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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 March 31, 2002

or

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

Commission File Number: 0-21088

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.)
9373 Towne Centre Dr., Suite 100, San Diego, California	**92121**
(Address of principal executive offices)	(Zip code)

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

Not Applicable
(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 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 April 30, 2002
20,076,344

VICAL INCORPORATED

FORM 10-Q

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Item 1. Financial Statements

VICAL INCORPORATED

BALANCE SHEETS

	March 31, 2002	December 31, 2001
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 27,638,249	$ 43,736,068
Marketable securities—available-for-sale	99,808,268	90,351,409
Receivables and other	4,263,878	4,635,534
Total current assets	131,710,395	138,723,011
Investment, at cost	5,000,000	5,000,000
Property and Equipment:		
Equipment	8,119,864	8,225,632
Leasehold improvements	4,750,124	4,800,503
	12,869,988	13,026,135
Less—accumulated depreciation and amortization	(8,348,968)	(7,966,257)
	4,521,020	5,059,878
Intangible assets, net	5,293,282	5,406,500
Other assets	629,115	305,345
	$ 147,153,812	$ 154,494,734
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 4,052,609	$ 4,492,005
Current portion of capital lease obligations	842,619	846,348
Current portion of notes payable	657,143	657,143
Current portion of deferred revenue	1,422,039	1,794,857
Total current liabilities	6,974,410	7,790,353
Long-Term Obligations:		
Long-term obligations under capital leases	1,411,358	1,616,677
Notes payable	809,524	973,810
Deferred revenue	1,669,699	1,954,926
Total long-term obligations	3,890,581	4,545,413
Commitments and contingencies		

Stockholders' Equity:		
Preferred stock, $0.01 par value—5,000,000 shares authorized—none outstanding	—	—
Common stock, $0.01 par value—40,000,000 shares authorized—20,076,344 and 20,056,344 shares issued and outstanding at March 31, 2002, and December 31, 2001, respectively	200,763	200,563
Additional paid-in capital	203,580,257	203,543,985
Accumulated other comprehensive income	133,695	816,665
Accumulated deficit	(67,625,894)	(62,402,245)
Total stockholders' equity	136,288,821	142,158,968
	$ 147,153,812	$ 154,494,734

See accompanying notes.

VICAL INCORPORATED

STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,	
	2002	**2001**
Revenues:		
License/royalty revenue	$ 1,033,232	$ 1,393,768
Contract revenue	478,115	1,037,972
	1,511,347	2,431,740
Operating Expenses:		
Research and development	5,999,632	5,290,149
General and administrative	1,720,180	1,679,366
	7,719,812	6,969,515
Loss from operations	(6,208,465)	(4,537,775)
Other income (expense):		
Investment income	1,054,787	2,625,134
Interest expense	(69,971)	(65,770)
Net loss	$ (5,223,649)	$ (1,978,411)
Net loss per common share (basic and diluted—Note 2)	$ (0.26)	$ (0.10)
Weighted average shares used in computing net loss per common share (Note 2)	20,059,310	20,014,118

See accompanying notes.

VICAL INCORPORATED

STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31,	
	2002	**2001**
OPERATING ACTIVITIES:		

Net loss	$ (5,223,649)	$ (1,978,411)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	675,564	362,991
Compensation expense related to grant of stock options	30,072	—
Change in operating assets and liabilities:		
Receivables and other	371,656	(687,849)
Other assets	(323,770)	22,063
Accounts payable and accrued expenses	(439,396)	(61,229)
Deferred revenue	(658,045)	(661,379)
Net cash used in operating activities	(5,567,568)	(3,003,814)
INVESTING ACTIVITIES:		
Sales of marketable securities	14,854,401	73,554,406
Purchases of marketable securities	(24,994,230)	(42,186,739)
Capital expenditures	(9,807)	(893,828)
Patent expenditures	(13,681)	(93,037)
Net cash provided from (used in) investing activities	(10,163,317)	30,380,802
FINANCING ACTIVITIES:		
Issuance of common stock	6,400	51,159
Proceeds from notes payable	—	799,448
Payments on notes payable	(164,286)	(71,429)
Principal payments under capital lease obligations	(209,048)	(181,726)
Net cash provided from (used in) financing activities	(366,934)	597,452
Net increase (decrease) in cash and cash equivalents	(16,097,819)	27,974,440
Cash and cash equivalents at beginning of period	43,736,068	16,480,087
Cash and cash equivalents at end of period	$ 27,638,249	$ 44,454,527
Interest paid	$ 70,767	$ 65,770
Supplemental Disclosure of Non-Cash Investing and Financing Activities-equipment acquired under capital lease financing	$ —	$ 438,321

