

VICAL INC  
Form 10-Q  
August 08, 2007  
Table of Contents

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2007

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

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**VICAL INCORPORATED**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

10390 Pacific Center Court

93-0948554  
(I.R.S. Employer

Identification No.)

92121

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**San Diego, California**  
(Address of principal executive offices)

**(858) 646-1100**

(Zip code)

(Registrant's telephone number, including area code)

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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 August 3, 2007: 39,193,359

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**Table of Contents**

**VICAL INCORPORATED**

**FORM 10-Q**

**INDEX**

**PART I. FINANCIAL INFORMATION**

ITEM 1. Financial Statements

Balance Sheets (unaudited) as of June 30, 2007, and December 31, 2006 3

Statements of Operations (unaudited) for the three and six months ended June 30, 2007 and 2006 4

Statements of Cash Flows (unaudited) for the six months ended June 30, 2007 and 2006 5

Notes to Financial Statements (unaudited) 6

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 11

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk 20

ITEM 4. Controls and Procedures 20

**PART II. OTHER INFORMATION**

ITEM 1A. Risk Factors 20

ITEM 4. Submission of Matters to a Vote of Security Holders 30

ITEM 6. Exhibits 31

SIGNATURE 32

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

	<b>June 30,</b>	<b>December 31,</b>
	<b>2007</b>	<b>2006</b>
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 25,111	\$ 19,363
Marketable securities, available-for-sale	54,391	78,519
Restricted marketable securities	2,651	2,511
Receivables and other	4,340	5,049
<b>Total current assets</b>	<b>86,493</b>	<b>105,442</b>
Property and equipment, net	13,031	13,500
Intangible assets, net	5,032	5,162
Other assets	867	1,145
<b>Total assets</b>	<b>\$ 105,423</b>	<b>\$ 125,249</b>
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,956	\$ 5,437
Current portion of equipment financing obligations	1,544	2,716
<b>Total current liabilities</b>	<b>5,500</b>	<b>8,153</b>
Long-term liabilities:		
Equipment financing obligations, net of current portion	386	711
Deferred rent	2,349	2,262
<b>Total long-term liabilities</b>	<b>2,735</b>	<b>2,973</b>
<b>Commitments and contingencies</b>		
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, 39,191 and 39,149 shares issued and outstanding at June 30, 2007, and December 31, 2006, respectively	392	391
Additional paid-in capital	300,558	299,581
Accumulated deficit	(203,816)	(186,022)
Accumulated other comprehensive income	54	173

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Total stockholders' equity	97,188	114,123
Total liabilities and stockholders' equity	\$ 105,423	\$ 125,249

See accompanying notes to unaudited financial statements

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Revenues:</b>				
Contract and grant revenue	\$ 2,980	\$ 7,100	\$ 3,830	\$ 12,679
License and royalty revenue	131	156	536	192
<b>Total revenues</b>	<b>3,111</b>	<b>7,256</b>	<b>4,366</b>	<b>12,871</b>
<b>Operating expenses:</b>				
Research and development	5,859	4,171	11,734	8,815
Manufacturing and production	4,216	4,499	8,163	8,051
General and administrative	2,340	2,406	4,633	4,848
<b>Total operating expenses</b>	<b>12,415</b>	<b>11,076</b>	<b>24,530</b>	<b>21,714</b>
Loss from operations	(9,304)	(3,820)	(20,164)	(8,843)
<b>Other income (expense):</b>				
Investment income	1,136	650	2,437	1,293
Interest expense	(29)	(74)	(67)	(167)
<b>Net loss</b>	<b>\$ (8,197)</b>	<b>\$ (3,244)</b>	<b>\$ (17,794)</b>	<b>\$ (7,717)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.21)</b>	<b>\$ (0.11)</b>	<b>\$ (0.45)</b>	<b>\$ (0.27)</b>
<b>Weighted average shares used in computing basic and diluted net loss per share</b>	<b>39,191</b>	<b>28,817</b>	<b>39,186</b>	<b>28,555</b>

