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

FORM 10-Q

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

For the quarterly period ended June 30, 2005

or

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

For the transition period from to .

Commission File Number: 000-21088

VICAL INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	**93-0948554**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10390 Pacific Center Court San Diego, California	**92121**
(Address of principal executive offices)	**(Zip code)**

(858) 646-1100
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or 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 an accelerated filer (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 July 27, 2005: 23,518,413

Table of Contents

VICAL INCORPORATED

FORM 10-Q

INDEX

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VICAL INCORPORATED

BALANCE SHEETS
(In thousands, except par value data)
(Unaudited)

	June 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,616	$ 17,666
Restricted cash equivalents	2,703	2,703
Marketable securities, available-for-sale	43,741	53,627
Receivables and other	4,894	3,412
Total current assets	63,954	77,408
Property and equipment, net	15,760	16,277
Intangible assets, net	5,583	5,775
Other assets	1,791	1,766
Total assets	$ 87,088	$ 101,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,752	$ 4,970
Current portion of equipment financing obligations	4,895	4,607
Deferred revenue	—	531
Total current liabilities	9,647	10,108
Long-term liabilities:		
Equipment financing obligations	4,458	5,822
Deferred rent	1,865	1,814
Other liabilities	500	573
Total long-term liabilities	6,823	8,209
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.01 par value, 40,000 shares authorized, 23,518 and 23,502 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively	235	235
Additional paid-in capital	221,584	221,341
Accumulated deficit	(151,077)	(138,517)
Accumulated other comprehensive loss	(124)	(150)
Total stockholders' equity	70,618	82,909
Total liabilities and stockholders' equity	$ 87,088	$ 101,226

See accompanying notes to unaudited financial statements

VICAL INCORPORATED

STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Revenues:				
Contract and grant revenue	$ 487	$ 3,815	$ 2,940	$ 4,102
License and royalty revenue	4,320	1,927	4,551	2,549
Total revenues	4,807	5,742	7,491	6,651
Operating expenses:				
Research and development	4,756	4,680	9,229	10,852
Manufacturing and production	3,353	3,975	7,265	5,978
General and administrative	1,923	2,535	4,038	4,481
Total operating expenses	10,032	11,190	20,532	21,311
Loss from operations	(5,225)	(5,448)	(13,041)	(14,660)
Other income (expense):				
Investment income	382	320	766	620
Interest expense	(139)	(188)	(285)	(351)
Net loss	$ (4,982)	$ (5,316)	$ (12,560)	$ (14,391)
Basic and diluted net loss per share	$ (0.21)	$ (0.23)	$ (0.53)	$ (0.66)
Weighted average shares used in computing basic and diluted net loss per share	23,517	23,476	23,513	21,896

See accompanying notes to unaudited financial statements

VICAL INCORPORATED

STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six months ended June 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (12,560)	$ (14,391)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,868	1,882
Write-off of abandoned patents	97	35
Compensation expense related to stock options and awards	203	294
Changes in operating assets and liabilities:		
Receivables and other	(1,230)	(295)
Other assets	498	114
Accounts payable and accrued expenses	(242)	907
Deferred revenue	(531)	(2,064)
Deferred rent	2	168
Net cash used in operating activities	(11,895)	(13,350)
Cash flows from investing activities:		
Maturities of marketable securities—including restricted	31,867	25,981
Purchases of marketable securities—including restricted	(21,955)	(30,981)
Maturities of restricted cash equivalents	—	2,222
Purchases of restricted cash equivalents	—	(544)
Purchases of property and equipment	(997)	(2,380)
Patent expenditures	(259)	(373)
Net cash provided by (used in) investing activities	8,656	(6,075)
Cash flows from financing activities:		
Proceeds from issuance of common stock	40	17,265
Payments on notes payable	—	(186)
Principal payments under equipment financing obligations	(2,368)	(2,114)
Proceeds from equipment financing arrangements	517	2,121
Net cash (used in) provided by financing activities	(1,811)	17,086
Net decrease in cash and cash equivalents	(5,050)	(2,339)
Cash and cash equivalents at beginning of period	17,666	16,574
Cash and cash equivalents at end of period	$ 12,616	$ 14,235
Supplemental information:		
Interest paid	$ 284	$ 383

See accompanying notes to unaudited financial statements

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS
June 30, 2005
(Unaudited)

1. GENERAL

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

The unaudited financial statements at June 30, 2005, and for the three and six months ended June 30, 2005 and 2004, have been prepared in accordance with accounting principles generally accepted in the U.S. 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, 2004, included in its Form 10-K filed with the Securities and Exchange Commission, or SEC.

Issuance of Common Stock

In March 2004, the Company raised approximately $17.3 million in net proceeds from the sale of approximately 3.4 million shares of its common stock at $5.50 per share in a registered direct offering to a select group of institutional investors. All of the common stock was offered by the Company pursuant to the shelf registration statement declared effective in December 2003. The shelf registration allows the Company to issue from time to time up to approximately $31.4 million of additional common or preferred stock.

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 Cash Equivalents

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, 2005, and December 31, 2004, restricted cash equivalents of $2.7 million were pledged as collateral for the letter of credit.

Revenue Recognition

The Company earns revenue by performing services under research and development agreements, grants, manufacturing contracts and from licensing its proprietary technology. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determined, and collection is reasonably assured.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

The Company enters into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used primarily for preclinical and clinical research. Under these contracts, revenue and related expenses are recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met. Advance payments received in excess of amounts earned are classified as deferred revenue.

Revenue under research and development agreements, grants, and manufacturing contracts, except for fixed-price contracts, is recognized as the research and development or manufacturing expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met.

Other revenues include amounts received from licensing the Company's proprietary technology, which occurs under a variety of circumstances including licenses, options and royalties. Any initial license or option payment received under a research and development agreement is recognized as revenue over the term of the research and development period. Upfront license payments are recognized as revenue upon contract signing only if the fee is nonrefundable and noncreditable, and if there are no performance obligations remaining. Payments for options to license the Company's technology are recognized as revenue over the option period. Royalty revenue is recognized when earned and when collectibility is reasonably assured.

Revenue from milestones are recognized as agreed-upon events representing the achievement of substantive steps in the development process are achieved, or as agreed-upon passages of time occur, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured.

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 0.1 million and 0.4 million for the three months ended June 30, 2005 and 2004, respectively, were excluded from the calculation because of their antidilutive effect. Common stock equivalents of 0.3 million and 0.5 million for the six months ended June 30, 2005 and 2004, respectively, were excluded from the calculation because of their antidilutive effect.

Stock-Based Compensation

The Company accounts for stock options issued under its stock incentive plan using the recognition and measurement principles of Accounting Principles Board, or APB, Opinion No. 25, "*Accounting for Stock Issued to Employees*," and its related interpretations, and has adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, "*Accounting for Stock-Based Compensation*," and its related interpretations.

Pro forma information regarding net loss and loss per share is required by SFAS No. 123 and has been determined as if the Company had accounted for its stock options under the fair value method of that Statement. The fair value for these options was estimated at the dates of grant using the Black-Scholes option valuation model. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

The Company's pro forma information is as follows (in thousands, except for per share information):

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Net loss, as reported	$(4,982)	$(5,316)	$(12,560)	$(14,391)
Add stock-based compensation expense included in reported net loss	120	217	203	294
Less stock-based compensation expense determined under fair value based method	(692)	(972)	(1,250)	(1,810)
Pro forma net loss	$(5,554)	$(6,071)	$(13,607)	$(15,907)
Basic and diluted net loss per share, as reported	$ (0.21)	$ (0.23)	$ (0.53)	$ (0.66)
Basic and diluted pro forma net loss per share	$ (0.24)	$ (0.26)	$ (0.58)	$ (0.73)
Weighted average fair value of stock options	$ 2.49	$ 3.71	$ 3.31	$ 4.38
Assumptions:				
Assumed risk-free interest rate	3.84%	3.75%	3.96%	3.03%
Assumed volatility	78%	80%	79%	81%
Expected option life	4 years	4 years	4 years	4 years
Dividend yields	—	—	—	—

Facility Consolidation

The Company completed the planned consolidation of its manufacturing operations into its primary facility during the three months ended June 30, 2005. As a result of this consolidation, the Company recorded charges of $0.4 million which were included in manufacturing and production expense during the three months ended June 30, 2005. The charges were primarily comprised of expenses associated with the remaining rent due under the lease for the vacated facility, which expires in November 2005. The remaining estimated accrued liability for the facility consolidation was $0.3 million as of June 30, 2005.

