

VICAL INC
Form 10-Q
November 09, 2006
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

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: 000-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	93-0948554 (I.R.S. Employer Identification No.)
10390 Pacific Center Court San Diego, California (Address of principal executive offices)	92121 (Zip code)
(858) 646-1100	
(Registrant's telephone number, including area code)	

(Former name, former address and former fiscal year, if changed since last report)

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

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to such filing requirements for the past 90 days. Yes No

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.

Large Accelerated filer Accelerated Filer Non-accelerated filer

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Total shares of common stock outstanding at October 31, 2006: 39,120,626

Table of Contents

VICAL INCORPORATED

FORM 10-Q

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

Balance Sheets (unaudited) as of September 30, 2006, and December 31, 2005 3

Statements of Operations (unaudited) for the three and nine months ended September 30, 2006 and 2005 4

Statements of Cash Flows (unaudited) for the nine months ended September 30, 2006 and 2005 5

Notes to Financial Statements (unaudited) 6

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 13

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk 22

ITEM 4. Controls and Procedures 22

PART II. OTHER INFORMATION

ITEM 1A. Risk Factors 23

ITEM 6. Exhibits 32

SIGNATURE 33

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****VICAL INCORPORATED****BALANCE SHEETS****(In thousands, except par value data)****(Unaudited)**

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,195	\$ 5,710
Marketable securities, available-for-sale	57,196	58,337
Restricted marketable securities	2,511	2,439
Receivables and other	4,433	5,778
Total current assets	74,335	72,264
Property and equipment, net	13,890	15,170
Intangible assets, net	5,111	5,481
Other assets	828	1,615
Total assets	\$ 94,164	\$ 94,530
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,942	\$ 4,687
Current portion of equipment financing obligations	2,960	4,093
Total current liabilities	6,902	8,780
Long-term liabilities:		
Equipment financing obligations, net of current portion	1,213	3,426
Deferred rent	2,215	2,018
Total long-term liabilities	3,428	5,444
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding		
Common stock, \$0.01 par value, 80,000 shares authorized, 31,596 and 28,261 shares issued and outstanding at September 30, 2006, and December 31, 2005, respectively	316	283
Additional paid-in capital	261,532	242,991
Accumulated deficit	(178,100)	(162,874)
Accumulated other comprehensive income (loss)	86	(94)
Total stockholders' equity	83,834	80,306
Total liabilities and stockholders' equity	\$ 94,164	\$ 94,530

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See accompanying notes to unaudited financial statements

Table of Contents**VICAL INCORPORATED****STATEMENTS OF OPERATIONS****(In thousands, except per share data)****(Unaudited)**

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Revenues:				
Contract and grant revenue	\$ 412	\$ 2,502	\$ 13,091	\$ 5,442
License and royalty revenue	154	205	346	4,756
Total revenues	566	2,707	13,437	10,198
Operating expenses:				
Research and development	4,038	4,252	12,853	13,481
Manufacturing and production	2,899	2,976	10,950	10,241
General and administrative	1,904	1,887	6,752	5,925
Total operating expenses	8,841	9,115	30,555	29,647
Loss from operations	(8,275)	(6,408)	(17,118)	(19,449)
Other income (expense):				
Investment income	824	406	2,117	1,172
Interest expense	(58)	(129)	(225)	(414)
Net loss	\$ (7,509)	\$ (6,131)	\$ (15,226)	\$ (18,691)
Basic and diluted net loss per share	\$ (0.24)	\$ (0.26)	\$ (0.52)	\$ (0.79)
Weighted average shares used in computing basic and diluted net loss per share	30,714	23,524	29,282	23,517

See accompanying notes to unaudited financial statements

Table of Contents

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2006	2005
Cash flows from operating activities:		
Net loss	\$ (15,226)	\$ (18,691)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,465	2,730
Write-off of abandoned patents	41	158
Compensation expense related to stock options and awards	1,376	317
Changes in operating assets and liabilities:		
Receivables and other	1,345	(1,147)
Other assets	786	670
Accounts payable, accrued expenses and other liabilities	(745)	(780)
Deferred revenue		(531)
Deferred rent	197	85
Net cash used in operating activities	(9,761)	(17,189)
Cash flows from investing activities:		
Maturities of marketable securities including restricted	113,481	54,745
Purchases of marketable securities including restricted	(112,233)	(36,034)
Maturities of restricted cash equivalents		2,703
Purchases of property and equipment	(627)	(1,645)
Patent expenditures	(228)	(479)
Net cash provided by investing activities	393	19,290
Cash flows from financing activities:		
Proceeds from issuance of common stock	17,289	91
Payment of withholding taxes for net settlement of restricted stock units	(90)	
Principal payments under equipment financing obligations	(3,346)	(3,615)
Proceeds from equipment financing arrangements		1,017
Net cash provided by (used in) financing activities	13,853	(2,507)
Net increase (decrease) in cash and cash equivalents	4,485	(406)
Cash and cash equivalents at beginning of period	5,710	17,666
Cash and cash equivalents at end of period	\$ 10,195	\$ 17,260
Supplemental information:		
Interest paid	\$ 225	\$ 408

See accompanying notes to unaudited financial statements

Table of Contents

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

September 30, 2006

(Unaudited)

1. GENERAL

Vical Incorporated, or the Company, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases.

The unaudited financial statements at September 30, 2006, and for the three and nine months ended September 30, 2006 and 2005, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and with accounting principles generally accepted in the U.S. applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. These unaudited financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2005, included in its Form 10-K filed with the SEC.

Issuance of Common Stock

In August 2006, the Company completed a \$9.8 million registered direct offering of its common stock to a single institutional investor, in which the Company sold approximately 2.1 million shares pursuant to effective shelf registration statements at a price of \$4.77 per share.

In June 2006, the Company received approximately \$6.9 million in proceeds from the sale of approximately 1.1 million shares of its common stock at \$6.50 per share in a private placement to AnGes MG, Inc., or AnGes, pursuant to a research and development agreement and a stock purchase agreement as described in Note 4.

See note 7 for a description of transactions involving the issuance of common stock that were completed after September 30, 2006.

Credit Facility

In August 2006, the Company entered into a financing arrangement, or Credit Facility, with Oxford Finance Corporation to provide for borrowing of up to \$10.0 million through December 31, 2006. The Credit Facility is governed by a Master Security Agreement dated August 23, 2006, and related documents. Under the terms of the Credit Facility, as the Credit Facility is utilized, separate promissory notes will be executed for each drawdown. The Company is required to repay any promissory notes issued under the Credit Facility in equal monthly installments over 36 months from the date of the applicable drawdown. The interest rate for each drawdown will be based on the three year United States Treasury Bill weekly average rate at the time of the applicable drawdown plus 6.50%. Any promissory notes will be collateralized by a first priority interest in all of the Company's assets except for its intellectual property. As of September 30, 2006, there were no borrowings outstanding under the Credit Facility.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders equity.

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Restricted Marketable Securities

The Company is required to maintain a letter of credit securing an amount equal to twelve months of the current monthly installment of base rent for the term of its primary facilities lease, which ends in August 2017. At September 30,

Table of Contents

2006, and December 31, 2005, restricted marketable securities of \$2.5 million and \$2.4 million, respectively, were pledged as collateral for this letter of credit.

Revenue Recognition

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin Topic 13, Revenue Recognition, and Emerging Issues Task Force No. 00-21, or EITF No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Contract Manufacturing Revenue. The Company's contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. In accordance with EITF No. 00-21, the Company analyzes its multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. If the delivered item does not have standalone value or the Company does not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred.

License and Royalty Revenue. The Company's license and royalty revenues are generated through agreements with strategic partners. Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the agreements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if the Company has continuing performance obligations. If the Company has continuing involvement through contractual obligations under such agreements, such up-front fees are deferred and recognized over the period for which the Company continues to have a performance obligation, unless all of the following criteria exist: (1) the delivered item(s) have standalone value to the customer, (2) there is objective and reliable evidence of the fair value of the undelivered item(s), and (3) there is no general right to return the delivered item(s).