See accompanying notes to unaudited financial statements

**Table of Contents**

**VICAL INCORPORATED**  
**STATEMENTS OF CASH FLOWS**

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (17,794)	\$ (7,717)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,714	1,660
Write-off of abandoned patents	7	42
Gain on sale of property and equipment	(50)	
Compensation expense related to stock options and awards	1,017	943
Changes in operating assets and liabilities:		
Receivables and other	709	(5,268)
Other assets	278	525
Accounts payable, accrued expenses and other liabilities	(1,486)	(1,362)
Deferred rent	92	135
<b>Net cash used in operating activities</b>	<b>(15,513)</b>	<b>(11,042)</b>
Cash flows from investing activities:		
Maturities of marketable securities including restricted	72,236	95,421
Purchases of marketable securities including restricted	(48,368)	(85,951)
Purchases of property and equipment	(832)	(352)
Sale of property and equipment	50	
Patent expenditures	(290)	(116)
<b>Net cash provided by investing activities</b>	<b>22,796</b>	<b>9,002</b>
Cash flows from financing activities:		
Proceeds from issuance of common stock	53	7,361
Payment of withholding taxes for net settlement of restricted stock units	(92)	(92)
Principal payments under equipment financing obligations	(1,496)	(2,508)
<b>Net cash (used in) provided by financing activities</b>	<b>(1,535)</b>	<b>4,761</b>
Net increase in cash and cash equivalents	5,748	2,721
Cash and cash equivalents at beginning of period	19,363	5,710
<b>Cash and cash equivalents at end of period</b>	<b>\$ 25,111</b>	<b>\$ 8,431</b>
Supplemental information:		
Interest paid	\$ 67	\$ 167

See accompanying notes to unaudited financial statements





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**Table of Contents**

**VICAL INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS**

**June 30, 2007**

**(Unaudited)**

**1. GENERAL**

Vical Incorporated, or the Company, a Delaware corporation, 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.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from research and development agreements with pharmaceutical collaborators and grant and contract arrangements with government entities. Most product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful. The Company expects to continue to incur substantial losses and not generate positive cash flows from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flows from operations. The Company anticipates that its available cash and existing sources of funding will be adequate to satisfy its cash needs through at least December 31, 2008.

The unaudited financial statements at June 30, 2007, and for the three and six months ended June 30, 2007 and 2006, 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, 2006, included in its Annual Report on Form 10-K filed with the SEC.

*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.

*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 June 30, 2007, and December 31, 2006, restricted marketable securities of \$2.7 million and \$2.5 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.

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## **Table of Contents**

### *Contract Manufacturing Revenue*

The Company's contract manufacturing arrangements typically require the delivery of multiple lots of clinical material. 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) delivery or performance is probable and within the Company's control for any items that have a right of return.

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 and 0.4 million for the three months ended June 30, 2007 and 2006, respectively, were excluded from the calculation because of their antidilutive effect. Common stock equivalents of 0.3 million and 0.4 million for the six months ended June 30, 2007 and 2006, respectively, were excluded from the calculation because of their antidilutive effect.

### *Income Taxes*

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes, or FIN 48, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 became effective for the Company beginning January 1, 2007.

At December 31, 2006, the Company had federal and state tax net operating loss, or NOL, carryforwards of approximately \$172.4 and \$64.0 million, respectively. The Company also had federal research and development and orphan drug credit carryforwards of \$13.6 million. These NOL and credit carryforwards begin to expire in 2007 unless previously utilized. In addition, the Company has research and development credits and manufacturers' investment credit carryforwards of \$5.5 million, as of December 31, 2006, to reduce future California income tax, if any. Because realization of such tax benefits is uncertain, the Company has provided a 100% valuation allowance as of December 31, 2006, and June 30, 2007.



**Table of Contents**

Utilization of the NOL and credit carryforwards may be subject to a substantial annual limitation due to ownership changes that have occurred previously or that could occur in the future pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company has not completed a study to assess whether a change in control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and the possibility of additional changes in the future. If the Company has experienced a change of control at any time since its formation, utilization of its NOL or credit carryforwards would be subject to an annual limitation under Sections 382 and 383 which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48. Interest and penalties related to uncertain tax positions will be reflected in income tax expense. All tax years remain subject to future examination by the tax jurisdictions in which we are subject to tax.

*Recent Accounting Pronouncements*

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115*, which is effective for fiscal years beginning after November 15, 2007. This statement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We are currently evaluating the potential impact of this statement.