Reclassifications

The Company has reclassified $1.7 million of net maturities and purchases of restricted cash equivalents in the Statement of Cash Flows from a financing activity to an investing activity for 2004, to conform to the current year presentation. The Company has reclassified $2.1 million of amounts borrowed under a financing agreement in the Statement of Cash Flows from an investing activity to a financing activity for 2004, to conform to the current year presentation. The Company has reclassified $0.1 million of purchases of property and equipment in its Statement of Cash Flows from an operating activity to an investing activity for 2004, to conform to current year presentation. In addition, the Company has segregated its research and development costs between research and development costs and manufacturing and production costs in the Statement of Operations for 2004, to conform to the current year presentation.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

2. RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123(R), "*Share-Based Payment,*" which is a revision of SFAS No. 123, "*Accounting for Stock-Based Compensation*". SFAS No. 123(R) requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. The compensation cost will be measured based on the fair value of the equity or liability instruments issued. On April 14, 2005, the SEC announced that the effective date of SFAS No. 123(R) will be postponed until January 1, 2006, for calendar year companies. The Company will adopt SFAS No. 123(R) on January 1, 2006. The Company has not determined the impact of adopting SFAS No. 123(R) on the statement of operations and earnings per share. Further, the Company does not yet know the impact that any future share-based payment transactions will have on its financial statements.

3. COMPREHENSIVE LOSS

Comprehensive loss consists of net loss and other comprehensive income or loss. Accumulated other comprehensive losses represents net unrealized losses on marketable securities. For the three months ended June 30, 2005 and 2004, other comprehensive income (loss) was $0.1 million and ($0.5) million, respectively, and total comprehensive losses were $4.9 million and $5.8 million, respectively. For the six months ended June 30, 2005 and 2004, other comprehensive income (loss) was $26,000 and ($12,000), respectively, and total comprehensive losses were $12.5 million and $14.4 million, respectively.

4. RECENT CONTRACT, GRANT AND LICENSE ACTIVITIES

Merck Option Exercise

In June 2005, Merck & Co., Inc., or Merck, exercised three options under a 2003 amendment to a 1991 research collaboration and license agreement granting Merck rights to use the Company's patented non-viral gene delivery technology in cancer vaccine applications. As a result of these option exercises the Company recognized license revenue totaling $3.0 million during the three months ended June 30, 2005.

AnGes License

In May 2005, AnGes MG, Inc., or AnGes, licensed exclusive, worldwide rights to use the Company's patented non-viral gene delivery technology in the development and commercialization of DNA-based products encoding Hepatocyte Growth Factor for cardiovascular applications. Under the terms of the license agreement, the Company received and recognized as revenue during the three months ended June 30, 2005, a nonrefundable and noncreditable upfront payment of $1.0 million.

NIH Contracts

Under subcontract agreements with the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institutes of Health, or NIH, the Company manufactures HIV, Ebola, West Nile Virus and severe acute respiratory syndrome, or SARS, DNA vaccines. These subcontracts are issued and managed on behalf of the VRC by SAIC-Frederick, Inc. under the umbrella of a federally funded contract with the NIH. Revenue recognized under these subcontracts was $32,000 and $3.8 million for the three months ended June 30, 2005 and 2004, respectively. Revenue recognized under these subcontracts was $1.1 million and $3.8 million for the six months ended June 30, 2005 and 2004, respectively.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

CMV Grants

The Company's research and development related to its cytomegalovirus, or CMV, vaccine program has been partially supported under grants from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, of the NIH. The most recent, in March 2005, was a three-year, $3.1 million Phase II Small Business Innovation Research, or SBIR, grant from the NIAID. The grant will partially fund the ongoing development of Vical's immunotherapeutic DNA vaccine against CMV disease. Revenue recognized under these grants was $0.1 million and $49,000 for the three months ended June 30, 2005 and 2004, respectively. Revenue recognized under these grants was $1.2 million and $0.3 million for the six months ended June 30, 2005 and 2004, respectively.

5. COMPOSITION OF CERTAIN BALANCE SHEET CAPTIONS

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

	June 30, 2005	December 31, 2004
Employee compensation	$1,542	$ 1,985
Accrued royalty	900	500
Accrued contract liabilities	395	492
Accounts payable	190	560
Other accrued liabilities	1,725	1,433
	$4,752	$ 4,970

6. COMMITMENTS AND CONTINGENCIES

If the Company fails to satisfy its contractual obligations to deliver the vaccines ordered by the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institutes of Health, or NIH, in the manner required by the Company's manufacturing agreements with the VRC, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreements in whole or in part, and the Company may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, and/or Government Furnished Equipment, or GFE, and/or other government property in its possession, and/or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected. Government agencies may fail to perform their responsibilities under these agreements and they may terminate the agreements.

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 of the Company.

In addition, the Company has undertaken certain commitments under agreements with its collaborators, and under employment agreements with its officers. Under license agreements with its collaborators, the Company has agreed to continue to maintain and defend the patent rights licensed to the collaborators.

7. RELATED-PARTY TRANSACTIONS

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, is no longer the Director of Strategic Planning at the VRC, for which the Company has manufacturing sub-contracts. Revenue recognized under these subcontracts was $32,000 and $3.8 million for the three months ended June 30, 2005 and 2004, respectively. Revenue recognized under these subcontracts was $1.1 million and $3.8 million for the six months ended June 30, 2005 and 2004, respectively.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery technologies, and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery technologies. Actual results could differ materially from those herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2004, and our other filings with the Securities and Exchange Commission, and those identified in the section of Item 2 entitled "Risk Factors" beginning on page 20 of this Report. As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

Overview

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

- Vaccines for use in high-risk populations for infectious disease targets for which there are significant U.S. needs;
- Vaccines for general pediatric or adult populations for infectious disease applications; and
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise;

We plan to continue leveraging our patented technologies through licensing and collaborations. We also plan to use our expertise, infrastructure, and financial strength to explore both in-licensing and acquisition opportunities.

We have established relationships through licensing our technologies to a number of commercial entities, including:

- Merck & Co., Inc., or Merck;
- Two divisions of the Sanofi-Aventis Group, or Sanofi-Aventis:
  - Sanofi Pasteur, and
  - Centelion SAS, or Centelion, a wholly-owned subsidiary of Aventis Pharmaceuticals S.A.;
- Merial Ltd., or Merial, a joint venture between Merck and Sanofi-Aventis;
- Corautus Genetics Inc., or Corautus;
- Aqua Health Ltd., or Aqua Health, an affiliate of Novartis Animal Health;
- Invitrogen Corporation, or Invitrogen; and
- AnGes MG, Inc., or AnGes.

We have also licensed complementary technologies from:

- The Wisconsin Alumni Research Foundation, or WARF;
- The University of Michigan;
- Inovio Biomedical Corporation, or Inovio (formerly Genetronics Biomedical Corporation);
- CytRx Corporation, or CytRx;

- The National Institutes of Health, or NIH; and
- The U.S. Centers for Disease Control and Prevention, or CDC.

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, cancer, and cardiovascular diseases. Our current independent development focus is on our cancer immunotherapeutics, Allovectin-7® and IL-2/Electroporation, or EP, as well as a novel plasmid DNA, or pDNA, vaccine for cytomegalovirus, or CMV. The table below summarizes our independent, collaborative and out-licensed product development programs.