See accompanying notes.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

MARCH 31, 2002

(UNAUDITED)

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization

Vical was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. We research and develop potential biopharmaceutical products based on our patented gene delivery technologies for the prevention and treatment of serious or life-threatening diseases.

Basis of Presentation

The information contained herein has been prepared in accordance with instructions for Form 10-Q. The information at March 31, 2002, and for the three-month periods ended March 31, 2002 and 2001, is unaudited. In the opinion of management, the information reflects all adjustments necessary to present fairly the financial position and results of operations for the interim periods. All such adjustments are of a normal recurring nature. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2001, included in our Form 10-K filed with the Securities and Exchange Commission.

Reclassifications

Certain amounts in the prior period financial statements have been reclassified to conform with current period presentation.

2. NET LOSS PER SHARE

Net loss per share (basic and diluted) for the three-month periods ended March 31, 2002 and 2001, has been computed using the weighted average number of common shares outstanding during the respective periods. Diluted loss per share does not include any assumed exercise of stock options, as the effect would be antidilutive. Options outstanding were 2,982,614 and 2,516,063 at average exercise prices of $16.11 and $14.52 at March 31, 2002 and 2001, respectively.

3. COMPREHENSIVE LOSS

Accumulated other comprehensive income (loss) represents net unrealized gains (losses) on marketable securities. Marketable securities consist of investments in debt instruments of financial institutions and corporations with strong credit ratings, and in U.S. government obligations. For the three-month periods ended March 31, 2002 and 2001, other comprehensive loss was $0.7 million and other comprehensive income was $0.5 million, respectively, and total comprehensive loss was $5.9 million and $1.5 million, respectively.

4. LEASED FACILITY; CREDIT LINE RENEWAL

In January 2002, we signed a 15-year lease for a new building in northern San Diego, California. The lease commences in June 2002. As this is a build-out process, phased-in occupancy of the new space should commence by the end of 2002. The new facility has approximately 68,400 square feet of manufacturing, research laboratory and office space. We will continue to hold the leases on our three existing facilities until they expire. We intend to sublease the space as it becomes vacant. The new lease requires us to pay taxes, insurance and operating costs. The lease provides for specified scheduled rent increases annually. We have the option to renew this lease for three additional five-year periods beyond its expiration, and we have a one-time purchase option at 110 percent of fair market value, which we can exercise in year nine of the lease. Minimum lease obligations on the new facility are as follows: $1.0 million in 2002, $2.3 million in 2003, $2.4 million in 2004, $2.5 million in 2005 and 2006, $2.6 million in 2007, and $29.0 million thereafter until conclusion of the lease term in August 2017.

Additionally, in January 2002, we renewed our capital equipment credit line and increased it to $4.3 million. This credit line will be used to finance laboratory and scientific equipment, and part of the equipment needed for the new facility.

5. RECENT ACCOUNTING PRONOUNCEMENTS

In June 2001, the Financial Accounting Standards Board, FASB, issued SFAS No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." The primary changes resulting from SFAS No. 142 consist of how goodwill and intangible assets will be segregated, amortized (or not amortized), reviewed for impairment (if any), and disclosed within the footnotes to financial statements. We do not currently have any goodwill. We implemented SFAS No. 142 in the first quarter of 2002. Implementation did not have a material impact on intangible assets and the respective results of operations, financial position and cash flows. SFAS No. 142 requires that assets which do not have indefinite lives be amortized over the expected useful life of those assets using a method of amortization which reflects the pattern in which the economic benefits of the assets are used up or otherwise consumed. We are amortizing our intangibles using the straight-line method as permitted under SFAS No. 142.