**2. STOCK-BASED COMPENSATION**

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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Research and development	\$ 250	\$ 157	\$ 425	\$ 338
Manufacturing and production	65	63	133	137
General and administrative	214	217	459	468
Total stock-based compensation expense	\$ 529	\$ 437	\$ 1,017	\$ 943

During the six months ended June 30, 2007 and 2006, the Company granted stock-based awards with a total estimated value of \$2.3 million and \$1.4 million, respectively. At June 30, 2007, total unrecognized estimated compensation cost related to unvested stock-based awards granted prior to that date was \$2.3 million, which is expected to be recognized over a weighted-average period of 1.4 years. Stock-based awards granted during the six months ended June 30, 2007 and 2006, represented 1.6% of outstanding common shares at the end of each period.

**3. COMPREHENSIVE LOSS**

Comprehensive loss consists of net loss and certain changes in equity that are excluded from net loss. Accumulated other comprehensive loss represents net unrealized losses on marketable securities. For the three months ended June 30, 2007 and 2006, other comprehensive loss was \$35,000 and \$145,000, respectively, and total comprehensive loss was \$8.2 million and \$3.4 million, respectively. For the six months ended June 30, 2007 and 2006, other comprehensive loss was \$120,000 and \$53,000, respectively, and total comprehensive loss was \$17.9 million and \$7.8 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 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 \$1.9 million for the three and six months ended June 30, 2007. The Company recognized revenue under this subcontract agreement of \$6.4 million and \$10.2 million for the three and six months ended June 30, 2006, respectively.

**5. OTHER BALANCE SHEET ACCOUNTS**

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

	June 30, 2007	December 31, 2006
Employee compensation	\$ 1,529	\$ 2,216
Accounts payable	529	542
Other accrued liabilities	1,898	2,679
	\$ 3,956	\$ 5,437

**6. COMMITMENTS AND CONTINGENCIES**

We have been obligated to remanufacture a component of a vaccine at our expense under our 2003 subcontract agreement with the VRC. We completed the remanufacturing of the vaccine component which was shipped and accepted by the VRC in June 2007.

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 the Company 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.

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 the Company's financial condition is not subject to reasonable estimates.





**Table of Contents**

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, are deemed to be material to the financial condition or results of operations of the Company.

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**Table of Contents**

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

This Quarterly Report on Form 10-Q, or Report, 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 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 projected 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, 2006, in our Quarterly Report on Form 10-Q for the three months ended March 31, 2007, and in our other filings with the SEC, and those identified in Part II, Item 1A entitled "Risk Factors" beginning on page 19 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. 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, adolescent and adult populations for infectious disease applications; and

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

We currently have four active independent development programs in the areas of infectious disease and cancer including:

A Phase 3 clinical trial using our Allovectin-7<sup>®</sup> immunotherapeutic in patients with metastatic melanoma which is being funded by AnGes MG, Inc., or AnGes, through cash payments and equity investments, under a research and development agreement;

A Phase 2 clinical trial using our cytomegalovirus, or CMV, DNA vaccine in hematopoietic cell transplant patients;

A Phase 1 clinical trial of electroporation-enhanced delivery of DNA encoding interleukin-2, or IL-2, utilizing our delivery technology with an initial indication in metastatic melanoma; and

A pandemic influenza DNA vaccine candidate using our proprietary Vaxfectin<sup>™</sup> adjuvant, which is expected to begin Phase 1 clinical testing in the second half of 2007.

**Table of Contents**

We have leveraged our patented technologies through licensing and collaborations, such as our licensing arrangements with Merck & Co., Inc., or Merck, the sanofi aventis Group, or sanofi aventis, and AnGes, among other research-driven biopharmaceutical companies. In 2005, the first product for one of our licensees 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. In 2007, another product utilizing our patented DNA delivery technology received conditional approval for use in animals. Our licensee, Merial Limited, a joint venture of Merck and sanofi aventis, received notification of conditional approval from the U.S. Department of Agriculture to market a therapeutic DNA vaccine designed to treat melanoma, a serious form of cancer, in dogs. We believe these approvals are important steps in the validation of our DNA delivery technology.

The NIH has clinical stage vaccine programs based on our technology in five infectious disease targets: HIV, pandemic influenza, Ebola, West Nile virus, or WNV, and severe acute respiratory syndrome, or SARS. We work with the NIH under Collaborative Research and Development Agreements, or CRADAs, and license agreements to further develop our technology under four of the five targets listed above. Under the agreements, the NIH fully funds the programs while in certain cases we maintain commercialization rights.