Product Area	Project Target and Indication(s)	Development Status[1]	Development Rights
Cancer			
Immunotherapeutic	High-dose Allovectin-7® for metastatic melanoma	Phase 2	Vical
”	IL-2/EP for solid tumors	Phase 1	Vical
Tumor-associated antigen therapeutic vaccines	Unspecified cancer[2]	Research	Sanofi Pasteur
”	Unspecified cancer[2]	Research	Merck
Infectious Disease			
Infectious disease vaccine	Cytomegalovirus	Phase 1	Vical
	Plasmodium falciparum (malaria)	Phase 1/2	Vical
”	*Bacillus anthracis* (anthrax)	Phase 1	Vical
”	Ebola virus	Phase 1	Vical/NIH
”	West Nile virus	Phase 1	Vical/NIH
”	SARS coronavirus	Phase 1	NIH
”	HIV—therapeutic	Phase 1	Vical/NIH
”	HIV—preventive	Phase 1	Merck
”	HIV—therapeutic	Phase 1	Merck
”	HIV EP—therapeutic	Research	Vical/NIH
”	Hepatitis B virus—preventive	Research	Merck
”	Hepatitis B virus—therapeutic	Research	Merck
”	Hepatitis C virus—preventive	Research	Merck
Cardiovascular			
Angiogenic growth factor	HGF, peripheral arterial disease	Phase 3	AnGes/Daiichi Pharma
”	HGF, ischemic heart disease	Phase 1	AnGes/Daiichi Pharma
”	VEGF-2, coronary artery disease	Phase 2	Corautus
”	FGF-1, peripheral arterial disease	Phase 2	Centelion
Veterinary			
Preventive infectious disease vaccine(s)			
	Infectious Haematopoietic Necrosis Virus	Approved in Canada	Aqua Health
”	Various undisclosed[2]	Research-Clinical	Merial
Protective cancer vaccine	Melonoma in dogs	Clinical	Merial

[1] “Research” indicates exploration and/or evaluation of a potential product candidate in a nonclinical laboratory setting. “Preclinical” indicates that a specific product candidate in a nonclinical setting has shown

functional activity that is relevant to a targeted medical need, and is in preparation for human clinical trials. “Phase 1” clinical trials include the first use of an investigational new drug in humans and are conducted in a small group of patients or normal volunteer subjects (20-80) to evaluate the safety, determine a safe dosage range, and identify side effects, and, if possible, gain early evidence on effectiveness. ”Phase 2” clinical trials are typically well controlled and conducted in a larger group of subjects (no more than several hundred) to evaluate effectiveness of an investigational drug for a defined patient population, and to determine common short-term side effects and risks associated with the drug. ”Phase 3” clinical trials are conducted in an even larger group of subjects (several hundred to thousands) to evaluate the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling. At times, a single trial may incorporate elements from different phases of development. An example might be a trial designed to determine both safety and initial efficacy. Such a trial may be referred to as a “Phase 1/2” clinical trial. For veterinary products, “Clinical” indicates testing in the target species.

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

See the section entitled “Business” in our Annual Report on Form 10-K for the year ended December 31, 2004, for a detailed discussion of our independent, collaborative and out-licensed product development programs.

Recent Events

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

- In July 2005, we announced that our licensee Aqua Health Ltd. of Canada, an affiliate of the Swiss-based company Novartis Animal Health, received notification of approval from the Canadian Food Inspection Agency to sell its proprietary product, APEX-IHN, a DNA vaccine to protect farm-raised salmon against Infectious Haematopoeitic Necrosis Virus.
- In May 2005, we announced that AnGes licensed exclusive, worldwide rights to use our patented non-viral gene delivery technology in the development and commercialization of DNA-based products encoding Hepatocyte Growth Factor, or HGF, for cardiovascular applications. Under the license agreement, we received an initial upfront payment of $1.0 million, and further development may lead to milestone and royalty payments. AnGes partnered with Daiichi Pharmaceutical Co., Ltd. for worldwide development and commercialization of DNA-based HGF for peripheral arterial disease and ischemic heart disease.
- In June 2005, we presented conclusions from our Phase 2 trial with high-dose Allovectin-7® and design of our Phase 3 trial for chemo-naive patients with metastatic melanoma. The data were featured at the annual meeting of the American Society of Clinical Oncology in a poster session led by Jon M. Richards, M.D., Ph.D., Division of Hematology/Oncology at Lutheran General Hospital in Park Ridge, Illinois, a principal investigator in our Allovectin-7® trials.
- Also in June 2005, we announced that Merck exercised three options under a 2003 amendment to an existing research collaboration and license agreement, granting Merck rights to use our patented non-viral gene delivery technology in cancer vaccine applications. As a result of the option exercise, we received a payment of $3.0 million, and further development may lead to milestone and royalty payments. In addition, we have certain co-promotion rights for therapeutic products resulting from the agreement.
- Also in June 2005, we announced that the Office of Orphan Products Development of the U.S. Food and Drug Administration, or FDA, has designated our bivalent, or two-plasmid, formulation of our vaccine against CMV as an orphan drug for the prevention of clinically significant CMV viremia, CMV disease and associated complications in at-risk hematopoietic cell transplant, or HCT, and solid organ transplant, or SOT, populations. We expect the vaccine to enter Phase 2 human trials in HCT donor-recipients in the second half of 2005.

- Also in June 2005, we announced the receipt of approximately $12.1 million in production orders for multiple clinical lots of DNA vaccines against HIV for the Dale and Betty Bumpers Vaccine Research Center, or VRC, at the National Institute of Allergy and Infectious Diseases of the NIH, under a subcontract managed by SAIC-Frederick, Inc. Production is scheduled to begin in the second half of 2005, with shipments anticipated in 2005 and 2006 in support of planned Phase 2 studies. We have produced multiple DNA vaccines for the VRC against infectious disease targets including Ebola, severe acute respiratory syndrome, or SARS, and West Nile virus.
- Also in June 2005, we entered into a Cooperative Research and Development Agreement with the NIH for development of a therapeutic DNA vaccine against HIV using EP.
- Also in June 2005, Vical's European Patent EP1026253 directed to the use of*in vivo* polynucleotide delivery for a variety of applications was opposed by 8 parties.
- Also in June 2005, Vical's Japanese patent JP3683798 directed to the use of cationic lipids for*in vivo* polynucleotide delivery was granted.
- In July 2005, we announced the initiation of a human Phase 1 study of an investigational method of delivering DNA expressing interleukin-2, or IL-2, a potent immune system stimulant, for patients with recurrent metastatic melanoma. Intravenous delivery of IL-2 protein is approved as a treatment for metastatic melanoma and renal cell carcinoma, but frequently causes severe systemic toxicities. The novel treatment approach being studied in this trial involves direct injection into a tumor lesion of pDNA encoding IL-2 followed by electroporation, the local application of electrical pulses designed to enhance the uptake of the pDNA into tumor cells. The pDNA is designed to cause cells within the tumor to produce high levels of IL-2 protein locally and stimulate the immune system to attack the tumor without the associated systemic toxicities.
- In August 2005, Merial advised us that initial trials of a pDNA melanoma vaccine for dogs have been completed and the vaccine is expected to receive approval for conditional USDA license use by early 2006.

Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products. We earn revenue by performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately $114.1 million in revenue under these types of agreements.

Revenues by source for each of the three and six months ended June 30, 2005 and 2004, were as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Source				
NIH contracts	$ —	$ 3.8	$ 1.3	$ 3.8
CMV grants	0.1	—	1.2	0.3
Other contracts and grants	0.4	—	0.4	—
Total contract and grant revenues	0.5	3.8	2.9	4.1
Sanofi-Aventis licenses	—	1.2	—	1.2
Merck license	3.0	—	3.0	—
AnGes license	1.0	—	1.0	—
Other royalties and licenses	0.3	0.7	0.6	1.4
Total royalty and license revenues	4.3	1.9	4.6	2.6
Total revenues	$ 4.8	$ 5.7	$ 7.5	$ 6.7

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Program				
Allovectin-7®	$ 1.2	$ 1.0	$ 2.3	$ 3.1
CMV	2.3	2.5	4.5	4.7
Anthrax	0.4	0.5	0.9	2.0
IL-2/EP	0.6	0.8	1.4	1.0
Other research, development, manufacturing and production	3.6	3.9	7.4	6.0
Total research, development, manufacturing and production	$ 8.1	$ 8.7	$ 16.5	$ 16.8

Since our inception, we estimate that we have spent approximately $230 million on research, development, manufacturing and production. Our current independent development focus is on novel DNA vaccines for CMV as well as our cancer immunotherapeutics Allovectin-7® and IL-2/EP. From inception, we have spent approximately $59 million on our Allovectin-7® program. In 2004, we completed a Phase 2 trial evaluating high-dose, 2 mg, Allovectin-7® as a standalone product. We have successfully completed a Special Protocol Assessment, or SPA, with the FDA for a Phase 3 trial of high-dose Allovectin-7® that would be needed to support submission of a Biologics License Application, or BLA. This and potential future trials would add to the time and cost of development of Allovectin-7®.