The Company recognizes royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of returns, cash discounts, and freight and warehousing, which may vary over the course of the license agreements. Payments received related to milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process.

Government Research Grant Revenue. The Company recognizes revenues from federal government research grants during the period in which the related expenditures are incurred.

Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under restricted stock units, or RSUs, as the effect would be antidilutive. Common stock equivalents of 0.3 million for the three and nine months ended September 30, 2006 and 2005, were excluded from the calculation because of their antidilutive effect.

Recent Accounting Pronouncements

In February 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 155, Accounting for Certain Hybrid Financial Instruments. SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation. As of September 30, 2006, the Company did not have any hybrid financial instruments subject to the fair value election under SFAS No. 155. The Company is required to adopt SFAS No. 155 effective at the beginning of 2007.

Table of Contents*Change in Accounting Method for Share-Based Compensation*

Effective January 1, 2006, the Company adopted SFAS No. 123R, Share-Based Payment, as interpreted by SEC Staff Accounting Bulletin No. 107 and began recording compensation expense associated with stock options and other forms of equity compensation based on their fair value.

2. STOCK-BASED COMPENSATION

On September 30, 2006, the Company had two stock-based compensation plans, which are described below. Total stock-based compensation expense of \$0.4 million and \$0.1 million was recognized for the three months ended September 30, 2006 and 2005, respectively. Total stock-based compensation expense of \$1.4 million and \$0.3 million was recognized for the nine months ended September 30, 2006 and 2005, respectively. Total stock-based compensation cost was allocated to research and development, manufacturing and production and general and administrative expense as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Research and development	\$ 177	\$ 44	\$ 514	\$ 125
Manufacturing and production	63		200	
General and administrative	193	71	662	192
Total stock-based compensation expense	\$ 433	\$ 115	\$ 1,376	\$ 317
Cash received from options exercised	\$ 173	\$ 50	\$ 674	\$ 91

Stock Incentive Plan

The Company has a stock incentive plan, under which 6,700,000 shares of common stock, subject to adjustment as provided in the plan, are reserved for issuance to employees, non-employee directors and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to non-employee directors which vest at the next annual meeting, options generally vest 25% on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. The plan also limits the number of options that may be granted to any plan participant in a single calendar year to 300,000 shares.

The Company has granted restricted stock units, or RSUs, to executive officers, other executives, and employees under the stock incentive plan. RSUs granted prior to 2005 vest quarterly over two years. RSUs granted during and after 2005 vest 25% on the first anniversary from the grant date, with the remaining portion vesting quarterly over the next three years. Once an RSU is vested the participant has the right to acquire common stock underlying the grant at par value. The participants are not entitled to vote or receive dividends on any shares of common stock covered by RSUs prior to the acquisition of such shares. Participants also are not entitled to sell or transfer any RSUs. Granted but unvested RSUs are forfeited at termination of employment.

Directors' Stock Option Plan

The Company also has a directors' stock option plan that provides for the issuance to non-employee directors of up to 210,000 shares of common stock, of which options for 202,500 shares have been granted through September 30, 2006. The plan expired in December 2004.

Change in Accounting Method for Share-Based Compensation

Effective January 1, 2006, the Company adopted SFAS No. 123R, Share-Based Payment, as interpreted by SEC Staff Accounting Bulletin No. 107 and began recording compensation expense associated with stock options and other forms of equity compensation based on their fair value. Prior to January 1, 2006, the Company accounted for stock options according to the provisions of Accounting Principles Board,

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or APB, Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. The Company adopted the modified prospective transition method provided for under SFAS No. 123R, and consequently has not retroactively adjusted results from prior periods. Under this transition method, stock-based

Table of Contents

compensation now includes 1) amortization related to the remaining unvested portion on January 1, 2006, of all stock option awards granted prior to January 1, 2006, over the remaining requisite service period based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, Accounting for Stock Based Compensation, adjusted for estimated forfeitures; and 2) amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123R. In addition, the Company records expense related to RSUs granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. The stock-based compensation expense includes an estimate for forfeitures and is recognized over the expected term of the award using the straight-line method. The expected forfeiture rate of all equity based compensation is based on observed historical patterns of the Company's employees and is estimated to be 11.2% annually for the three and nine months ended September 30, 2006.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton valuation model using the assumptions noted in the following table. The expected life of options is based on observed historical exercise patterns. The expected volatility of stock options is based upon the historical volatility of the Company's stock. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Assumptions:		
Assumed risk-free interest rate	4.74%	4.56%
Assumed volatility	68%	68%
Expected option life	3 to 6 years	3 to 6 years
Expected dividend yield		

As a result of the adoption of SFAS No. 123R, the Company's loss from operations and net loss for the three and nine months ended September 30, 2006, was \$0.4 million, or \$0.01 per share, and \$1.2 million, or \$0.04 per share, respectively, higher than under the Company's previous accounting method for stock-based compensation. However, there was no impact on the Company's cash flows for the nine months ended September 30, 2006, as a result of the adoption of SFAS No. 123R.

A summary of option activity under the plans as of September 30, 2006, and changes during the nine months then ended is presented below:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2005	3,790,474	\$ 9.09
Granted	468,050	\$ 5.09
Exercised	(180,528)	\$ 3.73
Forfeited	(572,603)	\$ 10.20
Outstanding at September 30, 2006	3,505,393	\$ 8.65

Exercisable at September 30, 2006	2,583,672	\$ 9.91
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The weighted average remaining contractual term of options outstanding and options exercisable at September 30, 2006, was 6.18 years and 5.32 years, respectively. The aggregate intrinsic value of options outstanding and options exercisable at September 30, 2006, was \$1.2 million and \$0.9 million, respectively. As of September 30, 2006, the total unrecognized compensation cost related to unvested options was \$1.9 million, which is expected to be recognized over a weighted-average period of 1.43 years. The weighted average grant-date fair value of options granted during the nine months ended September 30, 2006 and 2005, was \$2.78 per share and \$3.31 per share, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2006 and 2005, was \$0.5 million and \$43,000, respectively.

Table of Contents

A summary of the outstanding RSUs as of September 30, 2006, and changes during the nine months then ended is presented below:

	Shares	Weighted Average Grant-Date Fair Value per Share
Unvested at December 31, 2005	160,812	\$ 5.15
Granted	59,610	\$ 4.54
Vested	(66,438)	\$ 5.27
Cancelled	(28,742)	\$ 4.86
Unvested at September 30, 2006	125,242	\$ 4.87

The aggregate grant-date fair value of RSUs granted during the nine months ended September 30, 2006 and 2005, was \$0.3 million and \$0.8 million, respectively. As of September 30, 2006, the total unrecognized compensation cost related to unvested RSUs was \$0.7 million, which is expected to be recognized over a weighted average period of 1.88 years. The total fair value of shares subject to RSUs vested during the nine months ended September 30, 2006 and 2005, was \$0.4 million and \$0.2 million, respectively. As of September 30, 2006, there were 78,251 shares of common stock underlying RSUs that were fully vested but the issuance of such shares has been deferred.

Pro Forma Information under SFAS 123 for Periods Prior to the Adoption of SFAS 123R

For stock options granted prior to the adoption of SFAS No. 123R, if stock-based compensation expense for the Company's various stock option plans had been determined based upon estimated fair values at the grant dates in accordance with SFAS No. 123, the Company's pro forma net loss and basic and diluted net loss per share would have been as follows (in thousands, except per share data and assumptions):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss, as reported	\$ (6,131)	\$ (18,691)
Add stock-based compensation expense included in reported net loss	116	317
Less stock-based compensation expense determined under fair value based method for all awards	(664)	(1,914)
Pro forma net loss	\$ (6,679)	\$ (20,288)
Basic and diluted net loss per share, as reported	\$ (0.26)	\$ (0.79)
Basic and diluted pro forma net loss per share	\$ (0.28)	\$ (0.86)
Weighted average fair value of stock options	\$ 3.37	\$ 3.31
Assumptions:		
Assumed risk-free interest rate	3.85%	3.96%
Assumed volatility	72%	78%
Expected option life	3 to 6 years	3 to 6 years
Dividend yields		

3. COMPREHENSIVE LOSS

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Comprehensive loss consists of net loss and other comprehensive income or loss. Accumulated other comprehensive loss represents net unrealized losses on marketable securities. For the three months ended September 30, 2006 and 2005, other comprehensive income was \$0.2 million and \$0.1 million, respectively, and total comprehensive loss was \$7.3 million and \$6.1 million, respectively. For the nine months ended September 30, 2006 and 2005, other comprehensive income was \$0.2 million and \$0.1 million, respectively, and total comprehensive loss was \$15.0 million and \$18.6 million, respectively.