In addition, we have licensed complementary technologies from leading research institutions and pharmaceutical companies, as well as the NIH and the U.S. Centers for Disease Control and Prevention, or CDC. We also have granted non-exclusive, academic licenses to our DNA delivery technology patent estate to ten leading research institutions including Stanford, Harvard, Yale and the Massachusetts Institute of Technology, or MIT. 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.

**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 programs focus on metastatic melanoma, CMV, and pandemic influenza. The table below summarizes our independent programs and corporate and government collaborations.

<b>Product Description</b>	<b>Project Target/Indication(s)</b>	<b>Development Status<sup>1</sup></b>	<b>Primary Developer</b>
<b>Independent Programs</b>			
Infectious disease vaccine	Cytomegalovirus	Phase 2	Vical
	Pandemic influenza	Initiating Phase 1	Vical
Cancer immunotherapeutic	Allovecitin-7 <sup>®</sup> , metastatic melanoma	Phase 3	Vical
	IL-2/EP, metastatic melanoma	Phase 1	Vical
<b>Corporate Collaborations</b>			
Infectious disease vaccine	HIV	Phase 1	Merck
	Hepatitis B virus	Research	Merck
	Hepatitis C virus	Research	Merck
Tumor-associated antigen therapeutic vaccine	HER-2 and CEA, breast, colorectal, ovarian or non-small cell lung cancer	Phase 1	Merck
	Unspecified cancer <sup>2</sup>	Research	Merck
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	Initiating Phase 3	Sanofi aventis
Preventive infectious disease vaccine (animal health)	Apex-IHN <sup>®</sup> , infectious hematopoietic necrosis virus in salmon	Marketed in Canada	Aqua Health
	Various undisclosed <sup>2</sup>	Research-Clinical	Merial
Therapeutic cancer vaccine (animal health)	Canine melanoma	Conditional approval in the U.S.	Merial
<b>Government Collaborations</b>			
Infectious disease vaccine	Ebola virus	Phase 1	NIH
	West Nile virus	Phase 1	NIH
	SARS coronavirus	Phase 1	NIH
	HIV	Phase 2	NIH

<sup>1</sup> 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 are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. Phase 2 clinical trials are conducted with a larger group of patients 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 involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease to evaluate the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling. For life-threatening diseases, initial human testing generally is done in patients afflicted with the target disease rather than healthy subjects. These studies may provide results traditionally obtained in Phase 2 trials and are referred to as Phase 1/2 trials. In some special cases where the efficacy testing of a product may present a special challenge to testing in humans, such as in the case of a vaccine to protect healthy humans from a life-threatening disease that is not a naturally occurring threat, effectiveness testing may be required in animals.

<sup>2</sup> 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, 2006, 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 business:

#### *Influenza Program*

We received notification of IND allowance for our Phase 1 trial of Vaxfectin<sup>®</sup> -formulated pandemic influenza DNA vaccine, and now expect to initiate the trial earlier than originally planned in the second half of 2007.

#### *Grants Awarded*

We were awarded a three-year, \$6.0 million grant from the National Institute of Allergy and Infectious Diseases, part of the NIH, for further development of a cell-free DNA manufacturing process with the potential to produce several million doses of vaccines in a matter of days, compared with the several months or longer required for conventional vaccine production.

#### *Significant Milestones in Cancer Programs*

We have initiated more than 30 of the up to 60 planned clinical sites for our Phase 3 pivotal trial utilizing our Allovectin-7<sup>®</sup> cancer immunotherapeutic as first-line sole treatment in chemotherapy-naïve patients with recurrent Stage III or IV metastatic melanoma. Patient enrollment is ongoing.

Interim data on 19 subjects from our ongoing Phase 1 clinical trial were reported at a ASCO conference in June 2007. The data demonstrated that intratumoral delivery of plasmid DNA encoding interleukin-2 into melanoma tumors, followed by electroporation, was administered safely following sedative premedication. No serious adverse events related to the study drug or to the administration procedure were reported and the treatment was well-tolerated. The majority of related adverse events were localized to the treatment site, with the most frequent being mild injection site pain.

#### *Angiogenesis Partner Advancing toward Approvals*

Our licensee, AnGes, reported positive results following interim analysis of data from the first 41 subjects to complete a Phase 3 trial of an angiogenesis product candidate using our DNA delivery technology. Based on the findings that the primary efficacy endpoint in the trial had been achieved with statistical significance compared to a placebo and that there were no major safety concerns related to treatment, an Independent Data Monitoring Committee recommended stopping the trial early to prevent potential ethical issues against the placebo group subjects. AnGes announced it planned to end the trial and prepare an application for Japanese marketing approval.