Additionally, we are 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 $22 million on our CMV program, and approximately $4 million on our IL-2 EP program. We are in the early stages of clinical development of an anthrax vaccine candidate; however, due to the lack of additional government funding, we do not intend to pursue further development of our anthrax vaccine candidate at this time except for the ongoing development supported by a Small Business Innovation Research, or SBIR, grant.

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 expansion of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs due to increased contract manufacturing activities, increased costs of our facilities, and possible advancement toward commercialization activities.

Critical Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets,

liabilities, revenues and expenses, and disclosures of contingent assets and liabilities. Actual results could differ from those estimates. Specifically, management must make estimates in the following areas:

Intangible assets. We capitalize the license fees we pay to acquire access to proprietary technologies if the technologies are expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized using the straight-line method over the estimated average useful life of the technology, which is generally ten years. We also capitalize certain costs related to patent applications which have alternative future use in multiple research and development projects. Accumulated costs are amortized using the straight-line method over the estimated economic life of the patent, which is generally 20 years and usually commences at the time the patent application is filed. We review long-lived assets for impairment at least annually, quarterly for intangible assets, and whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. If assets are to be disposed of, they are reported at the lower of the carrying amount or fair value, less costs to sell. Loss of legal ownership or rights to patents or licensed technologies, or significant changes in our strategic business objectives and utilization of the assets, among other things, could give rise to asset impairment.

Deferred tax assets. Deferred tax assets are recorded net of a 100% valuation allowance. This valuation allowance reduces the gross deferred tax assets to the amount that we believe is more likely than not realizable. We considered projections of future taxable income, past operating results and tax planning strategies in making this determination.

Clinical trial expenses. We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the trial site and other external expenses related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the number of treatments for each patient. Treatment periods vary depending on the clinical trial. We make revisions to the clinical trial cost estimates as clinical trials progress. Clinical trial expense was $0.3 million and $0.2 million for the three months ended June 30, 2005 and 2004, respectively. Clinical trial expense was $0.5 million and $0.3 million for the six months ended June 30, 2005 and 2004, respectively. No material revisions to our previous clinical trial cost estimates were made in the periods presented.

Accruals for potential disallowed costs on contracts. We have contracts with agencies of the U.S. government under which we bill for direct and indirect costs incurred. These billed costs are subject to audit by government agencies, such as the NIH. We have established accruals of approximately $0.4 million at June 30, 2005, to provide for potential disallowed costs. In the event that the final costs allowed are different from what we have estimated, we adjust our estimated accrual, which could also affect our results of operations and cash flow. No material adjustments were made to our previously estimated accruals in the periods presented.

Revenue Recognition

We earn revenue by performing services under research and development contracts, grants, and manufacturing contracts, and from licensing our proprietary technologies. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determined, and collection is reasonably assured.

We enter into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used primarily for preclinical and clinical research. Under these contracts, revenue and related expenses are recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met. Advance payments received in excess of amounts earned are classified as deferred revenue.

Revenue under research and development contracts, grants, and manufacturing contracts, except for fixed-price contracts, is recognized as the research and development or manufacturing expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met.

Other revenues include amounts received from licensing our proprietary technologies, which occurs under a variety of circumstances including licenses, options and royalties. Any initial license or option payment received under a research and development services agreement is recognized as revenue over the term of the research and development period. Upfront license payments are recognized as revenue upon contract signing if the fee is nonrefundable and noncreditable, and if there are no performance obligations remaining. Payments for options to license our technologies are recognized as revenue over the option period. Royalty revenue is recognized when earned and when collectibility is reasonably assured.

Revenue from milestones are recognized as agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the agreed-upon passage of time occurs, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured.

Results of Operations

Three Months Ended June 30, 2005, Compared with Three Months Ended June 30, 2004

Total Revenues. Total revenues decreased $0.9 million, or 16%, to $4.8 million for the three months ended June 30, 2005, from $5.7 million for the three months ended June 30, 2004. Revenues from our contracts and grants were $0.5 million for the three months ended June 30, 2005, compared to $3.8 million for the three months ended June 30, 2004. Contract and grant revenue for the three months ended June 30, 2005, included revenues of $0.5 million related to various NIH grants while the prior year included $3.8 million in manufacturing contract shipments to the VRC under our NIH agreement.

License and royalty revenue was $4.3 million for the three months ended June 30, 2005, as compared with $1.9 million for the three months ended June 30, 2004. The increase in license and royalty revenue was primarily related to license fees received during the three months ended June 30, 2005, from Merck and AnGes which totaled $3.0 million and $1.0 million, respectively. During the three months ended June 30, 2004, we received license fees from Sanofi-Aventis which totaled $1.2 million.

Research and Development Expenses. Research and development expenses increased $0.1 million, or 1.6%, to $4.8 million for the three months ended June 30, 2005, from $4.7 million for the three months ended June 30, 2004. The increase was the result of a $0.4 million increase in royalty payments made to the WARF in connection with the Merck and AnGes license agreements which was partially offset by a decrease in facility costs, scientific supplies, and contract services.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased $0.6 million, or 15.6%, to $3.4 million for the three months ended June 30, 2005, from $4.0 million for the three months ended June 30, 2004. The decrease was the result of a $2.0 million decrease in net costs recognized related to various manufacturing programs for the VRC. That decrease was partially offset by a charge of $0.4 million related to the consolidation of our manufacturing facilities, higher costs for supplies of $0.3 million, and additional costs of $0.4 million related to maintenance and repair costs, utilities and depreciation. The primary focus of manufacturing and production during the three months ended June 30, 2005, was the production of plasmids to be used in the planned Phase 2 clinical trial of our bivalent CMV vaccine. The primary focus of manufacturing and production during the three months ended June 30, 2004, was the validation of our new manufacturing facility and the completion of our commitments under manufacturing contracts.

General and Administrative Expenses. General and administrative expenses decreased $0.6 million, or 24.1%, to $1.9 million for the three months ended June 30, 2005, from $2.5 million for the three months ended June 30, 2004. The decrease was primarily the result of severance costs of $0.5 million recorded in the prior year.

Investment Income. Investment income increased $0.1 million, or 19.4%, to $0.4 million for the three months ended June 30, 2005, from $0.3 million for the three months ended June 30, 2004. This increase was the result of higher rates of return on our investments partially offset by lower average cash and short-term investment balances.

Interest Expense. Interest expense decreased $0.1 million, or 26.6%, to $0.1 million for the three months ended June 30, 2005 from $0.2 million for the three months ended June 30, 2004. The decrease was primarily due to lower interest rates on our equipment financing obligations.

Six Months Ended June 30, 2005, Compared with Six Months Ended June 30, 2004

Total Revenues. Total revenues increased $0.8 million, or 12.6%, to $7.5 million for the six months ended June 30, 2005, from $6.7 million for the six months ended June 30, 2004. Revenues from our contracts and grants were $2.9 million for the six months ended June 30, 2005, compared with $4.1 million for the six months ended June 30, 2004. Revenues from manufacturing contract shipments to the VRC under our NIH agreement totaled $1.1 million and $3.8 million for the six months ended June 30, 2005 and 2004, respectively. Revenues from various NIH grants totaled $1.5 million and $0.3 million for the six months ended June 30, 2005 and 2004, respectively.

License and royalty revenue was $4.6 million for the six months ended June 30, 2005 compared with $2.6 million for the six months ended June 30, 2004. The increase in license and royalty revenue was primarily related to license fees received during the three months ended June 30, 2005 from Merck and AnGes which totaled $3.0 million and $1.0 million, respectively. During the six months ended June 30, 2004, we received license fees from Sanofi-Aventis and Corautus of $1.2 million and $0.5 million, respectively.

Research and Development Expenses. Research and development expenses decreased $1.6 million, or 15.0%, to $9.2 million for the six months ended June 30, 2005, from $10.9 million for the six months ended June 30, 2004. This decrease was primarily a result of the settlement of the WARF litigation recognized during the six months ended June 30, 2004.

