agreements that give us rights to use specified technologies in our research and development processes. If we are not able to continue to license this technology on commercially reasonable terms, our product development and research may be delayed. In addition, in the case of technologies that we have licensed, we do not have the ability to make the final decisions on how the patent application process is managed, and accordingly are unable to exercise the same degree of control over this intellectual property as we exercise over our internally developed technology. Our research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be diminished.

Financial Overview

Since our inception in 1993, we have used our resources primarily to conduct research and development activities for ADVEXIN therapy and, to a lesser extent, for other product candidates. At September 30, 2006, we had an accumulated deficit of $165.1 million. We anticipate we will incur losses in the future that may be greater than losses incurred in prior periods.

At September 30, 2006, we had cash, cash equivalents and short-term investments of $16.5 million, compared to $33.1 million at December 31, 2005. Cash and cash equivalents constituted $13.5 million and $28.1 million of these amounts at September 30, 2006, and December 31, 2005, respectively. Considering cash, cash equivalents and short-term investments in total, we used $16.6 million to operate our business during the nine months ended September 30, 2006. Considering cash and cash equivalents alone, exclusive of short-term investments, the change in those amounts during the nine months ended September 30, 2006 consisted of (1) $16.3 million used in operating activities, (2) $1.9 million provided by investing activities and (3) $210,000 used in financing activities. These

amounts are further detailed in the condensed consolidated statement of cash flows presented above.

We expect to incur substantial additional operating expense and losses over the next several years as our research, development, pre-clinical testing and clinical trial activities continue and as we evolve our operations and systems to support commercialization of

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our product candidates. These losses, among other things, have caused and may cause our total assets, stockholders equity and working capital to decrease. During the nine months ended September 30, 2006, we earned revenue or income from federal research grants, contract services and process development activities, the lease of a portion of our facilities to M. D. Anderson Cancer Center and interest income on cash placed in short-term, investment grade securities. There is no assurance we will continue to earn revenue from these sources in the future. In order to fund our operating losses, we will need to raise additional funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. We do not know whether such additional financing will be available when needed or on terms favorable to us or our stockholders.

In November 2005, we sold approximately 3.6 million shares of our common stock in a direct equity sale to Colgate-Palmolive pursuant to a shelf registration statement for an aggregate purchase price of approximately $20.0 million. Our net proceeds from this transaction, after related fees and expense, were approximately $19.6 million. See Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Business and Collaborative Arrangements Alliance with Colgate-Palmolive Company above for further discussion of our agreement with Colgate-Palmolive.

Conversion of Preferred Stock to Common Stock

In June 2005, the 100,000 issued and outstanding shares of our Series A Non-Voting Convertible Preferred Stock held by Aventis were converted into 2,343,721 shares of our common stock. Following the conversion, these shares of preferred stock were cancelled and are no longer issuable. We received no cash or other consideration in connection with this conversion.

Under a voting agreement related to these shares, Aventis must vote these shares in the same manner as the shares voted by a majority of the other stockholders on any corporate action put to a vote of our stockholders. This voting requirement terminates at the earliest of June 2011 or the sale of these shares pursuant to an effective registration statement, on the open market or to an Aventis non-affiliate, as defined in the voting agreement. Pursuant to a demand registration made by Aventis in accordance with the terms of a registration rights agreement related to these shares, in November 2005 we filed a Registration Statement on Form S-3 (File No. 333-129687)) to facilitate the public resale of up to 4,322,369 shares of our common stock held by Aventis, which includes the converted shares. This registration statement has been declared effective by the SEC and Aventis may resell these shares from time to time in the open market pursuant to the registration statement. We will not receive any of the proceeds from the sale of the shares held by Aventis. As of September 30, 2006, Aventis held approximately 3.7 million shares of our common stock subject to the voting agreement.

After this conversion, we have 5.0 million shares of authorized and unissued preferred shares, of which 100,000 shares have been cancelled and 4.9 million shares are undesignated and issuable.

Investment in SR Pharma plc

In July 2005, we purchased approximately 8.3% of the issued share capital of SR Pharma for approximately $3.0 million. As of September 30, 2006, the shares we purchased had a quoted market value of $2.4 million. SR Pharma is a European biotechnology company publicly traded on the Alternative Investment Market of the LSE that is developing oncology and other products.

Research Grants

We have received funding under a grant from the NCI to support our Phase 2 clinical trial of INGN 241 in patients with metastatic melanoma. We received grant funding and earned grant revenue under this grant of zero during the three months ended September 30, 2006 and September 30, 2005 and zero and $230,000 during the nine months ended September 30, 2006 and September 30, 2005, respectively.

Magnum, our wholly-owned subsidiary, received funding under a grant from the NIH for the development of complementary adenoviral vectors for the treatment of cancer. Grant funding received and grant revenue earned under this grant was zero and $302,000 during the three months ended September 30, 2006 and September 30, 2005, respectively, and $163,000 and $712,000 during the nine months ended September 30, 2006 and September 30, 2005, respectively. We have earned and received all amounts available under this grant.

The amount of grant funding, if any, available to us to perform research and development is dependent upon many factors, including the availability of grants from government agencies, our performing the work and incurring

the costs contemplated by the

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grants we currently have, our success in obtaining additional grants in the future and our compliance with statutes and regulations governing such grants.

Critical Accounting Policies

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

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

Marketable Securities. Our marketable securities consist of issued share capital of other public companies and are classified as available-for-sale. Unrealized gains and losses are computed using the published share price of the applicable stock exchange at the close of business on the last day of the reporting period and are reported as a separate component of accumulated other comprehensive income (loss) in shareholders equity until realized.

Intangible Assets. Grant rights acquired, which are presented as an intangible asset on our balance sheet, resulted from our asset acquisition related to the purchase of Magnum in October 2004. We have amortized that asset in its entirety to expense over its estimated life and have no further amortization to record relative to that item in the future.

Revenue Recognition. Contract services revenue is recognized when the related services are completed and delivered to the customer. Deferred revenue is recorded for cash received for which the related work has not been completed and/or the related expense has not been incurred. Grant revenue is recognized as research expense relating to a grant is incurred and the work contemplated under the grant has been performed. Rental income from the sublease of laboratory space to third parties under leases that have variable monthly rent amounts over the term of the lease is recognized on a straight-line basis over the term of the lease. Any cash payments received in excess of rental income recognized is recorded as deferred revenue. Rental income is included in other income in the accompanying condensed consolidated statement of operations.