#### *Increasing Applications for Vaxfectin<sup>®</sup> Adjuvant*

We recently announced that a measles DNA vaccine formulated with our Vaxfectin<sup>®</sup> adjuvant elicited protective levels of neutralizing antibodies in juvenile (1 - 2 year old) nonhuman primates confirmed by complete protection following challenge more than one year after vaccination intramuscularly or intradermally. Sterilizing immunity was evidenced by no clinical signs of disease and no detectable virus after challenge. In a separate study, the same vaccine elicited protective levels of neutralizing antibodies in infant (6 - 10 weeks old) nonhuman primates after intradermal injection with no vaccine-related adverse events.

In a recently completed animal study, a DNA vaccine formulated with our patented Vaxfectin<sup>®</sup> adjuvant and delivered by needle-free injection yielded significantly higher antibody responses than an unformulated DNA vaccine delivered by needle and syringe. In a separate animal study, electroporation following injection of unformulated vaccine yielded comparable improvements in antibody

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responses, but electroporation required anesthesia of the animals while needle-free injection of Vaxfectin -formulated vaccine was administered safely and tolerably without anesthesia.

**Table of Contents***CMV Vaccine Program*

We recently announced the enrollment of the 20th hematopoietic stem cell transplant recipient in our Phase 2 trial of a DNA vaccine against CMV. After the 20th recipient's two-month follow-up visit, an independent data safety monitoring board will conduct an interim evaluation of safety data for all subjects enrolled in the trial.

We recently announced that antigen-specific memory T-cell responses to cytomegalovirus, which may be important in protecting against CMV disease, were detected six months after DNA vaccination in a majority of CMV-seronegative subjects, using a cultured ELISPOT assay in a previously completed Phase 1 study.

**Research, Development and Manufacturing Programs**

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal amounts of revenue from the sale of commercially marketed products by our licensees. We earn revenue by performing services under research and development contracts, grants, manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$138 million in revenue under these types of agreements. Revenues by source were as follows (in millions):

Source	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
NIH contracts	\$ 1.9	\$ 6.4	\$ 1.9	\$ 10.2
CMV grants	1.0		1.0	1.0
Influenza grants			0.8	
Other contracts and grants	0.1	0.7	0.1	1.5
Total contract and grant revenues	3.0	7.1	3.8	12.7
Merial license			0.2	
Other royalties and licenses	0.1	0.2	0.4	0.2
Total royalty and license revenues	0.1	0.2	0.6	0.2
Total revenues	\$ 3.1	\$ 7.3	\$ 4.4	\$ 12.9

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

Program	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Allovectin-7®	\$ 2.4	\$ 2.0	\$ 4.2	\$ 3.2
Influenza	2.5		5.3	
CMV	1.5	1.5	3.3	3.3
IL-2/EP	0.2	0.4	0.3	1.0
Other research, development, manufacturing and production	3.5	4.8	6.8	9.4
Total research, development, manufacturing and production	\$ 10.1	\$ 8.7	\$ 19.9	\$ 16.9



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Since our inception, we estimate that we have spent approximately \$296 million on research, development, manufacturing and production. Our current independent development focus is on novel DNA vaccines for CMV and our cancer immunotherapeutics Allovectin-7<sup>®</sup> and IL-2/EP, as well as other preclinical targets. We also plan to initiate Phase 1 clinical testing of our influenza candidate in the second half of 2007.

We have initiated a Phase 3 clinical trial using Allovectin-7<sup>®</sup> in patients with recurrent metastatic melanoma which is being funded, up to certain limits, by AnGes through cash payments and equity investments under a research and development agreement. We are also in the early stages of clinical development of vaccine candidates for CMV and our IL-2/EP program for solid tumors and these programs will require significant additional costs to advance through development to commercialization. From inception, we have spent approximately \$71 million on our Allovectin-7<sup>®</sup> program, \$36 million on our CMV program, and \$7 million on our IL-2 EP program.

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## **Table of Contents**

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

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the advancement 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 consolidated 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: license and royalty agreements, manufacturing contracts, 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 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 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 arrangements 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 agreement, 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) delivery or performance is probable and within our control for any items that have a right of return.