6. SUBSEQUENT EVENT

In April 2002, we received a payment of $1.0 million from Merial for the exercise of additional options to license our technologies under a 1995 agreement for veterinary preventive infectious disease vaccines. The $1.0 million payment will be recognized as revenue in the second quarter.

FORWARD-LOOKING STATEMENTS

The statements incorporated by reference or contained in this report discuss our future expectations, contain projections of our results of operations or financial condition, and include other "forward-looking" information 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. Our actual results may differ materially from those expressed in forward-looking statements made or incorporated by reference in this report. Forward-looking statements that express our beliefs, plans, objectives, assumptions or future events or performance may involve estimates, assumptions, risks and uncertainties. Therefore, our actual results and performance may differ materially from those expressed in the forward-looking statements. Forward-looking statements often, although not always, include words or phrases such as the following:

- "will likely result,"
- "are expected to,"
- "will continue,"
- "is anticipated,"
- "estimate,"
- "intends,"
- "plans,"
- "projection," and
- "outlook."

You should not unduly rely on forward-looking statements contained or incorporated by reference in this report. Actual results or outcomes may differ materially from

those predicted in our forward-looking statements due to the risks and uncertainties inherent in our business, including risks and uncertainties in:

- clinical trial results,
- obtaining and maintaining regulatory approval,
- market acceptance of and continuing demand for our products,
- the attainment of patent protection for any of these products,
- our ability to defend against challenges to our patents,
- the impact of competitive products, pricing and reimbursement policies,
- our ability to obtain additional financing to support our operations,
- the continuation of our corporate collaborations, and
- changing market conditions (and other risks detailed below).

You should read and interpret any forward-looking statements together with the following documents:

- the risk factors contained in this report under the caption "Additional Business Risks,"
- our Annual Report on Form 10-K, and
- our other filings with the Securities and Exchange Commission.

Any forward-looking statement speaks only as of the date on which that statement is made. We will not update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

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

Overview

We research and develop potential biopharmaceutical products based on our patented gene delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of our gene delivery technologies include:

- Cancer vaccines and immunotherapies,
- Infectious disease vaccines, and
- Therapeutic proteins.

We are actively pursuing the refinement of our plasmids and lipids, development of future products, evaluation of potential enhancements to our core technologies and exploration of alternative gene delivery technologies. We also seek to develop additional applications for our technologies by testing new approaches to disease control or prevention. These efforts could lead to further independent product development or additional licensing opportunities. In addition, we continually evaluate compatible technologies or products that may be of potential interest for in-licensing or acquisition.

We collaborate with major pharmaceutical and biotechnology companies and government agencies, providing us access to complementary technologies or greater resources. These collaborations provide us with mutually beneficial opportunities to expand our product pipeline and serve significant unmet medical needs. We license intellectual property from companies holding complementary technologies in order to leverage the potential of our own gene delivery technology and to further the discovery of innovative new therapies for internal development. We license our intellectual property to other companies in order to leverage our technologies for applications that may not be appropriate for our independent product development efforts.

Recent Events

In our lead late-stage product development program, a low-dose Allovectin-7® cancer vaccine for malignant melanoma, the clinical data analyses are on schedule. Our Phase III registration trial completed enrollment of 200 patients in September 2001; the last patient completed the final on-study evaluation on April 2, 2002; and we are proceeding with the collection and audit of data from this trial as planned. Once the audit is complete, the database will be locked. In parallel, we have developed a process for adjudication of the clinical data by an independent group of radiologists and oncologists, and we intend to have the adjudication process reviewed by the U.S. Food and Drug Administration, FDA. We expect that the adjudication process will be finished and the final report of the study's primary endpoints will be reviewed in the second half of 2002, allowing us to determine whether the data are sufficient to support filing for marketing approval.