Research and Development Costs. In conducting our clinical trials of ADVEXIN therapy and other product candidates, we procure services from numerous third-party vendors. The cost of these services constitutes a significant portion of the cost of these trials and of our research and development expense in general. These vendors do not necessarily provide us billings for their services on a regular basis and, accordingly, are often not a timely source of information to determine the costs we have incurred relative to their services for any given accounting period. As a result, we make significant accounting estimates as to the amount of costs we have incurred relative to these vendors in each accounting period. These estimates are based on numerous factors, including, among others, costs set forth in our contracts with these vendors, the period of time over which the vendor will render the services and the rate of enrollment of patients in our clinical trials. Using these estimates, we record expense and accrued liabilities in each accounting period that we believe fairly represent our obligations to these vendors. Actual results could differ from these estimates, resulting in increases or decreases in the amount of expense recorded and the related accrual. We have consistently applied these estimation procedures in the past and plan to continue applying such procedures in the same manner during the foreseeable future. Our experience has been that our estimates have reasonably reflected the expense we actually incur.

Share-Based Compensation. Effective January 1, 2006, we adopted SFAS No. 123R, Accounting For Share-Based Compensation. From that date forward, we record share-based compensation expense for all stock options issued to all persons to the extent such options vest on January 1, 2006 or later. That expense is determined under the fair value method using the Black-Scholes option pricing model. We record that expense ratably over the period the stock options vest.

Prior to January 1, 2006, we applied APB No. 25, Accounting for Stock Issued to Employees and related interpretations for determining compensation expense related to our stock option grants. Under that principle, we

measured compensation expense for stock options issued to our directors and employees using the intrinsic value of the stock option at date of grant, which generally resulted in us recording no compensation expense since the intrinsic value of those stock options was typically zero at the date of grant

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due to the exercise price of those stock options being equal to the fair value of our shares on the date of grant. Compensation expense for stock options issued to all other persons was measured using the fair value of the stock option at the date of grant determined under the Black-Scholes option pricing model, which generally resulted in us recording a compensation expense.

The Black-Scholes option pricing model we use to compute share-based compensation expense requires extensive use of accounting judgment and financial estimates. Items requiring estimation include the expected term option holders will retain their vested stock options before exercising them, the estimated volatility of our common stock price over the expected term of a stock option, and the number of stock options that will be forfeited prior to the completion of their vesting requirements. Application of alternative assumptions could result in significantly different share-based compensation amounts being recorded in our financial statements.

We implemented SFAS No. 123R using the modified prospective transition method. Under this method, prior periods are not restated.

Recently Issued Accounting Pronouncements

See Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies-Share-Based Compensation above for discussion of a recently effective accounting pronouncement significant to us.

Results of Operations

Our operations consist primarily of the research and development of our product candidates and technologies described above in Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Product Development Overview. Our research and development expense includes, but is not limited to, expense related to personnel, facilities and equipment, pre-clinical research, clinical trials, manufacturing of materials for use in clinical trials, conducting data analysis and conducting regulatory documentation submissions to the FDA. Our research and development expense can be divided between programs in the pre-clinical stage and programs in the clinical stage, and general research and development expense attributable to all programs. We manage our business by tracking research and development expense in these categories in lieu of tracking research and development expense on a project-by-project basis. Tables setting forth the amount of research and development expense we have incurred in each of these categories are presented below under Comparison of Three Months Ended September 30, 2006 and September 30, 2005 and Comparison of Nine Months Ended September 30, 2006 and September 30, 2005.

To commercialize our product candidates, we must obtain certain regulatory approvals. Satisfaction of regulatory requirements typically takes many years and involves compliance with requirements covering pre-clinical research, clinical trials, manufacturing, quality control, labeling and promotion of drugs for human use. To obtain regulatory approvals, we must, among other requirements, complete clinical trials and other work demonstrating our product candidates are safe and effective for a particular cancer type or other disease. The FDA and other similar agencies throughout the world have substantial discretion over the work we must perform to obtain regulatory approval.

The likelihood that a product candidate will be commercially successful may be affected by a variety of factors, including, among others, the quality of the product candidate, the validity of the target and disease indication, early clinical data, competition, manufacturing capability and commercial viability. Because of the discretion of the FDA and similar agencies throughout the world, as well as the foregoing factors, we cannot predict with reasonable accuracy (1) the future expense we will incur developing these product candidates, (2) when we will complete our work in developing these product candidates or (3) when, if ever, we will earn significant revenue from approved products that might result from these product development programs.

For a discussion of the risks and uncertainties associated with developing our products, as well as the risks and uncertainties associated with potential commercialization of our product candidates, see Part II, Item 1A. Risk Factors, particularly the risk factors entitled:

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

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

timely basis, if at all ;

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

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

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 ;

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

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

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

Comparison of Three Months Ended September 30, 2006 and September 30, 2005

In the following comparison of the three months ended September 30, 2006, and September 30, 2005, references to the 2006 period refer to the three months ended September 30, 2006, and references to the 2005 period refer to the three months ended September 30, 2005.

Revenue

Contract Services, Grant and Other Revenue. For the 2006 and 2005 periods, we earned revenue from third parties under agreements to provide contract manufacturing process development and product production services. For the 2005 period, we also earned revenue from research grants from U.S. Government agencies. Total contract services, grant and other revenue was $733,000 for the 2006 period compared to $398,000 for the 2005 period, an increase of 84%. This increase was primarily due to an increase in contract services revenue as a result of the completion of certain contract services which allowed us to recognize revenue for those services that had been deferred in previous periods. The increase in contract services revenue was offset by a decrease in revenue earned under research grants from U.S. Government agencies as a result of us substantially completing, subsequent to the 2005 period, the work contemplated by those grants, including the work contemplated under the grant held by Magnum. There is significant competition for funding under grants from U.S. Government agencies such that we cannot predict the amount of such funding, if any, we might pursue or receive in the future.

Costs and Expense

Research and Development. Research and development expense consisted of the following (in thousands):

	Three months ended September 30,	
	2005	**2006**
Pre-clinical stage programs expense	$ 608	$ 201
Clinical stage programs expense	3,831	3,049
General research and development expense	651	1,006
Total research and development expense	$ 5,090	$ 4,256

Research and development expense included share-based compensation expense of $267,000 in the 2006 period and zero in the 2005 period.

The 16% decrease in research and development expense in the 2006 period compared to the 2005 period was a result of (1) lower costs in the 2006 period compared to the 2005 period since the 2005 period included higher costs related to our commencement of

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development and pursuit of an initial rolling BLA filing strategy for ADVEXIN therapy, (2) decreased expense related to the amortization of grant rights acquired in the purchase of Magnum as a result of the completion of work and funding under that grant in 2006, (3) decreased costs of manufacturing supplies of clinical materials as our manufacturing activities in earlier periods provided us with adequate quantities of clinical materials to conduct our clinical trials for the foreseeable future such that we were able to reduce such manufacturing activities in the 2006 period and (4) the expiration of the requirement to purchase additional shares of preferred stock of VirRx, discussed in the notes to our condensed consolidated financial statements under Investment in VirRx, Inc.