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 agreement. 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.

## **Table of Contents**

*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 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.

In the event we determine that the carrying value of intangible assets or long-lived assets is 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. As of June 30, 2007, our largest group of intangible assets with finite lives includes patents and patents pending for our DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$3.2 million.

### **Recent Accounting Pronouncements**

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

### **Results of Operations**

#### *Three Months Ended June 30, 2007, Compared with Three Months Ended June 30, 2006*

*Total Revenues.* Total revenues decreased \$4.2 million, or 57.1%, to \$3.1 million for the three months ended June 30, 2007, from \$7.3 million for the three months ended June 30, 2006. Revenues from our contracts and grants were \$3.0 million for the three months ended June 30, 2007, compared with \$7.1 million for the three months ended June 30, 2006. This

**Table of Contents**

decrease was primarily the result of a decrease in contract revenue. Contract revenue for the three months ended June 30, 2007 and 2006, included revenues of \$1.9 million and \$6.4 million, respectively, related to VRC manufacturing contract shipments.

*Research and Development Expenses.* Research and development expenses increased \$1.7 million, or 40.5%, to \$5.9 million for the three months ended June 30, 2007, from \$4.2 million for the three months ended June 30, 2006. This increase was primarily attributable to increased costs associated with our Allovectin-7<sup>®</sup> Phase 3 clinical trial, our CMV Phase 2 clinical trial and preclinical safety studies related to our influenza program.

*Manufacturing and Production Expenses.* Manufacturing and production expenses decreased \$0.3 million, or 6.3%, to \$4.2 million for the three months ended June 30, 2007, from \$4.5 million for the three months ended June 30, 2006. This decrease was primarily attributable to a decrease in costs recognized related to the shipment of vaccine components under our manufacturing subcontract agreement with the VRC.

*General and Administrative Expenses.* General and administrative expenses decreased \$0.1 million, or 2.7%, to \$2.3 million for the three months ended June 30, 2007, from \$2.4 million for the three months ended June 30, 2006. These expenses were consistent with the prior period.

*Investment Income.* Investment income increased \$0.5 million, or 74.9%, to \$1.1 million for the three months ended June 30, 2007, from \$0.6 million for the three months ended June 30, 2006. This increase was primarily the result of higher average cash and short-term investment balances and higher rates of return on our investments during the three months ended June 30, 2007.

*Interest Expense.* Interest expense decreased \$45,000, or 60.8%, to \$29,000 for the three months ended June 30, 2007, from \$74,000 for the three months ended June 30, 2006. The decrease was primarily the result of lower principal amounts outstanding on our equipment financing obligations.

***Six Months Ended June 30, 2007, Compared with Six Months Ended June 30, 2006***

*Total Revenues.* Total revenues decreased \$8.5 million, or 66.1%, to \$4.4 million for the six months ended June 30, 2007, from \$12.9 million for the six months ended June 30, 2006. Revenues from our contracts and grants were \$3.8 million for the six months ended June 30, 2007, compared with \$12.7 million for the six months ended June 30, 2006. This decrease was primarily the result of a decrease in contract revenue. Contract revenue for the six months ended June 30, 2007 and 2006, included revenues of \$1.9 million and \$10.2 million, respectively, related to VRC manufacturing contract shipments.

*Research and Development Expenses.* Research and development expenses increased \$2.9 million, or 33.1%, to \$11.7 million for the six months ended June 30, 2007, from \$8.8 million for the six months ended June 30, 2006. This increase was primarily attributable to increased costs associated with our Allovectin-7<sup>®</sup> Phase 3 clinical trial, our CMV Phase 2 clinical trial and preclinical safety studies related to our influenza program.

*Manufacturing and Production Expenses.* Manufacturing and production expenses increased \$0.1 million, or 1.4%, to \$8.2 million for the six months ended June 30, 2007, from \$8.1 million for the six months ended June 30, 2006. This increase was primarily attributable to an increase in scientific supplies used in the manufacture of product for use in our pre-clinical programs.

*General and Administrative Expenses.* General and administrative expenses decreased \$0.2 million, or 4.4%, to \$4.6 million for the six months ended June 30, 2007, from \$4.8 million for the six months ended June 30, 2006. This decrease was primarily attributable to a reduction of auditing fees associated with our compliance with Section 404 of the Sarbanes-Oxley Act.