A separate Phase II trial with high-dose Allovectin-7® advanced quickly through dose escalation and is now treating patients at the full 2 mg dose, compared with a 10 mcg dose in previous trials, and for the first time, in multiple tumors. The excellent safety profile of our Allovectin-7® cancer vaccine has allowed us to explore the potential for this significantly more aggressive treatment regimen. The trial is recruiting very well, with 67 patients already enrolled as of May 3, 2002, and we plan to achieve our initial target of enrolling 80 patients before year-end 2002.

In January 2002, Merck reported in the scientific journal, *Nature*, that a prime-boost vaccine regimen elicited an immune response in monkeys against a hybrid form of

HIV. The prime-boost regimen used by Merck in these trials also combined a naked DNA plus adjuvant prime vaccine with a non-replicating adenoviral vector boost vaccine. This vaccine combination was shown to provide potent cellular immune responses.

In February 2002 at the 9th Conference on Retroviruses and Opportunistic Infections, and in April 2002 at the Keystone Symposium on HIV-1 Protection and Control by Vaccination, Merck presented its initial human data from ongoing Phase I clinical trials of a vaccine candidate that uses our proprietary naked DNA technology. Merck's preliminary analysis suggests that HIV-1 *gag* vaccine candidates for the prevention and treatment of HIV-1 elicit specific antiviral cellular immune responses and are generally well-tolerated in the ongoing studies.

In February 2002, we signed a multi-year lease with Kilroy Realty Corporation, including an option to purchase, on a large, newly-constructed shell facility in northern San Diego designed specifically to accommodate build-out for biotech operations. As this is a build-out process, phased-in occupancy of the new space should commence by the end of 2002.

In March 2002, Robert C. Merton, Ph.D., joined our Board of Directors and agreed to serve as the chair of our Audit Committee. Dr. Merton has been the John and Natty McArthur University Professor at the Harvard Business School since 1998, and a faculty member at Harvard since 1988. He was awarded the Nobel Prize in economics in 1997.

In April 2002, Merial, a joint venture between Merck and Co., Inc. and Aventis S.A., paid us $1.0 million for the exercise of options to license our technologies for additional vaccine targets under a 1995 agreement for veterinary preventive infectious disease vaccines. The payment will be recognized as revenue in the second quarter of 2002. Under the agreement, we are entitled to receive payments upon the achievement of certain milestones and royalty payments on sales of commercialized vaccines.

Results of Operations

We recorded revenues of $1.5 million for the quarter ended March 31, 2002. License/royalty revenue of $1.0 million for the three months ended March 31, 2002, represented recognition of deferred license fees of $0.8 million primarily from Merial and Vascular Genetics Inc., VGI, and royalty revenue of $0.2 million. Contract revenue of $0.5 million was primarily from the National Institutes of Health, NIH, for manufacturing of DNA for infectious disease vaccines, and from the Office of Naval Research, ONR, for development work on a potential naked DNA vaccine to prevent malaria. The agreement between Vical and the ONR was amended and expires September 30, 2002.

We recorded revenues of $2.4 million for the quarter ended March 31, 2001. License/royalty revenue of $1.4 million primarily represented recognition of a milestone payment of $0.5 million from Centocor, recognition of deferred license fees of $0.7 million from Merial, Pfizer and VGI and royalty and other revenue of $0.2 million. Contract and grant revenue of $1.0 million included revenues from the ONR for development work on a potential naked DNA vaccine to prevent malaria, from the NIH, and from Pfizer.

Our license revenues are expected to decrease in 2002, primarily as a result of scheduled milestone payments from Merck in 2001 which will not recur in 2002. We also expect that revenue from contract research and development, and manufacturing will be lower in 2002.

Our total operating expenses for the quarter ended March 31, 2002, were $7.7 million compared with $7.0 million for the first quarter of 2001. Research and development expenses increased to $6.0 million for the three months ended March 31, 2002, from $5.3 million for the same period in 2001. The increase in research and development expenses generally was due to increased personnel-related and facilities costs, preclinical costs and amortization of licensed technology. General and

administrative expenses were $1.7 million for the three months ended March 31, 2002 and 2001, after reclassifying certain 2001 expenses to research and development to conform to their 2002 presentation.