Manufacturing and Production Expenses. Manufacturing and production expenses increased $1.3 million, or 21.5%, to $7.3 million for the six months ended June 30, 2005, from $6.0 million for the six months ended June 30, 2004. The increase was the result of increased expenses of $0.8 million related to additional maintenance and repair costs, utilities and depreciation, increased costs for supplies of $0.5 million, an increase of $0.4 million due to the reduction in costs capitalized for the validation of our manufacturing facility, a charge of $0.4 million taken in the current period related to the consolidation of our manufacturing facilities, and increased personnel costs of $0.2 million, all of which was partially offset by a decrease of $1.1 million in net costs recognized related to various manufacturing programs for the VRC. The primary focus of manufacturing and production during the six months ended June 30, 2005, was the production of plasmids to be used in the planned Phase 2 clinical trial of our bivalent CMV vaccine. The primary focus of manufacturing and production during the six months ended June 30, 2004, was the validation of our new manufacturing facility and the completion of our commitments under manufacturing contracts.

General and Administrative Expenses. General and administrative expenses decreased $0.5 million, or 9.9%, to $4.0 million for the six months ended June 30, 2005, from $4.5 million for the six months ended June 30, 2004. This decrease was primarily the result of severance costs of $0.5 million recorded in the prior year.

Investment Income. Investment income increased $0.2 million, or 23.5%, to $0.8 million for the six months ended June 30, 2005, from $0.6 million for the six months ended June 30, 2004. This increase was the result of higher rates of return on our investments partially offset by lower average cash and short-term investment balances.

Interest Expense. Interest expense decreased $0.1 million, or 19.1%, to $0.3 million for the six months ended June 30, 2005, from $0.4 million for the six months ended June 30, 2004. The decrease was primarily due to lower interest rates on our equipment financing obligations.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, public offerings of common stock, and revenues from collaborative agreements. From our inception through June 30, 2005, we have received approximately $114.1 million in revenues from performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately $220.0 million from the sale of equity securities. As of June 30, 2005, we had working capital of approximately $54.3 million, compared with $67.3 million at December 31, 2004. Cash, cash equivalents and marketable securities, including restricted securities, totaled approximately $59.1 million at June 30, 2005, compared with $74.0 million at December 31, 2004. The declines in our cash, cash equivalents and marketable securities in the six months ended June 30, 2005, were due primarily to cash used to fund our operations and to pay our long-term debt obligations.

Net cash used in operating activities was $11.9 million and $13.4 million for the six months ended June 30, 2005 and 2004, respectively. The relative decrease in net cash used in operating activities for the six months ended June 30, 2005 compared to the same period in the prior year reflects a decrease in the net loss partially offset by an increase in receivables balances, a decrease in deferred revenue for the comparable periods and higher net payments for accounts payable and accrued expenses.

Cash provided by (used in) investing activities was $8.7 million and $(6.1) million for the six months ended June 30, 2005 and 2004, respectively. The relative increase in cash provided by investing activities for the six months ended June 30, 2005 compared to the same period in the prior year was primarily the result of an increase in net maturities of investments.

Cash (used in) provided by financing activities was $(1.8) million and $17.1 million for the six months ended June 30, 2005 and 2004, respectively. The relative decrease in cash provided by financing activities for the six months ended June 30, 2005 compared to the same period in the prior year was primarily the result of the closing of our registered direct stock offering in March 2004 which provided $17.3 million of cash.

For the twelve months ending December 31, 2005, we have forecast a net loss of between $23 million and $26 million. We expect that our total net cash used in 2005 may differ from our projected net loss principally because of timing of cash receipts on certain contract work.

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. In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which allows us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock, of which approximately $31.4 million was remaining as of June 30, 2005. 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 operating needs through at least 2006.

Contractual Obligations

We have entered into an equipment financing arrangement which requires payments through 2009. As of June 30, 2005 we had $3.9 million in available credit which is available for drawdown through October 31, 2005. Financial covenants under the agreement include a requirement that we maintain specified levels of unrestricted cash and marketable securities. In the event of default on this covenant, we would be required to provide an irrevocable letter of credit equal to 100% of the then-outstanding balance of amounts financed.

We may be subject to contractual obligations under licensing and other agreements. Under the Merck, Sanofi Pasteur, Centelion, Merial, Corautus, Aqua Health, and AnGes agreements, we would be required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the WARF. The CytRx and Inovio agreements would 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.

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, 2005, we have employment agreements that contain severance arrangements with each of our three executive officers and three other executives. Under these agreements, we are obligated to pay severance if we terminate an executive officer's or other executive's employment without "cause," or if an executive officer or other executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance would consist of continued payments at the current base compensation rate, or current base compensation rate plus the prior year's cash bonus in the case of the CEO, for the period specified in each agreement, which ranges from 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 $1.4 million if each executive officer and other executive was terminated at June 30, 2005.

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.

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

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

For example, our independent product candidates currently in clinical evaluation are high-dose Allovectin-7® for the treatment of metastatic melanoma, which has completed Phase 2 clinical testing, our CMV vaccine, for which we currently plan to initiate Phase 2 clinical testing in 2005, our IL-2 EP program, which is currently in Phase 1 clinical testing and our anthrax vaccine, which is currently in Phase 1 clinical testing. We may not be able to identify and reach agreement with a potential partner for the further development and commercialization of Allovectin-7®. Failure to reach agreement with a partner may delay or prevent continued development, significantly increase our development and commercialization expenses, and slow market penetration. We may not, alone or with a potential partner, conduct a Phase 3 trial of Allovectin-7®. Endpoints in such a trial may not be achieved, and if achieved, may not establish sufficient safety and efficacy to support product approval. We may not conduct additional CMV vaccine trials, leading transplant centers may not participate 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. Our anthrax vaccine may not elicit sufficient antibody responses in humans. The additional outside funding needed to support further clinical development of our anthrax vaccine is unlikely under current federal government biodefense program priorities.

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

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

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. Some collaborators or licensees may not succeed in their product development efforts or devote sufficient time or resources to the programs covered by these arrangements, causing us to derive little or no revenue from these arrangements.

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

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

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

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

We have entered into agreements with government agencies, such as the NIH, and we intend to continue entering into these agreements in the future. For example, we have entered into an agreement to manufacture bulk DNA vaccines for the VRC. In connection with this agreement, the VRC has provided a 500-liter fermenter and related purification equipment as Government Furnished Equipment, or GFE, in our manufacturing facility. 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. If we fail to satisfy our contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or GFE or other government property in our possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on our financial results in the period or periods affected. 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 or ineligible to enter into future government agreements.

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

We apply for and have received funding from government agencies under Small Business Technology Transfer, or STTR, and SBIR grants. Eligibility of public companies to receive such grants is based on size and ownership criteria which are under review by the Small Business Administration and our eligibility may change in the future, and there can be no assurance that additional funding from this source will 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 $23.7 million, $24.5 million and $27.9 million for 2004, 2003 and 2002, respectively. As of June 30, 2005, we had incurred cumulative net losses totaling approximately $151.1 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. For the year ending December 31, 2005, we have forecast a net loss of between $23 million and $26 million. 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. For example, we currently have on file an effective shelf registration statement with the SEC which allows us to issue from time to time an aggregate of up to $50 million of common or preferred stock, less amounts raised to date. In March 2004, we raised approximately $18.6 million in gross proceeds pursuant to this registration statement from the sale of approximately 3.4 million shares of our common stock at $5.50 per share in a registered direct offering to a select group of institutional investors. However, we may not be able to raise additional funds on favorable terms, or at all. In 2004, we entered into an agreement with a leasing company to provide up to $8.5 million of lease financing through October 31, 2005. The agreement requires a non-interest-bearing cash security deposit in the amount of 60% of the amount of each drawdown. This financing involves restrictive financial covenants, including a requirement that we maintain unrestricted cash and marketable securities of at least $25 million or obtain a letter of credit from another lender in the amount of outstanding borrowings.

If we are unable to obtain additional funds, we may have to reduce our capital expenditures, 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.

We anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2006.

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

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

- The FDA has not established guidelines concerning the scope of clinical trials required for gene-based therapeutic and vaccine products;
- The FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products; and
- Current regulations and guidances are subject to substantial review by various governmental agencies.

Therefore, U.S. or foreign regulations could prevent or delay regulatory approval of our products or limit our ability to develop and commercialize our products. Delays could:

- Impose costly procedures on our activities;
- Diminish any competitive advantages that we attain; or
- Negatively affect our results of operations and cash flows.