*Investment Income.* Investment income increased \$1.1 million, or 88.6%, to \$2.4 million for the six months ended June 30, 2007, from \$1.3 million for the six months ended June 30, 2006. This increase was primarily the result of higher average cash and short-term investment balances and higher rates of return on our investments during the six months ended June 30, 2007.

*Interest Expense.* Interest expense decreased \$100,000, or 59.9%, to \$67,000 for the six months ended June 30, 2007, from \$167,000 for the six months ended June 30, 2006. The decrease was primarily the result of lower principal amounts outstanding on our equipment financing obligations.

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**Table of Contents****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 performing services and licensing our technology. From our inception through June 30, 2007, we have received approximately \$137.7 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 \$296.1 million from the sale of equity securities. As of June 30, 2007, we had working capital of approximately \$81.0 million, compared with \$97.3 million at December 31, 2006. Cash, cash equivalents and marketable securities, including restricted securities, totaled approximately \$82.2 million at June 30, 2007, compared with \$100.4 million at December 31, 2006. The decrease in our cash, cash equivalents and marketable securities for the six months ended June 30, 2007, was due primarily to the use of cash to fund our operations.

Net cash used in operating activities was \$15.5 million and \$11.0 million for the six months ended June 30, 2007 and 2006, respectively. The increase in net cash used in operating activities for the six months ended June 30, 2007, compared with the same period in the prior year, was primarily the result of an increase in our net loss due to a decrease in contract manufacturing revenues which was partially offset by the timing of cash receipts related to those revenues.

Net cash provided by investing activities was \$22.8 million and \$9.0 million for the six months ended June 30, 2007 and 2006, respectively. The increase in cash provided by investing activities for the six months ended June 30, 2007, compared with the same period in the prior year, was primarily the result of an increase in net maturities of investments.

Net cash (used in) provided by financing activities was (\$1.5) million and \$4.8 million for the six months ended June 30, 2007 and 2006, respectively. The increase in cash used in financing activities for the six months ended June 30, 2007, compared with the same period in the prior year, was primarily the result of a decrease in proceeds received from the issuance of common stock, which was partially offset by a reduction in the principal payments related to our equipment financing obligations.

We expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including continued increases in 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 two effective shelf registration statements that in the aggregate allow us to raise up to an additional \$111.6 million from the sale of common or preferred stock. However, additional financing may not be available on favorable terms or at all. If additional funding is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our cash 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%. 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 drawdown 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 the Merck, sanofi aventis, AnGes, Merial and Aqua Health agreements, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the Wisconsin Alumni Research Foundation. In addition, certain technology license agreements require us 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 to us.

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## **Table of Contents**

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 June 30, 2007, we have employment agreements that contain severance arrangements with each of our three executive officers and four of our other executives. Under these agreements, we are obligated to pay severance if we terminate such an executive officer's or other executive's employment without cause, or if such 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 six 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 \$1.5 million if each such executive officer and other executive was terminated at June 30, 2007.

### **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 \$0.3 million lower than the reported fair value of our non-equity investments at June 30, 2007. At June 30, 2007, our unrealized gain on non-equity investments was \$7,000. We expect higher investment income for the full year 2007 compared with 2006 due to higher 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 executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2007.

#### **Changes in Internal Controls**

There has been no change in our internal control over financial reporting during the three months ended June 30, 2007, 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 February 23, 2007.





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## **Table of Contents**

The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2006, as filed with the Securities and Exchange Commission.

***(\*)None of our independently developed product candidates has been approved for sale, and we have a limited number of independently developed 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 independently developed 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 product candidates. 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 product candidates are unsafe or ineffective. In this case, regulatory authorities will not approve them.

For example, our independently developed product candidates currently in ongoing clinical evaluation include Allovectin-7<sup>®</sup>, for which we announced initiation of Phase 3 clinical testing in 2007, our CMV vaccine, for which we initiated Phase 2 clinical testing in 2006, and our IL-2/EP program, which is currently in Phase 1 clinical testing. We may not sufficiently enroll patients in our Allovectin-7<sup>®</sup> trial and may not meet the primary endpoint of the trial as specified in our Special Protocol Assessment. 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, such as our influenza vaccine using Vaxfectin<sup>®</sup> as an adjuvant. We plan to initiate Phase 1 clinical testing of our influenza candidate in the second half of 2007. 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 a research and development agreement with AnGes, pursuant to which we rely on AnGes to fund the Phase 3 clinical trial of our cancer immunotherapeutic, Allovectin-7<sup>®</sup>, through cash payments and equity investments.