We expect research and development expense to increase in 2002 as we expand our preclinical programs to broaden our future pipeline. We further expect these efforts to drive increases in headcount, spending for outside services, and costs related to intellectual property. We also expect to incur increased costs as a result of relocation to a new facility and possible commencement of commercialization activities.

Investment income for the three-month period ended March 31, 2002, was $1.1 million. Investment income for the three months ended March 31, 2001, was $2.6 million, and included $0.3 million of realized gains on the sale of investments. The decrease primarily is due to lower rates of return and lower investment balances.

Our rate of return on investments, excluding realized gains on the sales of investments, has decreased as the Federal Reserve Board has continued to lower interest rates. Some of our investments were purchased prior to the reductions in interest rates, and currently are yielding higher returns than we could expect when reinvesting the proceeds upon sale or maturity. Thus, our interest yields and interest income are expected to be lower in 2002 than in 2001.

Our net loss was $0.26 per share for the three months ended March 31, 2002, compared with a net loss of $0.10 per share for the same period in the prior year. We expect to incur losses throughout the remainder of 2002 and we expect our net loss for the year ending December 31, 2002, to fall between $28 million and $32 million.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, four public offerings of common stock and revenues from collaborative agreements. Cash, cash equivalents and marketable securities totaled approximately $127.4 million at March 31, 2002, compared with $134.1 million at December 31, 2001. As of March 31, 2002, we had working capital of approximately $124.7 million compared with $130.9 million at December 31, 2001.

Cash used in operating activities increased to $5.6 million for the quarter ended March 31, 2002, compared with $3.0 million for the same period in 2001. The increase in cash used in operating activities was due to an increased net loss, decreases in accounts payable and deferred revenue, and an increase in other assets, primarily due to a rent deposit on the new facility. These changes were offset by the positive cash flow impact of a decrease in accounts receivable and increases in noncash charges such as depreciation and deferred compensation.

Cash used in investing activities was $10.2 million for the quarter ended March 31, 2002, compared with cash provided from investing activities of $30.4 million for the same period in 2001. In 2001, we sold marketable securities and invested in cash equivalents of a shorter term. Capital expenditures in 2002 decreased from the same period in the prior year.

Cash used in financing activities for the quarter ended March 31, 2002, was $0.4 million compared with cash provided from financing activities of $0.6 million for the same period in 2001. The decrease was primarily a result of having no proceeds from notes payable for the first quarter of 2002 compared with $0.8 million of proceeds from notes payable for the first quarter of 2001, combined with an increase in payments on notes payable and capital lease obligations for the first quarter of 2002 compared with the first quarter of 2001.

In 2002, we expect that our total net cash used will increase because of expected reductions in license and contract revenues, an anticipated decline in investment income, higher planned expenses related to preclinical research and development programs, and consolidation of our facilities in a new

location. Annual rent expense, excluding common area maintenance, is expected to be approximately $2.8 million for the new facility compared with a $1.6 million rent expense incurred in 2001 for the existing facilities. The new lease has specified annual rent increases. Under generally accepted accounting principles, we recognize level monthly rent expense over the entire lease period. This level monthly rent is calculated by adding the total rent payments over the entire lease period of fifteen years and then dividing the result by the 180 month term of the lease. Accordingly, this level rent per square foot is significantly higher than the actual base rent per square foot we will pay on the new facility in 2002. We will not begin paying rent on the new facility until September 2002.

Capital equipment spending will be significantly higher due to the new facility. In January 2002, we renewed our capital equipment credit line and increased it to $4.3 million. This credit line will be used to finance laboratory and scientific equipment, and part of the equipment needed for the new facility. We expect to need approximately $7 million in capital in excess of our current credit line and will seek to have the credit line increased or pursue additional financing with other parties. In the event we are unable to obtain this additional financing, we will need to use existing cash to fund the capital purchases.