Table of Contents**4. RECENT CONTRACT, GRANT AND LICENSE ACTIVITIES***NIH Vaccine Research Center*

In 2003, the Company entered into a subcontract agreement with the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institutes of Health, or NIH, to manufacture bulk DNA vaccines for the VRC. The subcontract agreement expired in July 2006 but was subsequently amended and extended until December 2006. The subcontract agreement is issued and managed on behalf of the VRC by SAIC-Frederick, Inc. under the umbrella of a federally funded contract with the NIH. The Company recognized revenue under this subcontract agreement of \$10.2 million and \$1.1 million for the nine months ended September 30, 2006 and 2005, respectively. The Company recognized revenue under this subcontract agreement of \$0.1 million for the three months ended September 30, 2005. No revenue was recognized under this subcontract agreement for the three months ended September 30, 2006.

AnGes Research and Development Agreement

On May 25, 2006, the Company entered into a research and development agreement, or R&D Agreement, with AnGes, whereby AnGes agreed to fund the Company's Allovectin-7[®] Phase 3 clinical trial. The funding will consist of purchases by AnGes of up to \$10.85 million of restricted shares of the Company's common stock and additional non-refundable cash payments by AnGes of up to \$11.75 million. If the project costs exceed the aggregate amount of \$22.6 million, the Company and AnGes have agreed to share the excess project costs up to certain limits. All of the funding provided by AnGes, including those funds used to purchase the Company's common stock, must be used for actual and documented costs related to the conduct of the Allovectin-7[®] Phase 3 trial.

Under the R&D Agreement, the Company has granted to AnGes exclusive marketing rights for Allovectin-7[®] in specified countries in Asia and AnGes has agreed to pursue regulatory approvals in those countries, subject to receipt by the Company of regulatory approval in the United States. The Company has also granted AnGes certain royalty-bearing licenses to its technology and know-how. AnGes is obligated to pay royalties to the Company on sales of Allovectin-7[®] in specified countries in Asia. AnGes also obtained the right to receive royalties from the Company on any commercial sales of Allovectin-7[®] in the United States. AnGes may also purchase supplies of Allovectin-7[®] from the Company for resale by AnGes in Asia.

The first installment of \$6.9 million was received by the Company upon execution of the R&D Agreement and the stock purchase agreement. In accordance with the terms of the stock purchase agreement AnGes was issued 1,061,538 shares of the Company's restricted common stock at \$6.50 per share in exchange for the first installment. The price per share for any future purchase of the Company's common stock under the stock purchase agreement is based on the volume weighted average price per share for the 30 trading days ending on the second trading day immediately preceding the date of such future purchase.

Under the stock purchase agreement, the Company has also granted AnGes limited rights to require the Company to register the shares of common stock under the Securities Act of 1933, as amended, upon the occurrence of certain events. AnGes has also agreed to certain transfer restrictions with respect to the shares of common stock sold under the stock purchase agreement and has further agreed to certain standstill provisions whereby AnGes will refrain from acquiring or taking certain other actions with respect to the Company's common stock, subject to certain exceptions.

5. OTHER BALANCE SHEET ACCOUNTS

Accounts payable and accrued expenses consisted of the following (in thousands):

	September 30, 2006	December 31, 2005
Employee compensation	\$ 1,682	\$ 2,115
Accounts payable	365	298
Accrued royalty		500
Other accrued liabilities	1,895	1,774
	\$ 3,942	\$ 4,687

Table of Contents**6. COMMITMENTS AND CONTINGENCIES**

If the Company fails to satisfy its contractual obligations to deliver the DNA vaccines ordered by the VRC in the manner required by the Company's manufacturing agreements with the VRC, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreements in whole or in part, and the Company may be required to perform corrective actions, including but not limited to remanufacturing vaccines or components thereof at the Company's expense, delivering to the VRC any uncompleted or partially completed work and/or any government property in its possession, and/or paying a third-party supplier selected by the VRC to complete any uncompleted work. For example, the Company has twice been obligated to remanufacture at its expense a component of a vaccine under its 2003 subcontract agreement with the VRC. The Company believes it will be able to deliver the remaining component of the vaccine in a timely manner in accordance with the terms of the contract. The performance of any future corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected.

European Patent 1026253, covering a significant portion of the Company's core DNA delivery technology, was granted in September 2004. European Patent 0465529 was granted to Vical in 1998, and was subsequently opposed by seven companies under European patent procedures. This 529 patent was revoked on formal grounds in October 2001 under an initial ruling by the Opposition Division of the European Patent Office, or EPO. In April 2002, the Company filed an appeal seeking to overturn this initial ruling. The claims that were allowed in the newly granted 253 patent generally cover the same subject matter as those claims in the 529 patent which were under appeal. For this reason, the Company withdrew from the 529 appeal upon grant of the 253 patent in September 2004. In September 2005, the 253 patent was opposed by eight parties. This opposition is ongoing. However, the Company may also use additional issued patents and patent applications that are pending in Europe to protect its core DNA delivery technology.

In addition, the Company's core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the Japanese Patent Office, or JPO, on formal and substantive grounds. The Company filed a rebuttal response to the revocation. Based on the Company's arguments and supporting evidence in that response, the JPO reinstated the patent in July 2003. Four Trial for Invalidation, or TFI, requests were filed in the JPO by two companies in 2003. The Company filed responses to the TFI requests in a timely manner. The JPO combined two of the four TFI requests into a single action, and in December 2004, ruled in the Company's favor on the combined TFI requests by accepting the corrected claims and finding the demand for the trials groundless. The Company is awaiting further action by the JPO on the other two TFI requests.

A European patent was issued in 2003 covering a range of applications of the Company's core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as the Company's clinical-stage Allovectin-9 treatment for melanoma, cationic lipid-formulated DNA vaccines such as the Company's investigational anthrax vaccine, and similar pharmaceutical products under development by others. This patent was opposed by two companies. The Company responded to the oppositions in a timely manner, and defended the patent at an oral hearing in March 2006 at the EPO. The patent was maintained in amended form. The Company is appealing certain rulings, and one of the opponents is appealing the decision to maintain the patent in amended form.

A European patent was issued to the Company in 2003 with broad claims related to gene-based, extra-tumoral delivery of any cytokines for the treatment of cancer. Delivery can be either free from or formulated with transfection-facilitating materials such as cationic lipids or polymers. Cytokines are proteins such as interleukins and interferons which regulate specific cell functions, and typically are used to stimulate an immune response against cancer cells. Three companies opposed this patent. The Company responded to the oppositions in a timely manner, and will continue to vigorously defend its position in upcoming oral hearings.

The Company prosecutes its intellectual property estate vigorously to obtain the broadest valid scope for its patents. Due to the uncertainty of the ultimate outcome of these matters, the impact on future operating results or our financial condition is not subject to reasonable estimates.

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which, individually or in the aggregate, is deemed to be material to the financial condition or results of operations of the Company.