We have limited experience in filing BLAs or New Drug Applications, or NDAs, with the FDA. Because a BLA or NDA must be filed with and approved by the FDA before a biologic product or new drug product, respectively, 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 United States may impede our ability to commercialize our products in those countries

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

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

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

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

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

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

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

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, diseases which can themselves be life-threatening. For example, one patient who had undergone treatment with Allovectin-7® for advanced metastatic melanoma died more than two months later of progressive disease and numerous other factors after receiving multiple other cancer therapies. The death was originally reported as unrelated to the treatment. Following an autopsy, the death was reclassified as "probably related" to the treatment because the possibility could not be ruled out. We do not believe Allovectin-7® was a significant factor in the patient's death. As another example, we may administer our investigational CMV vaccine to patients who are at risk of CMV reactivation. Although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events.

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

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

We are the assignee of 44 issued U.S. and foreign patents. We are also co-assignee, together with Sanofi Pasteur and the University of Texas Health Science Center, of two issued U.S. patents related to vaccines against Lyme disease. In addition, we have been granted a Japanese patent related to our core DNA delivery technology that is subject to Trials for Invalidation, or TFIs; a recently granted patent in Europe related to our core DNA delivery technology has been opposed by eight parties; a patent granted in Europe covering a range of applications of our core DNA delivery technology using cationic lipid formulations has been opposed; and a patent granted in Europe covering gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer has also been opposed.

We are also prosecuting 65 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. Seven of the pending foreign patent applications are international patent applications under the Patent Cooperation Treaty, or PCT, each of which preserves our right to pursue national-phase patent applications in a large number of foreign countries. In addition, we are co-assignee, together with Merck, of U.S. and foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

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

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

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

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

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

Our success will depend in part on our ability to obtain patent protection for our products and processes, both in the U.S. and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly 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 will be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. Moreover, if a competitor were to file a patent application claiming technology also invented by us, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

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

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

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

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

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. While we will seek to expand our technological capabilities to remain competitive, research and development by others will seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us. Additionally, even if our product development efforts are successful, and even if the requisite regulatory approvals are obtained, 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, and David C. Kaslow, our Chief Scientific 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 personnel with expertise in clinical trials, government regulation and manufacturing. We have not had any problem attracting and retaining key personnel and qualified staff. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel.

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. We may be unable to enter into any arrangement for the commercial

manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

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

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

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 beginning in 2006 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 HIPPA; 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 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 be required to incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. These risks are inherent in the development and manufacture of chemical and pharmaceutical products. 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. To date, no product liability claims have been filed against us. However, 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, 2002 to June 30, 2005, our stock price has ranged from $2.12 to $12.48. 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;
- Concern as to the safety of our potential products;
- 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.

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 frustrate 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.

In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock, of which to date we have issued approximately $18.6 million of common stock, which yielded approximately $17.3 million in net proceeds. 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.

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, 2005. At June 30, 2005, our unrealized loss on marketable securities was $0.1 million. We expect lower investment income in the full year 2005 compared with 2004 due to lower investment balances.

ITEM 4. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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, 2005.

Changes in Internal Controls

There has been no change in our internal control over financial reporting during the three months ended June 30, 2005, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may become a party to lawsuits involving various matters. We are unaware of any such lawsuits presently pending against us which, individually or in the aggregate, are deemed to be material to our financial condition.

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

The Annual Meeting of Stockholders of Vical Incorporated was held on May 19, 2005. 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 I directors to serve until the 2008 Annual Meeting of Stockholders and until their successors are elected. Elected to serve as directors were Robert C. Merton, Ph.D. and Vijay B. Samant. For each elected director the results of voting were: Robert C. Merton, Ph.D. 18,556,814 for and 3,532,659 withheld; and Vijay B. Samant 18,406,948 for and 3,682,525 withheld. Both of the nominees were re-elected to serve as directors. Our Class II directors, R. Gordon Douglas, M.D. and M. Blake Ingle, Ph. D., continue in office until the 2006 Annual Meeting of Stockholders. Our Class III directors, Robert H. Campbell and Gary A. Lyons, continue in office until the 2007 Annual Meeting of Stockholders.

(ii) To ratify the selection by the Audit Committee of our Board of Directors of Deloitte & Touche LLP as our independent auditors for the year ending December 31, 2005. The selection of Deloitte & Touche LLP as independent auditors for the year ending December 31, 2005, was ratified with the following votes: 21,968,587 for, 101,137 against, and 19,749 abstained.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(i)(1)	Restated Certificate of Incorporation.
3.1(ii)(1)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock Certificate.
10.41(2)	License Agreement dated May 24, 2005, between the Company and AnGes MG, Inc.
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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Church, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(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) The Company has requested confidential treatment for certain portions of this agreement which have been omitted and filed separately with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

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 5, 2005

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)

Exhibit 10.41

LICENSE AGREEMENT

This License Agreement ("Agreement") is made effective this 24th day of May, 2005 ("Effective Date"), by and between VICAL Incorporated, a Delaware corporation having its principal place of business at 10390 Pacific Center Court, San Diego, California 92121, USA ("VICAL"), and AnGes MG Inc., a corporation having a principal place of business at 7-7-15, Saito-Asagi, Ibaraki, Osaka, 567-0085, JAPAN ("Licensee").

WITNESSETH

WHEREAS, VICAL has certain Patent Rights as defined below and wishes to grant to Licensee, and Licensee wishes to obtain from VICAL, an exclusive license to such Patent Rights for use in Hepatocyte Growth Factor ("HGF") gene therapy applications in accordance with the terms of this Agreement.

NOW THEREFORE, the parties agree as follows:

ARTICLE I — DEFINITIONS

1.1 **Patent Rights** shall mean the patents listed in Exhibit A, attached hereto and incorporated herein by reference and all foreign and domestic applications and patents derived therefrom, including all continuations, continuations-in-part, division, reexaminations, reissues, substitutions, renewals, extensions, supplementary protection certificates and all patents granted thereon, which claim priority to any of the patents listed in Exhibit A. Patent Rights shall also mean patent applications existing as of the Effective Date that read to the Licensed Field, and will be added from time to time to Exhibit A when such patents issue.

1.2 **Licensed Products** shall mean and include any and all products the making, using, selling or importing of which would, but for the license granted in this Agreement, constitute an infringement of one or more Valid Claims of the Patent Rights.

1.3 **Valid Claim** shall mean any claim in an unexpired patent included within Patent Rights which claim has not been disclaimed or held invalid or unenforceable by an unappealed or unappealable decision of a court.

1.4 **Licensed Field** shall mean the manufacture, use and/or sale of the Licensed Products using the HGF Gene.

---

[*] – Certain portions of this Exhibit were omitted by means of redacting a portion of the text (the "Mark"). This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the Mark pursuant to an Application Requesting Confidential Treatment under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2.

1.5 **Licensed Territory** shall mean any country in which the making, using, selling or importing of Licensed Products would, but for the license granted in this Agreement, infringe one or more Valid Claims of the Patent Rights.

1.6 **Net Sales** shall mean the gross amount invoiced by Licensee or its Affiliates or its Partners from the sales of Licensed Products within the Licensed Field in the Licensed Territory to third party customers less:

a) cash, quantity and trade discounts actually allowed;

b) credits allowed for returned or damaged goods;

c) transportation costs, including insurance; and

d) sales, excise, value added, import and export taxes, and any tariffs and duties imposed on the transaction, if separately invoiced.

In the case of any sale of Licensed Products between or among Licensee and its Affiliates or Partners for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm's length sale thereafter to a third party customer. In the case of any sale of Licensed Products between or among Licensee and its Affiliates or Partners where Licensee or its Affiliate or Partner is the end user of such Licensed Product, Net Sales shall be calculated as above on the value that would be charged or invoiced to a third party end user in an arm's length sale.

1.7 **Earned Royalties** shall mean royalties paid or payable by Licensee to VICAL as determined with respect to Net Sales.

1.8 **Affiliate** means any corporation or other business entity in which Licensee owns or controls, directly or indirectly, at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors, or in which Licensee is owned or controlled directly or indirectly by at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors.

1.9 **Partner** means any third party company or legal entity which is not an Affiliate of Licensee, with which Licensee has a joint venture or collaboration or marketing/distribution or such other arrangement providing the third party company or entity the right to co-manufacture, co-develop, co-promote or co-market Licensed Products in the Licensed Field in conjunction with Licensee.

1.10 **HGF Gene** shall mean DNA sequences corresponding to the mRNA sequence defined by Genbank Accession number NM_000601 encoding human HGF (known variously as hepatocyte

growth factor, hepapoietin A, and scatter factor) which when expressed affords the human HGF protein or any isoform or therapeutically active truncation thereof.