We will attempt to sublease the space in our existing facilities as it becomes vacant in order to recover that portion of our existing rent payments plus amortization of leasehold improvements. However, if we are unable to do so, our net loss and cash outlays will increase accordingly.

We expect to incur substantial additional research and development expenses and general and administrative expenses, including continued increases in personnel costs, costs related to preclinical testing and clinical trials, outside services and facilities, and costs to maintain and enhance our intellectual property. 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 and enforcing patent claims, competing technological and market developments, the cost of manufacturing scale-up, and commercialization activities and arrangements. We intend to seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. We cannot assure that additional financing will 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 2003.

Additional Business Risks

You should carefully consider the risks described below, together with all of the other information included in this report and in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission, before deciding whether to invest in our common stock. In addition, the risks and uncertainties described below are not the only ones facing us because we are also subject to additional risks and uncertainties not presently known to 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, and you may lose all or part of your investment.

None of our products has been approved for sale. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

Very little data exists regarding the safety and efficacy of gene therapies. All of our potential products 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. 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. 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.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve our projected results or become profitable.

To date, we have not sold any products and do not expect to sell any products for the next few years. Our net losses were approximately $9.2 million, $8.5 million and $6.9 million for 2001, 2000 and 1999, respectively. As of March 31, 2002, we have incurred cumulative net losses totaling approximately $67.6 million. Moreover, we expect that our negative cash flow and losses from operations will continue and increase for the foreseeable future. For the year ending December 31, 2002, we have forecast a net loss of between $28 million and $32 million. We may not be able to achieve our projected results. 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 manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. We may not be able to raise additional funds on favorable terms, or at all. If we are unable to obtain additional funds, we may have to reduce our capital expenditures, scale back our development of new products, reduce our workforce and license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need will depend on many factors, including:

- the progress of our research and development programs,
- the scope and results of our preclinical studies and clinical trials,
- the time and costs involved in:
    - obtaining necessary regulatory approvals,
    - filing, prosecuting, enforcing and defending patent claims,
    - scaling up our manufacturing capabilities, and
- the commercial arrangements we may establish.

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

our products.

Our product candidates under development and those of our collaborators are subject to extensive and rigorous regulations by numerous governmental authorities in the United States 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 therapies,
- the FDA has not indicated how many patients it will require to be enrolled in clinical trials to establish the safety and efficacy of gene therapies, and
- current regulations 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 ability to receive royalties.

We understand that both the FDA and NIH are considering rules and regulations that would require public disclosure of commercial development data that is presently confidential. This potential disclosure of commercial confidential information, if implemented, may result in loss of advantage of competitive secrets.

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 then 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 on-going 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 Recombinant DNA Advisory Committee. The NIH could restrict or delay the development of our product candidates.

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-based gene therapy at the University of Pennsylvania in an investigator-sponsored trial was widely publicized. This death and other adverse events in the field of gene therapy could result in greater governmental regulation of gene therapies, including our non-viral gene delivery technology, and potential regulatory delays relating to the testing or approval of our product candidates. In addition, the field of gene therapy is under increased scrutiny, which may affect our product development efforts or clinical trials.

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.

The commercial success of our product candidates will depend in part on public acceptance of the use of gene therapies for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapies are unsafe and our gene therapies may not gain the acceptance of the public or the medical community. Negative public reaction to adverse events in our trials or gene therapy in general could result in greater government regulation and stricter labeling requirements of gene therapies, including our gene therapies, and could cause a decrease in the demand for any products we may develop.

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 may not receive any patents from our current applications. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technology. 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 technology or to provide any commercial advantage.

Our core gene delivery technology was covered by a patent issued in Europe, which was opposed by seven companies under European patent procedures. In April 2002, we filed an appeal seeking to overturn the initial ruling by the Opposition Division of the European Patent Office that revoked our patent on formal grounds. If we are not successful in the appeal and opposition proceedings we may lose part or all of our proprietary protection for our product candidates in Europe.