Table of Contents

7. SUBSEQUENT EVENTS

Issuance of Common Stock

In October 2006, the Company received approximately \$12.5 million in proceeds from the sale of approximately 2.5 million shares of its common stock at \$5.02 per share in a registered direct offering to institutional investors. Also in October 2006, the Company received approximately \$25.0 million in proceeds from the sale of approximately 5.0 million shares of its common stock at \$5.02 per share in a registered direct offering to Temasek Holdings (Private) Ltd. of Singapore. All of these shares were sold pursuant to a shelf registration statement which, after the offerings described above, allows the Company to raise up to an additional \$31.6 million from the sale of common or preferred stock.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery technologies, the future funding of our research and development efforts, and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery technologies. Actual results could differ materially from those herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2005, and our other filings with the SEC, and those identified in Part II, Item 1A entitled "Risk Factors" beginning on page 23 of this Report. As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

Overview

We research and develop biopharmaceutical products based on our patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. In addition, we have gained access to enhancing technologies through licensing and collaborative agreements. We believe the following areas of research offer the greatest potential for our product development efforts:

Vaccines for use in high-risk populations for infectious disease targets for which there are significant U.S. needs;

Vaccines for general pediatric or adult populations for infectious disease applications; and

Cancer vaccines or immunotherapies which complement our existing programs and core expertise.

In 2005, the first product utilizing our patented DNA delivery technology received approval for use in animals. Our licensee, Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of Novartis Animal Health, received approval from the Canadian Food Inspection Agency to sell a DNA vaccine to protect farm-raised salmon against an infectious disease. We believe this approval is an important step in the validation of our DNA delivery technology. We plan to continue leveraging our patented technologies through licensing and collaborations. We also plan to use our expertise, infrastructure, and financial strength to explore both in-licensing and acquisition opportunities.

We have licensed our technologies to:

Merck & Co., Inc., or Merck;

The Sanofi-Aventis Group, or Sanofi-Aventis;

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Merial Ltd., or Merial, a joint venture between Merck and Sanofi-Aventis;

Corautus Genetics Inc., or Corautus;

Aqua Health;

Invitrogen Corporation, or Invitrogen;

AnGes MG, Inc., or AnGes; and

Ten leading research institutions.

Table of Contents

We have also licensed complementary technologies from:

Wisconsin Alumni Research Foundation, or WARF;

The University of Michigan;

Inovio Biomedical Corporation, or Inovio (formerly Genetronics Biomedical Corporation);

CytRx Corporation, or CytRx;

The National Institutes of Health, or NIH; and

The U.S. Centers for Disease Control and Prevention, or CDC.

Table of Contents**Product Development**

We, together with our licensees and collaborators, are currently developing a number of DNA-based vaccines and therapeutics for the prevention or treatment of infectious diseases, cardiovascular diseases and cancer. Our current independent development focus is on our novel pDNA vaccines for cytomegalovirus, or CMV, and avian influenza, as well as our cancer immunotherapeutic, IL-2/electroporation, or EP. The table below summarizes our independent, collaborative and out-licensed product development programs.

Product Area	Project Target and Indication(s)	Development Status¹	Development Rights
<i>Infectious Disease</i>			
Infectious disease vaccine	Cytomegalovirus	Phase 2	Vical
	<i>Bacillus anthracis</i> (anthrax)	Phase 1	Vical
	Influenza	Preclinical	Vical
	Ebola virus	Phase 1	Vical/NIH
	West Nile virus	Phase 1	Vical/NIH
	HIV/EP	Research	Vical/NIH
	SARS coronavirus	Phase 1	NIH
	HIV	Phase 2	NIH
	HIV	Phase 1	Merck
	Hepatitis B virus	Research	Merck
Hepatitis C virus	Research	Merck	
<i>Cardiovascular</i>			
Angiogenic growth factor	HGF, peripheral arterial disease	Phase 3	AnGes/Daiichi Pharma
	HGF, ischemic heart disease	Phase 1	AnGes/Daiichi Pharma
	FGF-1, peripheral arterial disease	Phase 2	Sanofi-Aventis
<i>Cancer</i>			
Immunotherapeutic Tumor-associated antigen therapeutic vaccines	Alloectin-7 [®] for metastatic melanoma	Phase 3	Vical/AnGes
	IL-2/EP for metastatic melanoma	Phase 1	Vical
	HER-2 and CEA for breast, colorectal, ovarian or non-small cell lung cancer	Phase 1	Merck
	Unspecified cancer ²	Research	Merck
<i>Veterinary</i>			
Preventive infectious disease vaccine(s)	Infectious Hematopoietic Necrosis Virus	Marketed in Canada	Aqua Health
	Various undisclosed ²	Research-Clinical	Merial
Protective cancer vaccine	Melanoma in dogs	Conditional U.S. license expected in 2006	Merial

¹ Research indicates exploration and/or evaluation of a potential product candidate in a nonclinical laboratory setting. Preclinical indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is undergoing toxicology testing in preparation for filing an Investigational New Drug, or IND, application. Phase 1 clinical trials include the first use of an investigational new drug in humans and are conducted in a small group of patients or normal volunteer subjects (20-80) to evaluate safety, determine a safe dosage range, and identify side effects, and, if possible, gain early evidence on effectiveness. Phase 2 clinical trials are typically well controlled and conducted in a larger group of subjects (no more than several hundred) to evaluate effectiveness of an investigational drug for a defined patient population, and to determine common short-term side effects and risks associated with the drug. Phase 3 clinical trials are conducted in an even larger group of subjects (several hundred to thousands) to evaluate the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling. For veterinary products, Clinical indicates testing in the target species.

² Pursuant to our collaborative agreements, we are bound by confidentiality obligations to our collaborators that prevent us from publicly disclosing these targets and indications. Additionally, some project targets and indications cannot currently be disclosed because they have not yet been selected by our collaborators.

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See the section entitled "Business" in our Annual Report on Form 10-K for the year ended December 31, 2005, for a detailed discussion of our independent, collaborative and out-licensed product development programs.

Table of Contents

Recent Events

The following events have recently occurred with respect to our technologies and applications and financing activities:

In October 2006, we announced that data from a study in mice showed an adjuvant originally developed to boost the immune response to DNA vaccines also boosts the immune response to a conventional seasonal influenza vaccine. Results from the studies suggest that our patented vaccine adjuvant known as Vaxfectin™ has the potential to be used as a dose-sparing agent with conventional flu vaccines against seasonal or pandemic flu strains. We are developing a Vaxfectin™-formulated DNA vaccine designed to protect against emerging strains of flu virus that have the potential to cause a pandemic.

In October 2006, we announced that a single injection of our lead avian influenza DNA vaccine candidate provided 100% protection in ferrets against lethal challenge with a highly virulent H5N1 virus (Vietnam/1203/2004). Conventional vaccines under development for avian flu typically have required two or more doses in humans, even with novel adjuvants, to produce the immunogenicity levels expected to provide protection.

In October 2006, we announced conclusions from anthrax DNA vaccine studies in non-human primates. The conclusions included: 1) DNA vaccines encoding protective antigen, or PA, elicited protective immunity against lethal anthrax spore challenge that could not be predicted by post-vaccination antibody immune responses; 2) anthrax spore challenge resulted in more rapid and significantly higher anti-PA antibody responses and anthrax lethal toxin neutralizing antibody responses in DNA-vaccinated animals than in control animals; and 3) pseudochallenge with anthrax antigen also resulted in more rapid and measurably higher anti-PA antibody responses and anthrax lethal toxin neutralizing antibody responses in DNA-vaccinated animals than in control animals. The results of these studies suggest that the protective efficacy of DNA vaccines may be evaluable by measuring immune responses after a pseudochallenge with the same antigen that was encoded in the DNA vaccine rather than a challenge with the pathogen itself. This method may present a new pathway to evaluation of DNA vaccine efficacy.

In October 2006, we completed a \$25.0 million registered direct offering of our common stock to a single institutional investor, in which we sold approximately 5.0 million shares pursuant to an effective shelf registration statement.

In October 2006, we completed a \$12.5 million registered direct offering of our common stock to institutional investors, in which we sold approximately 2.5 million shares pursuant to an effective shelf registration statement.

In September 2006, we were issued U.S. Patent No. 7,105,574 covering both the novel Vaxfectin™ adjuvant and its use with conventional vaccines against infectious diseases and cancer.