General and Administrative. General and administrative expense was $2.5 million for the 2006 period compared to $1.7 million for the 2005 period. This expense included share-based compensation expense of $0.9 million in the 2006 period and zero in the 2005 period. This 47% increase in general and administrative expense was primarily due to higher share-based compensation expense resulting from the implementation of SFAS No. 123R, Share-Based Payments.

Share-Based Compensation Expense. Share-based compensation expense was $1.2 million for the 2006 period compared to zero for the 2005 period. The increase in this expense was due to the implementation of SFAS No. 123R, Share-Based Payments, discussed above under Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Share-Based Compensation.

Interest Income, Interest Expense and Other Income

Interest income was $226,000 for the 2006 period compared to $161,000 for the 2005 period, an increase of 40%. This increase was primarily due to higher interest rates earned on our invested funds during the 2006 period compared to the 2005 period.

Interest expense was $176,000 for the 2006 period compared to $153,000 for the 2005 period, an increase of 15%. This increase was primarily due to (1) additional borrowings subsequent to the 2005 period to finance equipment acquisitions and (2) higher interest rates charged on borrowings originating subsequent to the 2005 period.

Other income was $281,000 for the 2006 period and $277,000 for the 2005 period, an increase of 1%. This income is earned primarily from our sublease of space to M. D. Anderson Cancer Center and other miscellaneous activities. This increase was a result of normal fluctuations in various miscellaneous activities not significant to our overall operations.

Comparison of Nine Months Ended September 30, 2006 and September 30, 2005

In the following comparison of the nine months ended September 30, 2006, and September 30, 2005, references to the 2006 period refer to the nine months ended September 30, 2006, and references to the 2005 period refer to the nine months ended September 30, 2005.

Revenue

Contract Services, Grant and Other Revenue. For the 2006 and 2005 periods, we earned revenue primarily from (1) research grants from U.S. Government agencies and (2) third parties under agreements to provide contract manufacturing process development and product production services. Total contract services, grant and other revenue was $1.0 million for the 2006 period compared to $1.2 million for the 2005 period, a decrease of 17%. This decrease was due to decreased revenue earned under research grants from U.S. Government agencies as a result of us substantially completing, subsequent to the 2005 period, the work contemplated by those grants, including the work contemplated under the grant held by Magnum. The decrease in revenue earned under research grants was offset by an increase in contract services revenue as a result of the completion of certain contract services which allowed us to recognize revenue for those services that had been deferred in previous periods. There is significant competition for funding under grants from U.S. Government agencies such that we cannot predict the amount of such funding, if any, we might receive in the future.

Costs and Expense

Research and Development. Research and development expense consisted of the following (in thousands):

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	Nine months ended September 30,	
	2005	2006
Pre-clinical stage programs expense	$ 2,112	$ 1,022
Clinical stage programs expense	11,591	10,422
General research and development expense	2,326	2,754
Total research and development expense	$ 16,029	$ 14,198

Research and development expense included share-based compensation expense of $737,000 in the 2006 period and $396,000 in the 2005 period.

The 11% decrease in research and development expense in the 2006 period compared to the 2005 period was a result of (1) lower costs in the 2006 period compared to the 2005 period since the 2005 period included higher costs related to our commencement of development and pursuit of an initial rolling BLA filing strategy for ADVEXIN therapy, (2) decreased expense related to the amortization of grant rights acquired in the purchase of Magnum as a result of the completion of our work and related funding under that grant in 2006, (3) decreased costs of manufacturing supplies of clinical materials as our manufacturing activities in earlier periods provided us with adequate quantities of clinical materials to conduct our clinical trials for the foreseeable future such that we were able to reduce such manufacturing activities in the 2006 period and (4) the expiration of the requirement to purchase additional shares of VirRx, discussed in the notes to our condensed consolidated financial statements under Investment in VirRx, Inc.

General and Administrative. General and administrative expense was $9.6 million for the 2006 period compared to $5.5 million for the 2005 period. This expense included share-based compensation expense of $4.3 million in the 2006 period and $403,000 in the 2005 period. This 75% increase in general and administrative expense was primarily due to higher share-based compensation expense resulting from the implementation of SFAS No. 123R, Share-Based Payments. This implementation resulted in us recording share-based compensation expense for stock option grants to directors, officers and employees in the 2006 period for which there was no comparable expense recorded in the 2005 period as allowed by GAAP in effect during the 2005 period.

Share-Based Compensation Expense. Share-based compensation expense was $5.0 million for the 2006 period compared to $799,000 for the 2005 period. The 526% increase in this expense was due to the implementation of SFAS No. 123R, Share-Based Payments, discussed above under Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Share-Based Compensation.

Interest Income, Interest Expense and Other Income

Interest income was $792,000 for the 2006 period compared to $538,000 for the 2005 period, an increase of 47%. This increase was primarily due to higher interest rates earned on our invested funds during the 2006 period compared to the 2005 period.

Interest expense was $507,000 for the 2006 period compared to $461,000 for the 2005 period, an increase of 10%. This increase was primarily due to (1) additional borrowings subsequent to the 2005 period to finance equipment acquisitions and (2) higher interest rates charged on borrowings originating subsequent to the 2005 period.

Other income was substantially unchanged at $824,000 for the 2006 period as compared to $826,000 for the 2005 period,. This income is earned primarily from our sublease of space to M. D. Anderson Cancer Center and other miscellaneous activities. This decrease was a result of normal fluctuations in various miscellaneous activities not significant to our overall operations.

Liquidity and Capital Resources

In the following discussion of liquidity and capital resources, references to the 2006 period refer to the nine months ended September 30, 2006 and references to the 2005 period refer to the nine months ended September 30, 2005.

We have incurred annual operating losses since our inception. At September 30, 2006, we had an accumulated deficit of $165.1 million. From inception through September 30, 2006, we have financed our operations primarily from the following sources:

$49.7 million of collaborative research and development payments from Aventis;

$41.4 million of equity sales in December 2003 and December 2004 through registered direct offerings under a shelf registration filed with the SEC;

$39.4 million of private equity sales to Aventis;

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

$29.4 million of private equity sales, net of offering costs, to others (including $10.8 million from the private sale of our common stock in June 2003);

$21.8 million from contract services, grants, interest and other income;

$19.6 million of equity sales, net of offering costs, to Colgate-Palmolive pursuant to an alliance agreement entered into in November 2005;

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

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

$6.1 million in leases and notes payable from commercial lessors and lenders to acquire equipment pledged as collateral for those leases and notes.