1.11 **IHD** means ischemic heart disease.

1.12 **PAD** means peripheral arterial disease or any other use with the exception of IHD.

1.13 **Angiogenesis** means stimulation of new blood vessel growth in the context of cardiovascular disease

ARTICLE II — THE GRANT

2.1 VICAL hereby grants to Licensee and its Affiliates, subject to the terms and conditions hereof, an exclusive license under Patent Rights, to make, have made, use, import, sell, offer to sell and have sold the Licensed Products within the Licensed Field in the Licensed Territory. No license is granted outside the Licensed Field.

2.2 Licensee acknowledges that certain of the rights granted by VICAL to Licensee under this Article II are licensed to VICAL by the Wisconsin Alumni Research Foundation ("Licensor" or "WARF"), and such rights are subject to the applicable terms and conditions of the license agreement between VICAL and WARF (the "Licensor Agreement"), a redacted copy of which is attached as Exhibit B. In the event that the Licensor Agreement is terminated, the rights granted by VICAL to Licensee under this Article II, which are licensed to VICAL by Licensor under the Licensor Agreement, shall continue as a direct license from Licensor to Licensee on the terms set forth in the Licensor Agreement. Licensee acknowledges that such license provided directly from Licensor shall be limited in scope to that commensurate with the license granted under this Agreement. In such event, Licensee agrees to be bound by the terms of the Licensor Agreement (including royalty rates, product liability and other rights owing Licensor thereunder) as if Licensee were the licensee thereunder in the event of such termination.

2.3 Licensee may grant sublicenses under the license granted in Section 2.1 above only to Licensee's Partners and only to the extent that said sublicense is limited to the Partner's right to manufacture, use, sell and import Licensed Products within the Licensed Field in conjunction with Licensee. Within thirty (30) days of the execution of this Agreement, or in the case of Licensee's new Partner Agreements, within thirty (30) days of the execution of the Partner Agreement, Licensee shall notify its Partner(s) that Licensee may grant to the Partner only limited rights under the Patent

Rights for the Licensed Field and that the Partner will need a separate license from VICAL for the Partner's use, manufacture or sale of any additional products which are not made in conjunction with Licensee. Licensee shall be responsible to VICAL within the Licensed Field with respect to any actions or omissions of its Affiliates and Partners as if they were actions or omissions of Licensee. Licensee and its Affiliates may not grant any sublicense under the Patent Rights except as expressly provided in this Section 2.3.

2.4 Licensee agrees that it, including its Affiliates and Partners, will diligently pursue development and commercialization of Licensed Products. Licensee will provide to VICAL a written summary report summarizing Licensee's and its Affiliates' and Partners' development and commercialization plans and activities with respect to Licensed Products on an annual basis by December 31 of each year.

ARTICLE III — PAYMENTS, REPORTS, RECORD-KEEPING

3.1 In consideration of the rights granted to Licensee pursuant to Article II of this Agreement, Licensee agrees to make the following payments to VICAL:

(a) Non-refundable, Noncreditable, Upfront License Fee

One (1) Million dollars ($1,000,000) to be paid within thirty (30) days upon execution of this Agreement.

(b) Milestone Payments with respect to PAD

Each milestone payment shall be payable by Licensee within thirty (30) days of the date that the applicable milestone event with respect to PAD occurs to retain license rights.

(i) [*]

(ii) [*]

(c) Milestone Payments with respect to IHD

Each milestone payment shall be payable by Licensee within thirty (30) days of the date that the applicable milestone event with respect to IHD occurs to retain license rights.

(i) [*]

[*] – Confidential Treatment Requested

(ii) [*]

(d) Additional Milestone Payment with respect to PAD or IHD

[*]

(e) Sales Bonus Payments

(i) [*]

(ii) [*]

(iii) [*]

(f) Royalty Payments

(i) With respect to PAD; Earned Royalties in an amount equal to [*] of the Net Sales of Licensed Products to be paid on a quarterly basis.

(ii) With respect to IHD; Earned Royalties in an amount equal to [*] of the Net Sales of Licensed Products to be paid on a quarterly basis.

[*] – Confidential Treatment Requested

In the event that Vical grants to any third party a license under the Patent Rights for commercial human therapeutic use within the field of Angiogenesis upon royalty rates more favorable to such third party than those set forth in Section 3.1(f), Licensee shall have the right to such more favorable royalty rates, provided Licensee also accepts any less favorable terms which may accompany the same (which may include, without limitation, additional license fees and/or milestone payments).

3.2 After launch of Licensed Product, Licensee agrees to submit to VICAL within sixty (60) days after December 31, March 31, June 30 and September 30 of each calendar year, reports setting forth for the preceding three (3) month reporting period, the Net Sales of Licensed Products and royalty due thereon and with each such royalty report to pay the amount of royalty due. Each such royalty report will cover Licensee's most recently completed calendar quarter and will show:

(a) The gross sales and Net Sales of Licensed Products sold during the most recently completed calendar quarter;

(b) The name of each Licensed Product sold;

(c) The royalties, in U.S. dollars, payable with respect to sales of Licensed Products;

(d) The exchange rates used, if applicable; and

(e) The reconciliation of gross sales to Net Sales, using a schedule to detail amounts deducted from gross sales to arrive at Net Sales.

3.3 If no sales of Licensed Products have been made during any reporting period, a statement to this effect is required.

3.4 Licensee shall, and shall cause its Affiliates and Partners to, keep complete, true and accurate books of account and records of Licensed Products made, used and/or sold under this Agreement for the purpose of showing the derivation of all amounts payable to VICAL under this Agreement. Said books and records shall be kept at Licensee's (or its Affiliate's or Partner's) principal place of business for at least five (5) years following the end of a reporting period to which they pertain. VICAL is hereby granted by Licensee the right, upon reasonable written notice to Licensee, to retain an independent certified public accountant reasonably acceptable to Licensee and appropriately bound by confidentiality, to audit Licensee's (or its Affiliate's or Partner's) records solely to verify sales of the Licensed Products. VICAL shall bear the fees and expenses of such audit, but if an error in royalties of more than five percent (5%) of the total royalties due for any year is discovered in any audit, then Licensee shall bear the fees and expenses of that audit.

3.5 All payments due hereunder shall be payable in United States dollars. With respect to sales of Licensed Products invoiced in a currency other than United States dollars, the Net Sales amounts and the amounts due to Vical hereunder shall be expressed in the domestic currency of the party making the sale together with the US dollar equivalent, calculated using the arithmetic average of the mid-range exchange rates for the last business day of each month of the reporting period in which the Net Sales were made. The "Key Currency Cross Rates" as reported in The Wall Street Journal or any other publication as mutually agreed by the parties shall be used as the source for the exchange rates to calculate the average as defined in the preceding sentence. All payments due under this Agreement shall be without deduction of exchange, collection or other charges or any withholding tax.

ARTICLE IV — TERM AND TERMINATION

4.1 Unless terminated earlier in accordance with this Agreement, the term of this Agreement shall be until the expiration of the last to expire of the Patent Rights or until the Patent Rights are held invalid or unenforceable by a court or tribunal from which no appeal can be taken.

4.2 In the event that Licensee shall become insolvent, shall make an assignment for the benefit of its creditors, or shall have a petition in bankruptcy filed for or against it and such petition shall not have been discharged within ninety (90) days, VICAL may, at its option, terminate this Agreement upon thirty (30) days written notice. In addition, VICAL may terminate this Agreement upon or after the breach by Licensee of any material provision of this Agreement if Licensee has not cured such breach within thirty (30) days after written notice thereof by VICAL.

4.3 Licensee shall have the right to terminate this Agreement at any time by written notice to VICAL to that effect. Licensee shall have the right during a period of six (6) months following the effective date of such termination to sell or otherwise dispose of the Licensed Products existing at the time of such termination, and shall make a final report and payment of all royalties related thereto within sixty (60) days following the end of such period or the date of the final disposition of such inventory, whichever first occurs.

4.4 Expiration or termination of this Agreement shall not relieve the parties of any obligation or right accruing prior to such expiration or termination. Any expiration or termination of this Agreement will not affect the rights and obligations set forth in the following Articles: 3.4, 3.5, 4.3, 4.4, 6.6, 7.1, 8.1, 8.2 and 8.3.