Others may have or may receive patents that contain claims applicable to our products. These patents may impede our ability to commercialize our products.

The legal proceedings to obtain 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 United States 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 technology. 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 United States Patent and Trademark Office or in a foreign counterpart 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 technology. 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 technology.

Our products and processes may infringe, or be found to infringe on, 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. 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 may not be able to redesign our products or processes to avoid infringement.

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 technology 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 FDA approval 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 technology or products obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. Additionally, even if our product development efforts are successful, and even if the requisite regulatory approvals are obtained, our product may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our product candidates do not achieve market acceptance, we may lose our investment in that product, which may cause our stock price to decline.

The method of administration of some of our product candidates can cause adverse events in patients, including death.

Some of our potential products are designed to be injected directly into malignant tumors. There are medical risks inherent in direct tumor injections. For example, in clinical trials of our potential products, attending physicians have punctured patients' lungs in less than one percent of procedures, requiring hospitalization. In addition, a physician administering our product in an investigator-sponsored clinical trial inadvertently damaged tissue near the heart of a patient, which may have precipitated the patient's death. These events are reported as adverse events in our clinical trials and illustrate the medical risks related to direct injection of tumors. These risks may adversely impact market acceptance of some of our product candidates.

Commercialization of some of our potential products depends on collaborations with others. If our collaborators are not successful or if we are unable to maintain these collaborations or find collaborators in the future, we may not be able to develop these products.

Our strategy for the research, development and commercialization of some of our product candidates requires us to enter into contractual arrangements with corporate collaborators, licensors, licensees and others. Our success depends upon the performance by these collaborators of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect or we may not derive any revenue from these arrangements.

We have collaborative agreements with several pharmaceutical companies. We do not know whether these companies will successfully develop and market any products under their respective agreements. Moreover, some of our collaborators are also researching competing technologies to treat

the diseases targeted by our collaborative programs. We may be unsuccessful in entering into other collaborative arrangements to develop and commercialize our products.

We may suffer a material financial loss due to dilution if additional shares of VGI stock are issued at a price below our issuance price, or due to impairment which is other than temporary if VGI is unable to successfully complete its development plans.

In February 2000, we received Series B Preferred Stock in VGI in exchange for a license to our technology. This investment is recorded on our balance sheet at estimated fair value on the date of investment of $5.0 million. The preferred stock is convertible into common stock of VGI. VGI has issued shares of common and preferred stock at prices below our issuance price and, accordingly, the rate at which we could convert our preferred shares into common stock has changed and the percentage of our equity ownership in VGI has decreased. Our equity ownership in VGI will be reduced further if additional shares of VGI common or preferred stock are issued at prices below our issuance price.

VGI is a privately-held company developing gene-based delivery of the angiogenic growth factor VEGF-2 for cardiovascular applications. VGI has completed Phase I and Phase II trials. VGI still needs to raise substantial cash to complete its development plans, and there can be no assurance that the therapy will work or that the FDA will approve such a therapy. VGI, which currently has few employees and limited resources, may not be able to successfully commercialize a product even if it receives FDA approval. We do not believe there has been any impairment which is other than temporary to our investment to date, however, this may change depending on the funding and development status of VGI, which is beyond our control.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to pursue collaborations or develop our own products.

We are highly dependent on the principal members of our scientific, manufacturing, clinical, regulatory and management personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. 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 will 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 may not be successful in hiring or retaining qualified personnel.

We may not be able to manufacture products on a commercial scale.

We have limited experience in manufacturing our product candidates in commercial quantities. We may be dependent initially on corporate collaborators, licensees or others to manufacture our products commercially. We also will be required to comply with extensive regulations applicable to manufacturing facilities. We may be unable to enter into any arrangement for the manufacture of our products.

We may not be able to sublease our existing manufacturing, research laboratory and office sites upon completion of our new facility.

We currently hold three leases at three sites for our existing manufacturing, research laboratory and offices facilities, in addition to the new facility lease signed in January 2002. The leases on our existing facilities, excluding the new facility, do not terminate until 2004. These spaces will become progressively unnecessary during the scheduled phased-in occupancy of our new facility. We may be unable to sublease the sites as we vacate them.