At September 30, 2006, we had cash, cash equivalents and short-term investments of $16.5 million, compared to $33.1 million at December 31, 2005. Cash and cash equivalents constituted $13.5 million and $28.1 million of these amounts at September 30, 2006, and December 31, 2005, respectively. Considering cash, cash equivalents and short-term investments in total, we used $16.6 million to operate our business during the nine months ended September 30, 2006. Considering cash and cash equivalents alone, exclusive of short-term investments, the change in those amounts during the nine months ended September 30, 2006 consisted of (1) $16.3 million used in operating activities, (2) $1.9 million provided by investing activities and (3) $210,000 used in financing activities.

We expect to continue focusing our activities primarily on conducting Phase 3 and other clinical trials, conducting data analysis related to those trials, preparing regulatory documentation submissions to the FDA, producing ADVEXIN therapy and other clinical materials for use in our clinical trials and conducting pre-marketing activities for ADVEXIN therapy. We expect to continue our research and development of various other targeted molecular therapy technologies. If ADVEXIN therapy or any of our other product candidates are approved for commercial sale by the FDA, we expect to conduct activities supporting the marketing, sales, production and distribution of those products, either ourselves or in collaboration with other parties.

The majority of our expenditures for the foreseeable future will most likely be for our activities as they relate to ADVEXIN therapy. These activities may increase the rate at which we use cash in the future as compared to the cash we used for operating activities during the nine months ended September 30, 2006. We believe our existing working capital can fund our operations for the next 9 to 12 months, although we may have to make adjustments to the scope of operations to achieve that objective. Unforeseen events could shorten that time period.

Our existing resources may not be sufficient to support the commercial introduction of any of our product candidates. In order to fund our operating losses, we intend to raise additional funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. We do not know whether such additional financing will be available when needed or on terms favorable to us or our stockholders.

Net cash used in operating activities was $16.3 million for the 2006 period compared to $16.7 million for the 2005 period. This decrease was primarily due to:

A smaller net loss, exclusive of share-based compensation, in the 2006 period compared to the 2005 period. The $21.6 million net loss in the 2006 period compares to a net loss of $19.4 million in the 2005 period. These losses include share-based compensation expense, which does not use cash, of $5.0 million in the 2006 period and $550,000 in the 2005 period. Accordingly, the net loss before share-based compensation expense was $16.6 million in the 2006 period compared to $18.8 million in the 2005 period, a decrease of $2.2 million.

A smaller aggregate decrease in accounts payable and accrued liabilities in the 2006 period compared to the 2005 period. Changes in these accounts arise primarily from variations in the timing of payments to vendors

that is a function of the nature of vendors to whom we have obligations and variations in the terms of payment to them.

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A decrease in deferred revenue during the 2006 period compared to an increase in that amount during the 2005 period. Our deferred revenue and cash increase when we receive payments for contract manufacturing process development and product production services work in advance of completing the work to which the payments relate. Our deferred revenue decreases, with no effect on cash, as we complete that work and recognize the related revenue. The changes in deferred revenue vary based upon the timing of when we receive prepayments for this work and when we complete the work to support recognizing revenue. During the latter part of the 2006 period, we completed certain contract services for which revenue recognition had been previously deferred, which allowed us to recognize revenue for those services that had been deferred in previous periods thereby causing a decrease in deferred revenue.

A smaller decrease in other assets during the 2006 period compared to the 2005 period. Changes in other assets vary in direction and amount based on the timing of and dollars involved in transactions related to items such as prepaid expenses, grant funding receivable and deposits. The aggregate changes in prepaid assets during the 2006 and 2005 periods resulted from such activities that arose during the normal course of our business, with no component of those aggregate changes being material to our business taken as a whole.

Net cash provided by investing activities was $1.9 million for the 2006 period compared to net cash used in investing activities of $3.5 million for the 2005 period. This increase was primarily due to a lower level of net activity in purchases of short-term investments in the 2006 period compared to the 2005 period due to normal variations in the amount and timing of purchases and sales of short-term investments based on our operating needs for cash and cash equivalents and the availability of cash from sales of our common stock.

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

Net cash used by financing activities was $210,000 during the 2006 period compared to net cash provided by financing activities of $738,000 during the 2005 period. This change was due to:

A decrease in proceeds from sales of common stock due to a lower level of stock option exercises in the 2006 period compared to the 2005 period;

A decrease in proceeds from notes payable in the 2006 period compared to the 2005 period due to a decrease in purchases of property and equipment resulting in a reduced need for related financing; and

An increase in principal payments under notes payable in the 2006 period compared to the 2005 period due to additional borrowings subsequent to the 2005 period to finance equipment purchased during that period.

Under an agreement with VirRx, we have purchased shares of VirRx s Series A Preferred Stock. Key activity and provisions under this agreement include the following:

We have purchased VirRx s Series A Preferred Stock for cash in the amount of $2,475,000 during the period from inception of this agreement through September 30, 2006, and in the amount of $150,000 in the 2006 period (specifically during the three months ended March 31, 2006) and $450,000 in the 2005 period. These purchases are recorded as research and development expense. We have no plans at this time to purchase additional shares of this stock and are no longer required to make periodic purchases of Series A Preferred Stock under this agreement. We may be required to make additional stock purchases in the event VirRx reaches certain specified milestones as described below.

VirRx is required to use the proceeds from these stock sales in accordance with the terms of a collaboration and license agreement between VirRx and us for the development of VirRx s technologies. We may unilaterally terminate this collaboration and license agreement upon 90 days prior written notice.

Provided the collaboration and license agreement remains in place, we are required to make milestone stock purchases, either for cash or through the issuance of our common stock, upon the completion of Phase 1, 2 and 3 clinical trials involving technologies licensed under this agreement. We are required to make a $5.0 million cash milestone payment to VirRx, for

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which we receive no VirRx stock, upon approval by the FDA of a BLA for the first collaboration product based on these technologies. To the extent we have already made cash milestone payments, we may receive a credit of 50% of the Phase 2 clinical trial milestone payments and 25% of the Phase 3 clinical trial milestone payments against this $5.0 million cash milestone payment. The milestone stock purchases and cash payment are not anticipated to be required in the near future. We have an option to purchase all outstanding shares of VirRx at any time until March 2007.