ARTICLE V — ASSIGNMENT

5.1 This Agreement may be assigned as part of a transfer of all, or substantially all, of the business of either VICAL or Licensee to which this Agreement relates. This Agreement shall be binding upon and inure to the benefit of successors in interest and assigns. Both VICAL and Licensee agree to inform the other of such transfer promptly.

5.2 This Agreement may also be assigned by VICAL under the same terms and conditions contained herein with prior written consent of Licensee.

ARTICLE VI — REPRESENTATIONS

By Licensee :

6.1 Licensee warrants that prior to the Effective Date of this Agreement, there have been no commercial sales of products which would be characterized as Licensed Products had this Agreement been in force at the time of such commercial sales.

6.2 Licensee has the right, power and authority to enter into this Agreement and to perform Licensee's obligations hereunder.

6.3 The execution, delivery and performance of this Agreement by Licensee do not conflict with, violate or breach any agreement to which Licensee is a party, and there are no agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement.

By VICAL:

6.4 VICAL represents and warrants that it has the right, power and authority to grant to Licensee the license under the Patent Rights set forth in Section 2.1, and enter into this Agreement and perform VICAL's obligations hereunder.

6.5 The execution, delivery and performance of this Agreement, and the rights and licenses granted hereunder, by VICAL do not conflict with, violate or breach any agreement to which VICAL is a party, and there are no agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement. VICAL has not granted and will not during the term of this Agreement grant any license or other rights under its Patent Rights for use in the Licensed Field.

6.6 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO ANY OTHER PARTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE VII – CONFIDENTIALITY

7.1 Both parties agree to keep any information identified as confidential by the disclosing party confidential using methods at least as stringent as each party uses to protect its own confidential information. "Confidential Information" shall include Licensee's Development Plan and Development Reports, Sales Reports, the Patent Rights and all information concerning them and any other information exchanged between the parties which is either (1) marked confidential; (2) accompanied by correspondence indicating such information is confidential; or (3) orally disclosed and confirmed in writing as confidential within forty-five (45) days. Except as may be authorized in advance in writing by the disclosing party, the receiving party shall grant access to the Confidential Information only to its own directors and employees involved in activities relating to the Patent Rights and the receiving party shall require such individuals or parties to be bound by this Agreement as well. Licensee agrees that VICAL may provide information provided to VICAL by Licensee under Sections 2.4, 3.2 and 3.4 to Licensor to the extent required under the Licensor Agreement. The confidentiality and use obligations set forth above apply to all or any part of the Confidential Information disclosed hereunder for a period of ten (10) years, except to the extent that:

(a) either party can show by written record that it possessed the information prior to its receipt from the other party;

(b) the information was already available to the public or became so through no fault of the receiving party;

(c) the information is subsequently disclosed to receiving party by a third party that has the right to disclose it free of any obligations of confidentiality;

(d) the information was independently developed by the receiving party without reliance on the Confidential Information of the disclosing party; or

(e) the information is required to be disclosed by court order or by law, provided that if a party is so required to make any such disclosure of the Confidential Information of the other party, it will to the extent practicable give reasonable advance notice to the other party of such disclosure requirement and will use its commercially reasonable efforts, or will allow the other party, to secure confidential treatment of such information required to be disclosed..

7.2 Licensee may not use the name of VICAL, Licensor, the University of Wisconsin or any inventor of the inventions claimed by the Patent Rights in sales, promotion, advertising or any other form of publicity without the prior written approval of the entity or person whose name is proposed to be used.

ARTICLE VIII— GENERAL

8.1 All disputes, controversies, claims, questions or differences arising between the parties in relation to this Agreement, or for breach thereof, which cannot be settled amicably through mutual consultation between the parties within sixty (60) days of initial written request by either party, shall be finally settled by binding arbitration in San Diego, California pursuant to the rules of the American Arbitration Association ("AAA"). This Section 8.1 shall not apply to any conflict or dispute that concerns (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

8.2 The relationship between VICAL and Licensee shall be that of independent contractors. VICAL and Licensee shall have no other relationship other than as independent contracting parties. Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither shall be bound to the acts or conduct of the other.

8.3 Each party agrees to indemnify and hold the other party harmless from any and all damages, liabilities, losses, and costs or expenses suffered or incurred by the other party arising out of, or resulting from, any breach of its representations, warranties or covenants in the Agreement, except to the extent such damages, liabilities, losses, costs or expenses result from the gross negligence or willful misconduct of any such other party. In addition, Licensee hereby agrees to indemnify and hold VICAL and Licensor and their respective officers, directors, trustees, employees and agents harmless from any and all damages, liabilities, losses, and costs or expenses that they may suffer or incur arising out of, or resulting from, the development, manufacture, use, handling, storage, sale or other disposition of any Licensed Product by Licensee, its Affiliates or Partners (including, without limitation, claims of bodily injury or death and any product liability or similar suit or action), except to the extent such damages, liabilities, losses, costs or expenses result from the gross negligence or willful misconduct of any such indemnified party. In the event a party seeks indemnification under this Section 8.3, it shall inform the indemnifying party of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the indemnifying party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested in the defense of the claim.

8.4 Licensee will, and will cause its Affiliates and Partners, to maintain liability insurance coverage appropriate to the risks involved in development, production, distribution and commercialization of Licensed Products and, upon request of VICAL, will provide documentation showing that such insurance is being maintained.

8.5 If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and this Agreement will be construed as if the invalid, illegal or unenforceable provisions had never been contained in it.

8.6 Neither party may waive or release any of its rights or interests in this Agreement except in writing. Any delay or failure to assert any right arising from this Agreement shall not be deemed or construed to be a waiver of such right.

8.7 The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

ARTICLE IX — NOTICES; APPLICABLE LAW

9.1 Any notice, report or payment provided for in this Agreement shall be deemed sufficiently given when sent by facsimile or regular, certified or registered mail addressed to the party for whom intended at the following addresses, or to such address as either party may hereafter designate in writing to the other:

For VICAL:

Attn: Vice President, Business Development
Vical Incorporated
10390 Pacific Center Court
San Diego, CA 92121-4340
USA

Phone : 858-646-1144

Fax : 858-334-1450

For Licensee:

Attn : Manager,
Business Development & Licensing
AnGes MG, Inc.
5F, Mitasuzuki Bldg, 5-20-14
Shiba, Minato-ku, Tokyo, 108-0014 JAPAN

Phone: 81-3-5730-2489

Fax: 81-3-5730-2635

9.2 This agreement shall be construed, interpreted, and applied in accordance with the laws of California.

9.3 To the extent required by applicable law, Licensee shall, and shall cause its Affiliates and Partners to, mark all Licensed Products or their container in accordance with the patent marking laws of the country in which such Licensed Products are manufactured, used or sold.

ARTICLE X — INTEGRATION

10.1 This Agreement constitutes the entire agreement between the parties relating to the subject matter thereof, and all prior negotiations, representations, agreements and understandings are merged into, extinguished by, and completely expressed by it. This Agreement cannot be changed orally, but only in writing and if signed by both parties. This Agreement shall be binding on the heirs, successors, and assigns of the parties hereto. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, both VICAL and Licensee have executed this Agreement by their respective and duly authorized officers on the day and year written. This Agreement is effective as of the Effective Date.

Vical Incorporated	AnGes MG, Inc.
By /S/ VIJAY B. SAMANT	By /S/ EI YAMADA, PH.D.
Date: May 24, 2005	Date: May 24, 2005
Name: Vijay B. Samant	Name: Ei Yamada, Ph. D.
Title: President and Chief Executive Officer	Title: CEO

Exhibit A

United States

[*]

[*]

[*]

[*]

[*]

US [*] is specifically excluded, but the continuation [*] is included.

Japan

[*]

Europe

[*]

Canada

[*]

---

[*] – Confidential Treatment Requested

EXHIBIT 31.1

CERTIFICATION

I, Vijay B. Samant, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2005

/s/ VIJAY B. SAMANT

Vijay B. Samant
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Jill M. Church, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2005

/s/ JILL M. CHURCH

Jill M. Church
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Vijay B. Samant, the Chief Executive Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: August 5, 2005

/s/ VIJAY B. SAMANT

Vijay B. Samant
Chief Executive Officer

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-Q TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-Q), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Jill M. Church, the Chief Financial Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: August 5, 2005

/s/ JILL M. CHURCH

Jill M. Church
Chief Financial Officer

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-Q TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-Q), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.