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 cancer products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. In order to market and sell our proprietary cancer 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. Our inability to successfully employ qualified marketing and sales personnel and develop our sales and marketing capabilities will harm our business.

Health care 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 the extent to which reimbursement for our products and related treatments will be available from:

- government health administration authorities,
- private health coverage insurers,
- managed care organizations, and
- other organizations.

If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing our potential products.

There are efforts by governmental and third-party payers to contain or reduce the costs of health care through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

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 health care 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 radioactive 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, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. 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. These risks are inherent in the development of chemical and pharmaceutical products. Although we currently maintain product liability

insurance, we may not have sufficient insurance coverage and we may not be able to obtain sufficient coverage 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. We also have liability for products manufactured by us on a contract basis for third parties. If we are sued for any injury caused by our technology or products, our liability could exceed our total insurance coverage and 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 paid for them.

The market price of our common stock, like that of many other life sciences companies, has been highly volatile and is likely to continue to be highly volatile. 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 those of our collaborators or competitors or for gene therapies in general,
- evidence of the safety or efficacy of our potential products or the products of our competitors,
- the announcement by us or our competitors of technological innovations or new products,
- governmental regulatory actions,

- changes or announcements in reimbursement policies,
- developments with our collaborators,
- developments concerning our patent or other proprietary rights or those of our competitors, including litigation and challenges to our proprietary rights,
- 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, and
- changes in estimates of our performance by securities analysts.

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

In the past, stockholders have often 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. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and divert management's attention and resources, and could seriously harm our business.

Our anti-takeover provisions could discourage potential takeover attempts and make attempts by stockholders to change management more difficult.

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan adopted in March 1995, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved by our Board of Directors and may have the effect of deterring hostile takeover attempts.

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. No investments in equity securities are made in our investment portfolio which consists of cash equivalents and marketable securities. The average maturity of our investments is approximately nine months. Our investments are all 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 $1.3 million lower than the reported fair value of our investments at December 31, 2001, and $1.0 million lower than the reported fair value at March 31, 2002. At March 31, 2002, our unrealized gain on marketable securities had decreased to $0.1 million from $0.8 million at December 31, 2001.

Our rate of return on investments, excluding realized gains on the sales of investments, has decreased as the Federal Reserve Board has repeatedly lowered interest rates. Some of our investments were purchased prior to the reductions in interest rates, and currently are yielding higher returns than we could expect when reinvesting the proceeds upon sale or maturity. Thus, our interest yields and investment income are expected to be lower in 2002 than in 2001.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In April 2002, we filed an appeal on the initial ruling by the Opposition Division of the European Patent Office to revoke on formal grounds our patent covering the nonviral delivery of genetic material. According to European patent procedures, issued patents may be opposed by parties interested in challenging the issued claims. The patent covering our core gene delivery technology was issued in 1998 and was subsequently opposed by seven companies. The Opposition Division ruled that, as a result of amendments to the claims made during the process of obtaining the European patent and during the opposition process, the claims did not comply with European patent laws. Our appeal will seek to overturn the revocation, and we may also use additional patent applications that are pending in Europe to secure patent protection for our core gene delivery technology. We intend to vigorously defend our patent position in Europe.

In the ordinary course of business, we are a party to lawsuits involving employee-related matters. We do not believe that an unfavorable outcome in any of these matters would have a material adverse effect on our financial condition or results of operations.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

None

(b) Reports on Form 8-K

On April 23, 2002, we filed a Form 8-K reporting the termination of the engagement of our former independent auditor, Arthur Andersen LLP.

On May 3, 2002, we filed a Form 8-K reporting the engagement of KPMG LLP as our independent auditor for the year ending December 31, 2002.

SIGNATURES

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

Vical Incorporated

Date: May 13, 2002

By: /s/ MARTHA J. DEMSKI

Martha J. Demski
Vice President and Chief Financial Officer (on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

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