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

Total debt service payments for October 1, 2006 through December 31, 2006	$ 347
Total debt service payments due during the year ending December 31:	
2007	1,314
2008	989
2009	789
2010	735
Thereafter	10,409
Total debt service payments	14,583
Less portion representing interest	(6,290)
Total principal balance at September 30, 2006	$ 8,293
Principal balance presented on the September 30, 2006 balance sheet as liabilities in these categories:	
Current portion of notes payable	$ 743
Notes payable, net of current portion	7,550
Total principal balance at September 30, 2006	$ 8,293

We have a fixed rent obligation under a ground lease for the land on which we built our facilities. Since this lease is an operating lease, there is no liability reflected on our balance sheet for this item, which is in accordance with GAAP. We make total annual rent payments of $156,000 under this lease which will continue until the expiration of its initial term in September 2026. Such payments are subject to adjustment in the future for inflation. Future minimum annual rental payments due under all operating leases are as follows (in thousands):

October 1, 2006 through December 31, 2006	$ 123
Year ending December 31,	
2007	483
2008	468
2009	287
2010	156
Thereafter	2,459
Total minimum lease payments under operating leases	$ 3,976

In the normal course of business, we may enter into various long-term agreements with vendors to provide services to us. Some of these agreements may require up-front payment prior to services being rendered, some may require periodic monthly payments and some may provide for the vendor to bill us for their services as they are rendered. In

substantially all cases, we may cancel these agreements at any time with minimal or no penalty and pay the vendor only for services actually rendered. Regardless of the timing of the payments under these agreements, we record the expense incurred in the periods in which the services are rendered.

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

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We have a consulting agreement with Jack A. Roth, M.D., Chairman of the Department of Thoracic and Cardiovascular Surgery and Director of the W. M. Keck Center for Cancer Gene Therapy at The University of Texas M. D. Anderson Cancer Center where he holds the Bud Johnson Clinical Distinguished Chair. Dr. Roth is the primary inventor of the technology upon which our ADVEXIN therapy is based and numerous other technologies we utilize. We licensed Dr. Roth s inventions from M. D. Anderson Cancer Center. Dr. Roth is our Chief Medical Advisor and chairman of our scientific advisory board. His duties involve the regular interaction and consultation with our scientists and others on our behalf. As compensation for his services and responsibilities, this consulting agreement provides for payments to Dr. Roth of $205,000 per annum, with that amount subject to adjustment for inflation in the future. These payments continue through the end of the consulting agreement term on September 30, 2009. We may terminate this agreement at our option upon one year s advance notice. If we had terminated this agreement as of September 30, 2006, we would have been obligated to make final payments totaling $205,000. Dr. Roth is one of our stockholders.

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

We sublease a portion of our facilities to M. D. Anderson Cancer Center. They are obligated to pay us rent and facilities operating expense reimbursements of approximately $29,000 per month during the non-cancelable term of this lease, which expires in 2009.

Non-Audit Services of Independent Registered Public Accounting Firm

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates, foreign currency exchange rates and equity prices. Our risks, risk management strategies and sensitivity analyses estimating the effects of changes in fair values for each of these exposures at September 30, 2006 are outlined below. Actual results may differ materially from our sensitivity analyses based on changes in the timing and amount of interest rate, foreign currency exchange rate and equity price movements and our actual exposures.

Our market risk profile has not changed significantly from that described in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our fixed rate long-term debt and short-term investments in investment grade securities, which consist primarily of federal government obligations. Investments are classified as held-to-maturity and are carried at amortized cost. We do not hedge interest rate exposure or invest in derivative securities. We have performed sensitivity analyses as of September 30, 2006 and December 31, 2005 using a modeling technique that measures the change in our interest income arising from a hypothetical 100-basis point decrease in the levels of interest rates across the entire yield curve, with all other variables held constant. The analyses cover our fixed rate long-term debt and short-term investments. The analyses use actual maturities for our fixed rate long-term debt and short-term investments. The discount rates we used were based on the market interest rates in effect at September 30, 2006 and December 31, 2005. The sensitivity analyses indicated a hypothetical 100-basis point decrease in the interest rates of our investments at the investment balances as of September 30, 2006 would decrease our interest income by approximately $165,000 per year and approximately $41,250 per quarter, compared to a decrease in our interest income of approximately $331,000 per year and approximately $82,750 per quarter as of December 31, 2005.

At September 30, 2006, the fair value of our fixed-rate debt approximated its carrying value based upon discounted future cash flows using current market prices.

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Equity Price Risk and Foreign Currency Exchange Rate Risk

From time to time, we may invest in marketable securities of public companies, typically in the form of equity instruments, for business and strategic purposes. We own British Pound-denominated shares in SR Pharma, a publicly traded company listed on the Alternative Investment Market of the LSE. These marketable securities are classified as available-for-sale. Unrealized gains and losses in these marketable securities and the related foreign currency translation adjustments are reported as a separate component of accumulated other comprehensive income (loss) in stockholders equity until realized. We are exposed to market risk for changes in equity prices and foreign currency translation adjustments as a result of our investments in marketable securities.

These marketable securities are subject to significant fluctuation in fair value due to the volatility of the industry in which SR Pharma participates and changes in the relative foreign currency values. We do not hedge our equity price risk or foreign currency translation exposure or invest in derivative securities. We have performed sensitivity analyses as of September 30, 2006 and December 31, 2005 using a modeling technique that measures the change in the fair values arising from a hypothetical 10% decline in the stock price of our marketable securities, a hypothetical 10% decline in foreign currency exchange rates relative to the U.S. dollar and a simultaneous hypothetical 10% decline in the stock price of our marketable securities and in foreign currency exchange rates relative to the U.S. dollar, with all other variables held constant. The analyses cover all of our public company marketable securities. The foreign currency exchange rates we used were based on market rates in effect at September 30, 2006 and December 31, 2005. The sensitivity analyses indicated that:

A hypothetical 10% decrease in the stock price of our marketable securities as of September 30, 2006 would decrease the value of those marketable securities by approximately $238,000, compared to a decrease in the fair value of those marketable securities of approximately $290,000 as of December 31, 2005;

A hypothetical 10% decrease in the value of the British Pound as of September 30, 2006 would decrease the fair value of our marketable securities by approximately $238,000, compared to a decrease in the fair value of our marketable securities of approximately $290,000 as of December 31, 2005; and

A hypothetical 10% decrease in the stock price of our marketable securities and a hypothetical 10% decrease in the value of the British Pound, in each case as of September 30, 2006, would decrease the fair value of our marketable securities by approximately $452,000, compared to a decrease in the fair value of our marketable securities of approximately $550,000 as of December 31, 2005.

Our purchase price for these SR Pharma marketable securities was approximately $3.0 million. At September 30, 2006 and December 31, 2005, the quoted value of these marketable securities was approximately $2.4 million and $2.9 million, respectively. The impact of the foreign currency translation adjustment in the relative values of the Pound and the U.S. dollar was not material during this period.

Item 4. Controls and Procedures

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

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

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PART II
OTHER INFORMATION

Item 1. Legal Proceedings

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

We do not believe that the outcome of any present, or all litigation in the aggregate, will have a material effect on our business. You can read the discussion of our opposition of the patents under Part II, Item 1A. Risk Factors.