In September 2006, we granted non-exclusive, academic licenses to our DNA delivery technology patent estate to six additional research institutions: Fred Hutchinson Cancer Research Center, Texas Tech University Health Sciences Center, University of Iowa, University of Notre Dame, University of Pittsburgh, and University of Washington. The academic licenses are intended to encourage widespread commercial use of our innovative DNA delivery technologies in the development of new antibodies, vaccines, therapeutic proteins, and diagnostics. The non-exclusive academic licenses allow university researchers to use our technology free of charge for educational and internal, non-commercial research purposes. In exchange, we have the option to exclusively license from the universities potential commercial applications stemming from their use of the technology on terms to be negotiated.

In August 2006, we announced that a prime-boost vaccine regimen tested in 40 HIV-uninfected subjects in a NIH sponsored Phase I clinical trial was safe and well-tolerated, and was highly effective in inducing T-cell immune responses with multiple functions that may be important for controlling HIV infection. The trial involved priming an immune response with three doses of a plasmid DNA

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vaccine, based on our proprietary DNA delivery technology, and boosting the response with a single dose of adenoviral vector vaccine given at a later date.

In addition, our licensee Corautus recently announced that it did not plan to conduct further clinical trials for pDNA-based delivery of VEGF-2 for the treatment of peripheral arterial disease or coronary artery disease.

Table of Contents

In August 2006, we completed a \$9.8 million registered direct offering of our common stock to a single institutional investor, in which we sold approximately 2.1 million shares pursuant to effective shelf registration statements.

Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products. We earn revenue by performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$132.0 million in revenue under these types of agreements.

Revenues by source were as follows (in millions):

Source	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
NIH contracts	\$	\$ 0.1	\$ 10.2	\$ 1.1
U.S. Navy contracts		0.9		0.9
CMV grants		0.1	1.0	1.3
Anthrax grants		1.2	0.4	1.2
Other contracts and grants	0.4	0.2	1.5	0.9
Total contract and grant revenues	0.4	2.5	13.1	5.4
Merck license				3.0
AnGes license				1.0
Other royalties and licenses	0.2	0.2	0.3	0.8
Total royalty and license revenues	0.2	0.2	0.3	4.8
Total revenues	\$ 0.6	\$ 2.7	\$ 13.4	\$ 10.2

Research, development, manufacturing and production costs by major program, as well as other costs were as follows (in millions):

Program	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Allovecin-7®	\$ 1.3	\$ 1.5	\$ 4.5	\$ 3.9
CMV	1.6	1.9	4.9	6.4
Anthrax		0.3	0.4	1.3
IL-2/EP	0.2	0.5	1.3	1.9
Other research, development, manufacturing and production	3.8	3.0	12.7	10.2
Total research, development, manufacturing and production	\$ 6.9	\$ 7.2	\$ 23.8	\$ 23.7

Since our inception, we estimate that we have spent approximately \$268 million on research, development, manufacturing and production. Our current independent development focus is on novel DNA vaccines for CMV and influenza and our cancer immunotherapeutic, IL-2/EP. We are in the early stages of clinical development of our vaccine candidate for CMV and our IL-2/EP program for solid tumors with an initial indication for metastatic melanoma, and in preclinical development of our influenza vaccine candidate, and these programs will require significant additional costs to advance through development to commercialization. From inception, we have spent approximately \$30 million on our CMV program, and approximately \$6 million on our IL-2/EP program.

We are currently performing preclinical testing of vaccine candidates for human and avian influenza under separate grants. We have several other product candidates in the research stage. It can take many years from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the FDA or comparable foreign agencies. The

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outcome of the research is unknown until each stage of the testing is completed, up through and including the registration clinical trials. Accordingly, we are unable to predict which

Table of Contents

potential product candidates we may seek to develop, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA or comparable foreign agencies.

We have also spent approximately \$66 million from inception on our Allovectin-7[®] program. We have successfully completed a Special Protocol Assessment, or SPA, with the FDA for a Phase 3 clinical trial of Allovectin-7[®] that would be needed to support submission of a Biologics License Application, or BLA. Under our R&D Agreement with AnGes, we expect to complete the Phase 3 trial without significant additional independent expenditures. However, preparations for the BLA filing and commercialization, if pursued, are expected to require significant additional funds.

In addition, we are in the early stages of clinical development of an anthrax vaccine candidate, however, due to the lack of additional government funding, we do not intend to pursue further development of our anthrax vaccine candidate at this time except for the ongoing non-clinical development supported by a Small Business Innovation Research, or SBIR, grant.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the expansion of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs due to increased contract manufacturing activities, increased costs of our facilities, and possible advancement toward commercialization activities.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, actual results may differ from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: manufacturing contracts, license and royalty agreements, and grant revenues. Our critical accounting policies also include recognition of research and development expenses and the valuation of long-lived and intangible assets.

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin Topic 13, Revenue Recognition and Emerging Issues Task Force No. 00-21, or EITF No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Contract Manufacturing Revenue. Our contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. In accordance with EITF No. 00-21, we analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If the delivered item does not have standalone value or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred.

License and Royalty Revenue. Our license and royalty revenues are generated through agreements with strategic partners. Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by us under the agreements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if we have continuing performance obligations. If we have continuing involvement through contractual obligations under such agreements, such up-front fees are deferred and recognized over the period for which we continue to have a performance obligation, unless all of the following criteria exist: (1) the delivered item(s) have standalone value to the customer, (2) there is objective and reliable evidence of the fair value of the undelivered item(s), and (3) there is no general right to return the delivered item(s).

Table of Contents

We recognize royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of returns, cash discounts, and freight and warehousing, which may vary over the course of the license agreements. Payments received related to milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process.

Government Research Grant Revenue. We recognize revenues from federal government research grants during the period in which the related expenditures are incurred.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred.

We assess our obligations to make milestone payments that may become due under licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

The technology is in the early stage of development and has no alternative uses;

There is substantial uncertainty of the technology or product being successful;

There will be difficulty in completing the remaining development; and

There is substantial cost to complete the work.

Capitalization and Valuation of Long-Lived and Intangible Assets

Intangible assets with finite useful lives consist of capitalized legal costs incurred in connection with patents, patent applications pending and technology license agreements. Payments to acquire a license to use a proprietary technology are capitalized if the technology is expected to have alternative future use in multiple research and development projects. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter.

For patents pending, we amortize the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents and patent applications pending that we abandon, we charge the remaining unamortized accumulated costs to expense.

Intangible assets and long-lived assets are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that the carrying value of intangible assets or long-lived assets are not recoverable, their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or

A significant negative industry or economic trend.

When we determine that the carrying value of intangible assets or long-lived assets are not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets. Our largest group of intangible assets with finite lives was patents and patents pending for our DNA delivery technology which had a net carrying value of approximately \$3.1 million

at September 30, 2006.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements impacting our business, see Note 1 of the Notes to Financial Statements included in this Report.

Table of Contents

Change in Accounting Method for Share-Based Compensation

As a result of the adoption of SFAS No. 123R, as discussed in Note 2 of the Notes to Financial Statements included in this Report, our loss from operations and net loss for the three and nine months ended September 30, 2006, was \$0.4 million, or \$0.01 per share, and \$1.2 million, or \$0.04 per share, respectively, higher than under our previous accounting method for share-based compensation.

Results of Operations

Three Months Ended September 30, 2006, Compared with Three Months Ended September 30, 2005

Total Revenues. Total revenues decreased \$2.1 million, or 79.1%, to \$0.6 million for the three months ended September 30, 2006, from \$2.7 million for the three months ended September 30, 2005. Revenues from our contracts and grants were \$0.4 million for the three months ended September 30, 2006, compared with \$2.5 million for the three months ended September 30, 2005. Contract and grant revenue for the three months ended September 30, 2005, included revenues of \$1.2 million and \$0.9 million related to our anthrax grant and our contract with the U.S. Navy, respectively. License and royalty revenue was \$0.2 million for the three months ended September 30, 2006 and 2005.

Research and Development Expenses. Research and development expenses decreased \$0.2 million, or 5.0%, to \$4.0 million for the three months ended September 30, 2006, from \$4.2 million for the three months ended September 30, 2005. This decrease was primarily the result of a reduction in the use of outside contractors to conduct safety studies.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased \$0.1 million, or 2.6%, to \$2.9 million for the three months ended September 30, 2006, from \$3.0 million for the three months ended September 30, 2005. This decrease was primarily the result of a reduction in use of scientific supplies used in the manufacturing process.