Some collaborators or licensees may not succeed in their product development efforts, such as Corautus, with whom we entered into a termination agreement relating to a license of our core DNA delivery technology for specific cardiovascular applications. 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.

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.

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**Table of Contents**

*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 receive grants from governmental agencies and 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 expired in July 2007. We do not expect to receive future material orders for the manufacture of bulk DNA from the subcontractor as the subcontractor has built its own DNA vaccine manufacturing facility to manufacture future VRC production orders.

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 these sources may not be available.

*(\*)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 \$23.1 million, \$24.4 million and \$23.7 million for the years ended December 31, 2006, 2005 and 2004, respectively. As of June 30, 2007, we had incurred cumulative net losses totaling approximately \$203.8 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 two effective shelf registration statements that in the aggregate allow us to raise up to an additional \$111.6 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.

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**Table of Contents**

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 provided only limited 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 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](http://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.

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## **Table of Contents**

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 or the perception of 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 commercial success of some of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. Serious adverse events, including patient deaths, have occurred recently in clinical trials utilizing viral delivery systems to deliver therapeutic genes to the patient's targeted cells. Although none of our current products or studies utilize viral delivery systems, these recent adverse events, as well as any other adverse events in the field of gene therapy that may occur in the future, may negatively influence public perception of gene therapy in general. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community.

Future adverse events in gene therapy or the biotechnology industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials.

In addition, any adverse events that may occur in our clinical trials and any resulting publicity may cause regulatory delays or otherwise affect our product development efforts or clinical trials. 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, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. For example, one patient in our Allovectin-7<sup>®</sup> Phase 2 trial conducted in 2000, died from progressive disease more than two months after receiving Allovectin-7<sup>®</sup> and 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-7<sup>®</sup> was a significant factor in the patient's death. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, in our CMV 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.

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## **Table of Contents**

***(\*)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 55 issued U.S. and foreign patents. 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. Among these issued patents, a Japanese patent related to our core DNA delivery technology was the subject of four Trials for Invalidation, or TFI s, in which the patent was maintained in amended form without further appeal; 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. 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.

We are also prosecuting 102 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. Three 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.

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 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

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## **Table of Contents**

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.

### ***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.

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**Table of Contents**

***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 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.

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



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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.

**Table of Contents**

***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, 2005, to June 30, 2007, our stock price has ranged from \$3.46 to \$7.58. 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;

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.

**Table of Contents**

*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 two effective shelf registration statements that in the aggregate allow us to raise up to an additional \$111.6 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Our Annual Meeting of Stockholders was held on May 23, 2007. At this meeting, we solicited the vote of the stockholders on the proposals set forth below and received for each proposal the votes indicated below:

- (i) To elect two Class III directors to serve until the 2010 Annual Meeting of Stockholders and until their successors are elected. Elected to serve as Class III directors were Robert H. Campbell and Gary A. Lyons. For each elected director the results of voting were: Robert H. Campbell 33,148,322 for and 3,516,945 withheld; and Gary A. Lyons 33,151,729 for and 3,513,538 withheld. Our Class I directors, Robert C. Merton, Ph.D. and Vijay B. Samant, continue in office until the 2008 Annual Meeting of Stockholders. Our Class II director, R. Gordon Douglas, M.D., continues in office until the 2009 Annual Meeting of Stockholders.
  
- (ii) To amend our Amended and Restated Stock Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under the plan by 1,000,000 shares. The amendment was approved with the following votes: 18,001,991 for, 4,558,997 against, 155,787 abstained and 13,948,492 broker non-votes.
  
- (iii) To ratify the selection by the Audit Committee of our Board of Directors of Ernst & Young LLP as our independent auditors for the year ending December 31, 2007. The selection of Ernst & Young LLP as independent auditors for the year ending December 31, 2007, was ratified with the following votes: 35,745,919 for, 875,196 against and 44,152 abstained.

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**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
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.
10.1(3)	Amended and Restated Stock Incentive Plan of Vical Incorporated.
31.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	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 Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Church, Chief Financial Officer, 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 exhibit 99.1 filed with the Company's Registration Statement on Form S-8 (No. 333-143885) filed on June 19, 2007.

**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: August 8, 2007

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)