Item 1A. Risk Factors

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

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

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

In order to commercialize our product candidates, we must obtain certain regulatory approvals. Satisfaction of regulatory requirements typically takes many years, and involves compliance with requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. To obtain regulatory approvals, we must, among other requirements, complete clinical trials demonstrating our product candidates are safe and effective for a particular cancer type or other disease. Regulatory approval of a new drug is never guaranteed. The FDA and foreign regulatory authorities have substantial discretion in the approval process. Despite the time and experience exerted, failure can occur at any stage, and we could encounter problems causing us to abandon clinical trials.

We have completed or are conducting clinical trials of our lead product candidate, ADVEXIN therapy, for the treatment of various cancers. Current or future clinical trials may demonstrate ADVEXIN therapy is neither safe nor effective.

We have completed or are conducting clinical trials of INGN 241, a product candidate based on the mda-7 tumor suppressor. We will need to continue conducting significant research and animal testing, referred to as pre-clinical testing, to support performing clinical trials for our other product candidates. It will take us many years to complete pre-clinical testing and clinical trials, and failure could occur at any stage of testing. Current or future clinical trials may demonstrate INGN 241 or our other product candidates are neither safe nor effective.

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

- the product candidate is less effective and/or more toxic than current therapies;
- the presence of unforeseen adverse side effects of a product candidate, including its delivery system;
- a longer than expected time required to determine whether or not a product candidate is effective;

the death of patients during a clinical trial, even if the product candidate did not cause those deaths;

the failure to enroll a sufficient number of patients in our clinical trials;

the inability to produce sufficient quantities of a product candidate to complete the trials; or

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the inability to commit the necessary resources to fund the clinical trials.

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

Despite the FDA s designation of ADVEXIN therapy as a Fast Track product, we may encounter delays in the regulatory approval process due to additional information requirements from the FDA, unintentional omissions in our BLA for ADVEXIN therapy, or other delays in the FDA s review process. Similarly, although we have an agreement with the European Medicines Agency (EMEA) to file for marketing approval for ADVEXIN therapy under the EMEA s Exceptional Circumstances provisions., we may encounter delays in the regulatory approval process due to additional information requirements from the EMEA, unintentional omissions in our Marketing Authorization Application filed with the EMEA, or other delays in the EMEA s review process. We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA or EMEA policy during the period of product development, clinical trials and FDA and EMEA regulatory review.

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

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

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

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

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

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

We have generated operating losses since we began operations in June 1993. As of September 30, 2006, we had an accumulated deficit of approximately $165.1 million. We expect to incur substantial additional operating expense and

losses over the next several years as our research, development, pre-clinical testing and clinical trial activities increase. As we expand our operations and develop

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systems to support commercialization of our product candidates, these losses, among other things, have had, and are expected to continue to have, an adverse impact on our total assets, stockholders equity and working capital.

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

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

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

We expect we will fund our operations over approximately the next 9 to 12 months with our current working capital, which we accumulated primarily from sale of equity securities, income from contract services and research grants, debt financing of equipment acquisitions, the lease of a portion of our facilities to M. D. Anderson Cancer Center and interest on invested funds. We intend to raise additional capital sooner, however, under various circumstances, including if we experience:

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

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

higher than expected costs to obtain regulatory approvals;

higher than expected costs to pursue our intellectual property strategy;

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

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

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

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

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

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

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

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

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

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

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

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funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms not favorable to us. If we are not able to raise additional funds, we may have to delay, reduce or eliminate our clinical trials and our development programs.

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

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

If we do not continue to receive grant funding from federal agencies and others, we may be unable to continue our research and development programs for certain of our product candidates at current levels or in the manner we have planned for the future.

We rely on grants from third parties, generally federal agencies, to provide the funding necessary to conduct our research and development programs for some of our technologies and product candidates. Funding of these grants is typically subject to government appropriations. These grants often contain provisions that allow for termination at the convenience of the government. Further, these grants are subject to complex federal guidelines and regulations. If federal agencies or regulatory authorities determine that we, or the programs for which we desire to receive or have received grant funding, do not qualify for funding, our scientific or product development programs could be slowed or stopped and we may suffer financial losses and be unable to successfully commercialize our products.

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

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

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

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

The United States Senate has held hearings concerning the adequacy of regulatory oversight of recombinant DNA therapy clinical trials, as well as the adequacy of research subject education and protection in clinical research in general, and to determine whether

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additional legislation is required to protect volunteers and patients who participate in such clinical trials. The Recombinant DNA Advisory Committee, which acts as an advisory body to the NIH, has expanded its public role in evaluating important public and ethical issues in recombinant DNA therapy clinical trials. Implementation of any additional review and reporting procedures or other additional regulatory measures could increase the costs of or prolong our product development efforts or clinical trials.

We report to the FDA and other regulatory agencies serious adverse events, including those we believe may be reasonably related to the treatments administered in our clinical trials. Such serious adverse events, whether treatment-related or not, could result in negative public perception of our treatments and require additional regulatory review or measures, which could increase the cost of or prolong our clinical trials.

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

Patient enrollment may be slow and patients may discontinue their participation in clinical studies, which may negatively impact the results of these studies, and extend the timeline for completion of our and our collaborator s development programs for our product candidates.

The time required to complete clinical trails is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including:

the size of the patient population;

the nature of the clinical protocol requirements;

the diversion of patients to other trials or marketed therapies;

the ability to recruit and manage clinical centers and associated trials;

the proximity of patients to clinical sites; and

the patient eligibility criteria for the study.

We are subject to the risk that patients enrolled in our and our collaborator s clinical studies for our product candidates may discontinue their participation at any time during the study as a result of a number of factors, including, withdrawing their consent or experiencing adverse clinical events which may or may not be related to our product candidates under evaluation. We are subject to the risk that if a large number of patients in any one of our studies discontinue their participation in the study, the results from that study may not be positive or may not support an NDA for regulatory approval of our product candidates.

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

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

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

Our commercial success will depend in part on obtaining patent protection for our products and other technologies and successfully defending these patents against third-party challenges. Our patent position, like that of other

biotechnology and pharmaceutical companies, is highly uncertain. One uncertainty is the United States Patent and Trademark Office, or PTO, or the courts, may deny or significantly narrow claims made under patents issued to us or patent applications we file. This is particularly true

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for patent applications or patents that concern biotechnology and pharmaceutical technologies, such as ours, since the PTO and the courts often consider these technologies to involve unpredictable sciences. Another uncertainty is any patents that may be issued or licensed to us may not provide any competitive advantage to us because they may not effectively preclude others from developing and marketing products like ours. Also, our patents may be successfully challenged, invalidated or circumvented in the future. In addition, our competitors, many of which have substantial resources and have made significant investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use and sell our potential products either in the United States or in international markets.