General and Administrative Expenses. General and administrative expenses were unchanged at \$1.9 million for the three months ended September 30, 2006 and 2005, respectively.

Investment Income. Investment income increased \$0.4 million, or 103.0%, to \$0.8 million for the three months ended September 30, 2006, from \$0.4 million for the three months ended September 30, 2005. This increase was primarily the result of higher rates of return on our investments during the three months ended September 30, 2006, and higher average cash and short-term investment balances.

Interest Expense. Interest expense decreased \$71,000, or 55.0%, to \$58,000 for the three months ended September 30, 2006, from \$129,000 for the three months ended September 30, 2005. The decrease was primarily the result of lower principal amounts outstanding on our equipment financing obligations.

Nine Months Ended September 30, 2006, Compared with Nine Months Ended September 30, 2005

Total Revenues. Total revenues increased \$3.2 million, or 31.8%, to \$13.4 million for the nine months ended September 30, 2006, from \$10.2 million for the nine months ended September 30, 2005. Revenues from our contracts and grants were \$13.1 million for the nine months ended September 30, 2006, compared with \$5.4 million for the nine months ended September 30, 2005. Revenues from the shipment of clinical lots of DNA vaccines to the VRC totaled \$10.2 million and \$1.1 million for the nine months ended September 30, 2006 and 2005, respectively. Revenues from various NIH grants, including grants related to CMV, totaled \$2.8 million and \$3.2 million for the nine months ended September 30, 2006 and 2005, respectively.

License and royalty revenue was \$0.3 million for the nine months ended September 30, 2006, compared with \$4.8 million for the nine months ended September 30, 2005. The nine months ended September 30, 2005, included license fees received from Merck and AnGes, which totaled \$3.0 million and \$1.0 million, respectively.

Research and Development Expenses. Research and development expenses decreased \$0.6 million, or 4.7%, to \$12.9 million for the nine months ended September 30, 2006, from \$13.5 million for the nine months ended September 30, 2005. The nine months ended September 30, 2005, included royalty payments made to the WARF in connection with the Merck and AnGes license fees. In addition, we had a lower average headcount during the nine months ended September 30, 2006, when compared to the prior period.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$0.7 million, or 6.9%, to \$10.9 million for the nine months ended September 30, 2006, from \$10.2 million for the nine months ended September 30,

Table of Contents

2005. This increase was primarily the result of the recognition of contract manufacturing costs associated with the shipment of clinical lots of DNA vaccines to the VRC during the current period. This increase was offset by a decrease in facility related costs in the current period as a result of the shutdown of one of our facilities in the prior period and a decrease in the use of scientific supplies used in the manufacturing process.

General and Administrative Expenses. General and administrative expenses increased \$0.8 million, or 14.0%, to \$6.7 million for the nine months ended September 30, 2006, from \$5.9 million for the nine months ended September 30, 2005. The increase was primarily the result of increased stock compensation expense related to the implementation of SFAS No. 123R.

Investment Income. Investment income increased \$0.9 million, or 80.6%, to \$2.1 million for the nine months ended September 30, 2006, from \$1.2 million for the nine months ended September 30, 2005. This increase was primarily the result of higher rates of return on our investments during the nine months ended September 30, 2006, and higher average cash and short-term investment balances.

Interest Expense. Interest expense decreased \$0.2 million, or 45.7%, to \$0.2 million for the nine months ended September 30, 2006, from \$0.4 million for the nine months ended September 30, 2005. The decrease was primarily the result of lower principal amounts outstanding on our equipment financing obligations.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, public offerings of common stock, and revenues from collaborative agreements and grants. From our inception through September 30, 2006, we have received approximately \$132.1 million in revenues from performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$258.3 million from the sale of equity securities. As of September 30, 2006, we had working capital of approximately \$67.4 million, compared with \$63.4 million at December 31, 2005. Cash, cash equivalents and marketable securities, including restricted securities, totaled approximately \$69.9 million at September 30, 2006, compared with \$66.5 million at December 31, 2005. The increase in our cash, cash equivalents and marketable securities in the nine months ended September 30, 2006, was due primarily to the sale of our common stock which was offset by the use of cash to fund our operations and to pay our equipment financing obligations.

Net cash used in operating activities was \$9.8 million and \$17.2 million for the nine months ended September 30, 2006 and 2005, respectively. The decrease in net cash used in operating activities for the nine months ended September 30, 2006, compared with the same period in the prior year, was primarily the result of a decrease in our net loss due to the gross profit derived from the VRC production orders and by a decrease in accounts receivable balances.

Net cash provided by investing activities was \$0.4 million and \$19.3 million for the nine months ended September 30, 2006 and 2005, respectively. The decrease in cash provided by investing activities for the nine months ended September 30, 2006, compared with the same period in the prior year, was primarily the result of a decrease in net maturities of investments in marketable securities.

Net cash provided by (used in) financing activities was \$13.9 million and (\$2.5) million for the nine months ended September 30, 2006 and 2005, respectively. The increase in cash provided by financing activities for the nine months ended September 30, 2006, compared with the same period in the prior year, was primarily the result of the sale of our common stock which was partially offset by a decrease in proceeds from equipment financing arrangements.

We expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including continued personnel costs, costs related to preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization costs. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. We have on file a shelf registration statement, which was declared effective in March 2006, that allows us to raise up to an additional \$31.6 million from the sale of common or preferred stock. However, additional financing may not be available on favorable terms or at all.

Table of Contents

If additional funding is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least December 31, 2008.

Contractual Obligations

In December 2004, we modified an equipment financing agreement which provided for \$5.3 million of financing, with interest rates ranging from 3.0% to 3.2%, with payments of principal and interest due through 2009. A portion of the financing was used to repay outstanding debt of approximately \$2.2 million under another credit facility. Additional amounts were used to finance equipment purchases. The draw down period for this equipment financing arrangement ended in October 2005. The agreement requires a non-interest-bearing cash security deposit in the amount of 60.0% of the amount of each draw down, which amounts are included in current and long-term other assets. This financing involves restrictive financial covenants, including a requirement that we maintain unrestricted cash and marketable securities of at least \$25.0 million or obtain a letter of credit from another lender in the amount of outstanding borrowings.

Under certain licensing agreements with collaborators, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the WARF and the University of Michigan. Pursuant to certain agreements whereby we have licensed technology from others, we may be required to make payments if we or our sublicensees advance products through clinical development. For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties.

In addition, we have undertaken certain commitments under license agreements with collaborators, and under indemnification agreements with our officers and directors. Under the license agreements with our collaborators, we have agreed to continue to maintain and defend the patent rights licensed to the collaborators. Under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

As of September 30, 2006, we had employment agreements that contained severance arrangements with each of our three executive officers and three other executives. Under these agreements, we are obligated to pay severance if we terminate an executive officer's or other executive's employment other than for cause or disability, or if an executive officer or other executive resigns for good reason, as defined in the agreements, within the periods set forth therein. The severance would consist of continued payments at the current base compensation rate, or current base compensation rate plus the prior year's cash bonus in the case of the CEO, for the period specified in each agreement, which ranges from nine to twelve months. These agreements also specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from us. The maximum payments due under these employment agreements would have been \$1.2 million if each executive officer and other executive was terminated at September 30, 2006.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents, both restricted and non-restricted, and marketable securities. The average maturity of our non-equity investments is approximately nine months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and marketable securities using the following assumptions: a 12-month time horizon, a 9-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$0.1 million lower than the reported fair value of our non-equity investments at September 30, 2006. At September 30, 2006, our unrealized gain on non-equity investments was \$0.1 million. We expect lower investment income for the full year 2006 compared with 2005 due to lower investment balances.

ITEM 4. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Report. Based on this evaluation, our principal

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executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2006.

Table of Contents

Changes in Internal Controls

There has been no change in our internal control over financial reporting during the three months ended September 30, 2006, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this Report, and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risk factors below contain certain changes from the risk factors disclosed in our Annual Report on Form 10-K filed on March 10, 2006.

None of our independently developed products has been approved for sale, and we have a limited number of independent product candidates in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our independent product candidates are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our products. Limited data exist regarding the safety and efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our potential products are unsafe or ineffective. In this case, regulatory authorities will not approve them.

For example, our independent product candidates currently in ongoing clinical evaluation include our CMV vaccine, for which we initiated Phase 2 clinical testing in early 2006, and our IL-2/EP program, which is currently in Phase 1 clinical testing. We may not conduct additional CMV vaccine trials, leading transplant centers may not participate or sufficiently enroll patients in our trials, and our CMV vaccine may not elicit sufficient immune responses in humans. We may not conduct additional IL-2/EP trials, and our IL-2/EP program may not demonstrate sufficient safety and efficacy to support product approval.

Additionally, we are in various stages of development with several other product candidates. These product candidates will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not support approval by the FDA or comparable foreign agencies. Even if approved, our products may not be commercially successful. If we fail to develop and commercialize our products, we may be forced to curtail or cease operations.

Our revenues partially depend on the development and commercialization of products in collaboration with others to whom we have licensed our technologies or on whom we rely to support our development and commercialization efforts. If our collaborators or licensees are not successful or cease to support our development and commercialization efforts, or if we are unable to find collaborators or licensees in the future, we may not be able to derive revenues from these arrangements or may be forced to curtail our development and commercialization of certain products.

We have licensed, and may continue to license, our technologies to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues partially depend upon the performance by these collaborators and licensees of their responsibilities under these arrangements. In addition, we have entered into an R&D Agreement with AnGes, pursuant to which we rely on AnGes to help fund further development of our cancer immunotherapeutic, Allovectin-7[®].

Some collaborators or licensees may not succeed in their product development efforts, such as Corautus, which recently announced that it did not plan to conduct further clinical trials for the treatment of peripheral arterial disease or coronary artery disease involving pDNA-based delivery of VEGF-2. Other collaborators or licensees may not devote sufficient time or resources to the programs covered by these arrangements, causing us to derive little or no revenue from these arrangements, or may cease to support our development and commercialization efforts.

Table of Contents

Our collaborators and licensees may breach or terminate their agreements with us, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our products, and we may be forced to curtail or cease operations.

A significant portion of our revenue is derived from agreements with government agencies, which are subject to termination and uncertain future funding.

We have entered into agreements with government agencies, such as the NIH, and we intend to continue entering into these agreements in the future. For example, we have entered into agreements to manufacture DNA vaccines for the VRC. Our business is partially dependent on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time. For example, our 2003 subcontract agreement to manufacture bulk DNA vaccines for the VRC expires in December 2006.

If we fail to satisfy our remaining contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the 2003 subcontract agreement, we may be required to perform corrective actions, including but not limited to remanufacturing vaccines or components thereof at our expense, delivering to the VRC any uncompleted or partially completed work and/or other government property in our possession, and/or paying a third-party supplier selected by the VRC to complete any uncompleted work. For example, we have twice been obligated to remanufacture at our expense a component of a vaccine under our 2003 subcontract agreement with the VRC. We believe we will be able to deliver the remaining component of the vaccine in a timely manner in accordance with the terms of the contract. The performance of any future corrective actions could have a material adverse impact on our financial results in the period or periods affected.

There are only a limited number of other contractors that could manufacture bulk DNA in the unlikely event that we were unable to perform our remaining responsibilities under the 2003 subcontract agreement. The price these other contractors might charge could be more than what we would charge based on their capacity, utilization, size of order and other factors. Accordingly, we are unable to estimate a range of potential cost that we could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that we were unable to meet.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Many of our government agreements are subject to audits which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering or ineligible to enter into future government agreements.

We apply for and have received funding from various government agencies. Eligibility of public companies to receive grants, such as Small business Technology Transfer, or STTR, and SBIR grants, may be based on size and ownership criteria which are under review by the Small Business Administration, or SBA. As a result, our eligibility may change in the future, and additional funding from this source may not be available.

Table of Contents

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold or received approval to sell any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$24.4 million, \$23.7 million and \$24.5 million for the years ended December 31, 2005, 2004 and 2003, respectively. As of September 30, 2006, we had incurred cumulative net losses totaling approximately \$178.1 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. We have on file a shelf registration statement, which was declared effective in March 2006, that allows us to raise up to an additional \$31.6 million from the sale of common or preferred stock. However, we may not be able to raise additional funds on favorable terms, or at all.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

The progress of our research and development programs;

The scope and results of our preclinical studies and clinical trials; and

The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

The regulatory approval process is expensive, time consuming and uncertain, which may prevent us from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators and licensees are subject to extensive and rigorous regulations by numerous governmental authorities in the U.S. and other countries. The regulations are evolving and uncertain. The regulatory process can take many years and require us to expend substantial resources. For example:

The FDA has not established guidelines concerning the scope of clinical trials required for gene-based therapeutic and vaccine products;

The FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products; and

Current regulations and guidances are subject to substantial review by various governmental agencies. Therefore, U.S. or foreign regulations could prevent or delay regulatory approval of our products or limit our ability to develop and commercialize our products. Delays could:

Impose costly procedures on our activities;

Diminish any competitive advantages that we attain; or

Negatively affect our results of operations and cash flows.

We have no experience in filing BLAs with the FDA. Because a BLA must be filed with and approved by the FDA before a biologic product may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our products, which in turn would delay or prevent us from commercializing those

Table of Contents

products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the U.S. may impede our ability to commercialize our products in those countries.

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we must sponsor and file a regulatory application for each proposed use. We must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The results obtained so far in our clinical trials may not be replicated in our ongoing or future trials. This may prevent any of our potential products from receiving FDA approval.

We use recombinant DNA molecules in our product candidates, and therefore we also must comply with guidelines instituted by the NIH and its Office of Biotechnology Activities. The NIH could restrict or delay the development of our product candidates.

In March 2004, the NIH Office of Biotechnology Activities and the FDA Center for Biologics Evaluation and Research launched the jointly developed Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. In its current form, GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials, and includes special security features designed to protect patient privacy and confidential commercial information. These security features may be inadequate in design or enforcement, potentially resulting in disclosure of confidential commercial information. We understand that both the FDA and the NIH are considering rules and regulations that would require public disclosure of additional commercial development data that is presently confidential. In addition, the NIH, in collaboration with the FDA, has developed an Internet site, ClinicalTrials.gov, which provides public access to information on clinical trials for a wide range of diseases and conditions. Such disclosures of confidential commercial information, whether by implementation of new rules or regulations, by inadequacy of GeMCRIS security features, or by intentional posting on the Internet, may result in loss of advantage of competitive secrets.

A rule published in 2002 by the FDA, known commonly as the Animal Rule, established requirements for demonstrating effectiveness of drugs and biological products in settings where human clinical trials for efficacy are not feasible or ethical. The rule requires as conditions for market approval the demonstration of safety and biological activity in humans, and the demonstration of effectiveness under rigorous test conditions in up to two appropriate species of animal. We believe that with appropriate guidance from the FDA, we may seek and win market approval under the Animal Rule for certain DNA-based products for which human clinical efficacy trials are not feasible or ethical. At the moment, however, we cannot determine whether the Animal Rule would be applied to any of our products, or if applied, that its application would result in expedited development time or regulatory review.

Adverse events in the field of gene therapy, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

The death in 1999 of a patient undergoing a viral-delivered gene therapy at the University of Pennsylvania in an investigator-sponsored trial was widely publicized. In October 2002, January 2003, and January 2005, three children in France who received viral-delivered ex vivo gene transfer for the treatment of X-linked Severe Combined Immunodeficiency Disease, called X-SCID or bubble boy syndrome, were diagnosed with leukemia that was potentially caused by the integration of the viral delivery vehicle in or near a cancer-causing region of the children's genome. Certain gene therapy clinical trials were placed on clinical hold following the second child's death, and the trial in which the children had been enrolled was again placed on hold following the third child's death. In October 2004, the FDA requested that clinical trials of another company's viral-delivered gene therapy product candidate be placed on clinical hold pending review of information pertaining to potential adverse events. A portion of one of the trials was subsequently allowed to resume.