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

Through our exclusive license from The University of Texas System for technology developed at M. D. Anderson Cancer Center, we have obtained and are currently seeking further patent protection for adenoviral p53, including ADVEXIN therapy, and its use in cancer therapy. Further, the PTO issued us United States patents for our adenovirus production technology and our purified adenoviral compositions. We also control, through licensing arrangements, United States patents for combination therapy involving the p53 tumor suppressor and conventional chemotherapy or radiation, the use of adenoviral p53 in cancer therapy, adenoviral p53 as a product, the core DNA of adenoviral p53, pharmaceutical compositions of adenoviral p53 and clinical applications of such pharmaceutical compositions, as well as patents covering our mda-7 technology. Our competitors may challenge the validity of one or more of our patents in the courts or through an administrative procedure known as an interference, in which the PTO determines the priority of invention where two or more parties are claiming the same invention. The courts or the PTO may not uphold the validity of our patents, we may not prevail in such interference proceedings regarding our patents and none of our patents may give us a competitive advantage. In this regard, we have been notified by the PTO that an unidentified third party is attempting to provoke an interference with one of our patents directed to adenoviral p53 therapy. We do not at present know the identity of this party and cannot assess the likelihood of an interference actually being declared. Should that party prevail in an interference proceeding, a patent may issue to that party that is infringed by, and therefore potentially preclude our commercialization of, products like ADVEXIN therapy that are used for adenoviral p53 therapy.

Schering-Plough filed with the European Patent Office, or EPO, an opposition against our European patent directed to combination therapy with p53 and conventional chemotherapy and/or radiation. An opposition is an administrative proceeding instituted by a third party and conducted by the EPO to determine whether a patent should be maintained or revoked, in part or in whole, based on evidence brought forth by the party opposing the patent. In February 2006, the Technical Board of Appeals of the EPO held a final oral proceeding concerning Schering-Plough s opposition and determined our patent should be maintained as amended. No further appeal by Schering-Plough is possible.

We rely on trade secrets law to protect technology where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. In addition, we generally require employees, academic collaborators and consultants to enter into confidentiality agreements. Despite these measures, we may not be able to adequately protect our trade secrets or other proprietary information. We are a party to various license agreements that give us rights to use specified technologies in our research and development processes. If we are not able to continue to license this technology on commercially reasonable terms, our product development and research may be delayed. In addition, in the case of technologies that we have licensed, we do not have the ability to make the final decisions on how the patent application process is managed, and accordingly are unable to exercise the same degree of control over this intellectual property as we exercise over our internally developed technology. Our research collaborators and

scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be diminished.

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

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aware of a number of issued patents and patent applications related to recombinant DNA therapy, the treatment of cancer and the use of the p53 and other tumor suppressors. Schering-Plough, including its subsidiary Canji, controls various United States applications and a European patent and applications, some of which are directed to therapy using p53, and others to adenoviruses containing p53, or adenoviral p53, and to methods for carrying out therapy using adenoviral p53. Adenoviral p53 technology underlies our ADVEXIN therapy product candidate. Furthermore, we are aware of a United States patent directed to replication-deficient recombinant adenoviral vectors apparently controlled by Transgene SA (Transgene). While we believe the claims of the Transgene adenoviral vector patent are invalid or not infringed by our products, Transgene could assert a claim against us.

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

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

We have recently been involved in patent opposition proceedings before the EPO, in which we have sought to have the EPO revoke three different European patents owned or controlled by Canji/Schering-Plough. These European patents relate to the use of p53, or the use of tumor suppressors, in the preparation of therapeutic products. In one opposition involving a Canji European patent directed to the use of a recombinant tumor suppressor, the EPO revoked the European patent in its entirety in a final, non-appealable decision. In the second opposition, involving a patent that is directed to therapeutic and other applications of the p53 and that is owned by Johns Hopkins and, we understand, controlled by Schering-Plough, the EPO recently revoked the patent in its entirety. The patent owner appealed this decision and the final hearing before the EPO Technical Board of Appeals was held in June 2005, at which time the Technical Board of Appeals confirmed the final revocation of all claims of this patent relevant to clinical therapeutic applications of p53. In a third case involving the use of p53, the European patent at issue was initially upheld, but finally revoked in a hearing held in late April 2004.

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

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. The defense and prosecution of intellectual property lawsuits, PTO interference proceedings, and related legal and

administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. An adverse determination may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on

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satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products, if any. These outcomes could materially harm our business, financial condition and results of operations.

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

Our business depends in part on patents licensed from third parties. Those third-party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of product candidates could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform would be severely adversely affected.

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

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

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

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

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

- they are more effective than alternative treatments;
- their side effects are acceptable to patients and doctors;

insurers and other third-party healthcare payers will provide adequate reimbursement for them;

we produce and sell them at a profit; and

we market ADVEXIN therapy, INGN 241, INGN 225 and other product candidates effectively.

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We must achieve significant market share and obtain high per-patient prices for our products to achieve profitability.

ADVEXIN therapy, our lead product candidate will, if approved, initially be targeted for the treatment of recurrent head and neck cancer, a disease with an annual incidence of approximately 40,000 patients in the United States. As a result, our per-patient prices must be sufficiently high in order to recover our development costs and achieve profitability. Until additional disease targets with larger potential markets are approved, we believe we will need to market worldwide to achieve significant market penetration. If we are unable to obtain sufficient market share for our drug products at a high enough price, or obtain expanded approvals for larger markets, we may not achieve profitability or be able to independently continue our product development efforts.

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

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

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

Our current manufacturing facilities have not yet been subject to a Pre-Approval Inspection by the FDA or other global regulatory authorities. Failure to pass Pre-Approval Inspections may significantly delay approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. Further, the FDA and foreign regulatory authorities have the authority to perform unannounced periodic inspections of our manufacturing facilities to ensure compliance with CGMP and foreign regulatory requirements. Our facilities in Houston, Texas are our only manufacturing facilities. If these facilities were to incur significant damage or destruction, then our ability to manufacture ADVEXIN therapy, INGN 241 or any other product candidates would be significantly hampered, and our pre-clinical testing, clinical trials and commercialization efforts would be delayed.

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

Canji controls a United States patent and the corresponding international applications, including a European counterpart, relating to the purification of viral or adenoviral compositions. While we believe our manufacturing

process does not infringe this patent, Canji could still assert a claim against us. We may also become subject to infringement claims or litigation if our manufacturing process infringes other patents. The defense and prosecution of intellectual property suits and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain.

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

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

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

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

decreased demand for our product candidates;

injury to our reputation and significant media attention;

withdrawal of clinical trial volunteers;

substantial delay in FDA or foreign regulatory authority approval;

costs of litigation; and

substantial monetary awards to plaintiffs.

We currently maintain product liability insurance with coverage of $5.0 million per occurrence with a $10.0 million annual aggregate limit. This coverage may not be sufficient to protect us fully against product liability claims. We intend to expand our product liability insurance coverage beyond clinical trials to include the sale of commercial products if we obtain marketing approval for any of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or limit the commercialization of our products.

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

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

Our stock price may fluctuate substantially.

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

progress and results of our pre-clinical and clinical trials;

announcement of technological innovations by us or our competitors;

developments concerning proprietary rights, including patent and litigation matters;

publicity regarding actual or potential results with respect to products under development by us or by our competitors;

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regulatory developments;

the announcement of new products by us or our competitors;

quarterly variations in our or our competitors results of operations;

failure to achieve operating results projected by securities analysts;

changes in earnings estimates or recommendations by securities analysts;

developments in our industry; and

general market conditions and other factors.

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

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

For planning purposes, we estimate the timing of a variety of clinical, regulatory and other milestones, such as when a certain product candidate will enter clinical development, when a clinical trial will be completed or when an application for regulatory approval will be filed. Some of our estimates are included in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006. Our estimates are based on present facts and a variety of assumptions. Many of the underlying assumptions are outside of our control. If milestones are not achieved when we expect them to be, investors could be disappointed, and our stock price may decrease.

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

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

potential exposure to unknown liabilities of acquired companies;

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

diversion of management time and attention and other resources;

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

the incurrence of amortization expense; and

possible dilution to our stockholders.

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

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

We depend, to a significant extent, on the efforts of our key employees, including senior management and senior scientific, clinical, regulatory, manufacturing and other personnel. The development of new therapeutic products requires expertise from a number of different disciplines, some of which is not widely available. We depend upon our scientific staff to discover new product candidates and to develop and conduct pre-clinical studies of those new potential products. Our clinical and regulatory staff is

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responsible for the design and execution of clinical trials in accordance with FDA and foreign regulatory authority requirements and for the advancement of our product candidates toward FDA and foreign regulatory authority approval. Our manufacturing staff is responsible for designing and conducting our manufacturing processes in accordance with the FDA s CGMP requirements. The quality and reputation of our scientific, clinical, regulatory and manufacturing staff, especially the senior staff, and their success in performing their responsibilities, are a basis on which we attract potential funding sources and collaborators. In addition, our Chief Executive Officer and other executive officers are involved in a broad range of critical activities, including providing strategic and operational guidance. The loss of these individuals, or our inability to retain or recruit other key management and scientific, clinical, regulatory, manufacturing and other personnel, may delay or prevent us from achieving our business objectives. We face intense competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, SFAS 123R, Share-Based Payment, became effective for us on January 1, 2006. This statement requires that employee share-based compensation be measured based on its fair value on the grant date and treated as an expense that is reflected in the financial statements over the related service period. SFAS 123R has had a significant impact on our results of operations for the three and nine months ended September 30, 2006. Using the Black-Scholes option pricing model to compute share-based compensation expense as we do requires extensive use of accounting judgment and financial estimates. Items requiring estimation include the expected term optionholders will retain their vested stock options before exercising them, the estimated volatility of our common stock price over the expected term of a stock option and the number of stock options that will be forfeited prior to the completion of their vesting requirements. Application of alternative assumptions could result in significantly different share-based compensation amounts being recorded in our financial statements. We anticipate that SFAS No. 123R will continue to have a significant impact on our results of operations for the remainder of 2006 and subsequent periods.

Our corporate governance structure, including provisions in our certificate of incorporation and by-laws, and Delaware law, may prevent a change in control or management that stockholders may consider desirable.

Section 203 of the Delaware General Corporation Law and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include the inability of stockholders to act by written consent or to call special meetings, the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval and the fact that our board of directors is divided into three classes serving staggered thee-year terms.

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

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

Dr. John N. Kapoor, the Chairman of our Board of Directors, is also associated with EJ Financial, a healthcare investment firm that is wholly owned by him, and therefore may have conflicts of interest in allocating his time among us and his other business activities, and he may have legal obligations to multiple entities. We have entered into a consulting agreement with EJ Financial. The consulting agreement provides we will pay EJ Financial $175,000 per year for certain management consulting services, which is based on anticipated time spent by EJ Financial personnel on our affairs. EJ Financial is also involved in the management of healthcare companies in various fields,

and Dr. Kapoor is involved in various capacities with the management and operation of these companies. In addition, EJ Financial is involved with other companies in the cancer field. Although these companies are pursuing different therapeutic approaches for the treatment of cancer, discoveries made by one or more of these companies could render our products less competitive or obsolete.

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

In October 2004, we acquired all of the outstanding capital stock of Magnum, a company owned at the time of this acquisition by one of our executive officers. We paid approximately $1.75 million for the Magnum stock by (1) issuing approximately 252,000 shares of our common stock valued at approximately $1.48 million at the acquisition date and (2) assuming liabilities of approximately $272,000. With respect to the common stock we issued for the acquisition, 50% of the shares were held by an independent escrow agent for a period of approximately one year subsequent to the acquisition date to satisfy the indemnification obligations of the selling shareholder under terms of the purchase agreement. Such shares have since been released from escrow. Magnum s primary asset is the funding it receives under a research grant from the NIH, which supplements our ongoing research and development programs. During the three months ended March 31, 2006, we earned $163,000 of revenue under this grant, which completed the funding available to us under this grant. In the event certain of Magnum s technologies result in commercial products, we may be obligated to pay royalties related to the sales of those products to certain third parties.

We have relationships with Jack A. Roth, M.D., and M. D. Anderson Cancer Center, both of whom are affiliated with The Board of Regents of the University of Texas System, one of our stockholders. For more information concerning these relationships, see our Notes to Consolidated Financial Statements beginning on page F-7 of our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006.

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

(a) On November 1, 2006, we entered into an amendment to our license agreement with The University of Texas M. D. Anderson Cancer Center, which amendment is effective as of August 1, 2006. In connection with this amendment, we obtained a worldwide, exclusive license to a family of patent applications directed to combination therapy using ADVEXIN therapy with inhibitors of epidermal growth factor receptors (EGFr inhibitors) such as Erbitux®, Vectibix®, Tarceva® and Iressa®. The amendment has been filed with this report as Exhibit 10.57.

(b) None.

Item 6. Exhibits

Exhibit Number	Description of Document
10.57	Amendment No. 4 to Patent and Technology License Agreement, effective as of August 1, 2006, between Introgen and The Board of Regents of the University of Texas System, M. D. Anderson Cancer Center
31.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

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

INTROGEN THERAPEUTICS, INC.

November 6, 2006

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

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