In 2003, the FDA proposed a new rule on Safety Reporting Requirements for Human Drug and Biological Products that would change the reporting requirements for drugs and biological products, such that any serious adverse event that cannot be definitely excluded as related to the product will be reported in an expedited manner. At present, sponsors of clinical research typically report on an annual basis all serious adverse events that have been deemed to be unlikely or improbable. The effect of this proposed rule will likely be to increase the number of expedited reports of serious adverse events to the FDA, which may create a perception of increased adverse events and higher risk profiles, despite no change in the actual severity or the actual number of adverse events that occur in the course of a product's development.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, diseases which can themselves be life-threatening. For example, one patient who had undergone treatment with Allovectin-7®

Table of Contents

for advanced metastatic melanoma died more than two months later of progressive disease and numerous other factors after receiving multiple other cancer therapies. The death was originally reported as unrelated to the treatment. Following an autopsy, the death was reclassified as probably related to the treatment because the possibility could not be ruled out. We do not believe Allovectin® was a significant factor in the patient's death. As another example, in our Phase 2 trial, we are administering our investigational CMV vaccine to patients who are at risk of CMV reactivation. Although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events.

These adverse events, and real or perceived risks, could result in greater government regulation and stricter labeling requirements for DNA-based vaccines or therapies, and may adversely impact market acceptance of some of our product candidates. Increased scrutiny in the field of gene therapy also may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

We are the assignee or co-assignee of 50 issued U.S. and foreign patents. We are also co-assignee, together with Sanofi Pasteur and the University of Texas Health Science Center, of two issued U.S. patents related to vaccines against Lyme disease. Among these issued patents, a Japanese patent related to our core DNA delivery technology is the subject of two Trials for Invalidation, or TFIs; a recently granted patent in Europe related to our core DNA delivery technology has been opposed by eight parties; a patent granted in Europe covering a range of applications of our core DNA delivery technology using cationic lipid formulations was opposed, maintained in amended form and is currently in appeal proceedings; and a patent granted in Europe covering gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer has also been opposed.

We are also prosecuting 61 pending patent applications in the U.S. and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners. Two of the pending foreign patent applications are international patent applications under the Patent Cooperation Treaty, each of which preserves our right to pursue national-phase patent applications in a large number of foreign countries. In addition, we are co-assignee, together with Merck, of U.S. and foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

We may not receive any patents from our current patent applications. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies and products. Finally, others may challenge or seek to circumvent or invalidate our patents. In that event, the rights granted under our patents may be inadequate to protect our proprietary technologies or to provide any commercial advantage.

Once issued, we maintain our patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated.

For example: in Europe, four patents granted to us have been opposed and one was revoked as a consequence of opposition; in Japan, one patent granted to us was opposed and subsequently subjected to TFIs; and in Canada, a protest was lodged against a patent application filed by us. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

Some components of our gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our success will depend in part on our ability to obtain patent protection for our products and processes, both in the U.S. and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly

Table of Contents

uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. Moreover, if a competitor were to file a patent application claiming technology also invented by us, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. In addition, we could be required to pay money damages. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we may have to obtain licenses to test, use or market these products. Our business will suffer if we are not able to obtain licenses at all or on terms commercially reasonable to us and we are not able to redesign our products or processes to avoid infringement.

We have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

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

We compete with companies, including major pharmaceutical and biotechnology firms, that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technologies from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us. Furthermore, our products may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our products do not achieve market acceptance, we may lose our investment in that product, which could have a material adverse impact on our operations.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to achieve our business objectives.

We are highly dependent on our principal scientific, manufacturing, clinical, regulatory and management personnel, including Vijay B. Samant, our President and Chief Executive Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. We do not maintain key person life insurance on any of our personnel. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as additional personnel with expertise in clinical trials, government regulation and manufacturing. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel and therefore we may not be able to achieve our business objectives.

Table of Contents

We have limited experience in manufacturing our product candidates in commercial quantities. We may not be able to comply with applicable manufacturing regulations or produce sufficient product for contract or commercial purposes.

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we may need to complete the installation and validation of additional large-scale fermentation and related purification equipment to produce the quantities of product expected to be required for commercial purposes. We have limited experience in manufacturing at this scale. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional large-scale equipment, or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing service arrangements.

We may initially depend on third parties to manufacture our product candidates commercially.

We may initially depend on collaborators, licensees or other third parties to manufacture our product candidates in commercial quantities. There are a limited number of third parties that could manufacture our product candidates. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the U.S., but we currently do not possess pharmaceutical marketing or sales capabilities. To market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time-consuming and could delay any product launch. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, we may not be able to generate sufficient product revenue to become profitable.

Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

Government health administration authorities;

Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;

Private health coverage insurers;

Managed care organizations; and

Other organizations.

If we fail to obtain appropriate reimbursement, we could be prevented from successfully commercializing our potential products. There are efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various means, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which provides a new Medicare prescription drug benefit that was recently

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implemented and mandates other reforms. We expect that there will continue to be a number of legislative proposals to implement government controls. The adoption of such proposals or reforms could impair our business.

Certain portions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, have become effective and may complicate the process by which clinical trials may be initiated. We believe we have taken the necessary action to ensure compliance with HIPAA; however, the specific nature and degree of impact are not yet fully known.

Table of Contents

Additionally, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and minor amounts of low-level radioactive compounds. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We have insurance that covers our use of hazardous materials with the following coverage limits: up to \$25,000 per occurrence for losses related to the release of bio-contaminants, \$1 million per occurrence for losses from refrigerant contamination and \$25,000 per occurrence for losses from radioactive contamination. Any liability could exceed the limits or fall outside the coverage of our insurance. We could incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2003, to September 30, 2006, our stock price has ranged from \$2.12 to \$8.14. The following factors, among others, could have a significant impact on the market price of our common stock:

The results of our preclinical studies and clinical trials or announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;

Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors;

The announcement by us or our collaborators, licensees or competitors of technological innovations or new products;

Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;

Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;

Geopolitical developments, natural or man-made disease threats, or other events beyond our control;

U.S. and foreign governmental regulatory actions;

Changes or announcements in reimbursement policies;

Period-to-period fluctuations in our operating results;

Market conditions for life science stocks in general;

Table of Contents

Changes in the collective short interest in our stock;

Changes in estimates of our performance by securities analysts; and

Our cash balances, need for additional capital, and access to capital.

We are at risk of securities class action litigation due to our expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws include anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may discourage or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

The issuance of preferred stock could adversely affect our common stockholders.

We have on file an effective shelf registration statement that allows us to raise up to an additional \$31.6 million from the sale of common or preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(i)(1)	Restated Certificate of Incorporation.
3.1(ii)(1)	Amended and Restated Bylaws.
3.2(i)(2)	Certificate of Amendment to Restated Certificate of Incorporation.
4.1(1)	Specimen Common Stock Certificate.
10.29(3)	Employment Agreement dated June 17, 2002, between the Company and Alain Rolland.
10.52(4)	Master Security Agreement dated August 23, 2006, between the Company and Oxford Finance Corporation.
10.53	Amendment dated May 19, 2006, to Employment Agreement dated June 17, 2002, between the Company and Alain Rolland.
31.1(i)	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2(i)	Certification of Jill M. Church, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Church, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- (1) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.
- (2) Incorporated by reference to exhibit 4.2 filed with the Company's Registration Statement on Form S-8 (No. 333-135398) filed on June 28, 2006.
- (3) Incorporated by reference to the exhibit of the same number filed with the Company's Quarterly Report on Form 10-Q filed on November 14, 2002.
- (4) Incorporated by reference to the exhibit of the same number filed with the Company's Current Report on Form 8-K filed on August 25, 2006.

Table of Contents

SIGNATURE

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

Vical Incorporated

Date: November 8, 2006

By: /s/ JILL M. CHURCH
Jill M. Church
Vice President, Chief Financial Officer and Secretary

(on behalf of the registrant and as the registrant's Principal
Financial and Accounting Officer)