



Vical

2008 Annual Report

## HIGHLIGHTS

- **Phase 3 pivotal trial of Allovectin-7<sup>®</sup> as front-line therapy in metastatic melanoma**
  - Established first sales and marketing partnership with Eczacibasi in Turkey
  - Targeting completion of enrollment of planned 375 subjects by end of 2009
- **Phase 2 trial of vaccine to prevent cytomegalovirus reactivation in transplant patients**
  - Completed trial enrollment with full 80 subjects in recipient-only arm of trial
  - Encouraging immunogenicity data on first 33 subjects released in November 2008
  - First clinical efficacy data on full 80 recipient-only subjects expected in second quarter of 2009
- **Phase 1 trial of vaccine for H5N1 pandemic influenza**
  - Breakthrough immunogenicity data for DNA vaccines
  - Novel Vaxfectin<sup>®</sup> adjuvant well-tolerated in first-in-man study
- **Phase 3 angiogenesis programs**
  - AnGes has filed for Japanese market approval
  - Sanofi-aventis advanced multinational Phase 3 trial; filing for marketing approval expected in 2010
- **Compelling animal data with Vaxfectin<sup>®</sup> adjuvant**
  - Dose sparing of protein-based seasonal influenza vaccine
  - Dose sparing of protein-based H5N1 vaccine
  - 100% protection against measles in juvenile and infant nonhuman primates
  - Significantly enhanced immunogenicity against four dengue virus strains
  - Cellular immune response against peptide based cancer vaccine

## CONDENSED FINANCIAL INFORMATION (Unaudited)

	<u>2008</u>	<u>2007</u>	<u>2006</u>
	<i>(in thousands, except per share data)</i>		
<b>Statement of Operations Data (for full year)</b>			
Revenues	\$ 7,956	\$ 5,512	\$ 14,740
Operating expenses	45,299	45,774	41,157
Loss from operations	(37,343)	(40,262)	(26,417)
Net investment income	447	4,368	3,269
Net loss	(36,896)	(35,894)	(23,148)
Net loss per common share (basic and diluted)	\$ (0.93)	\$ (0.92)	\$ (0.74)
Weighted average shares used in per share calculation	39,856	39,190	31,434
<b>Balance Sheet Data (at end of year)</b>			
Cash, cash equivalents, marketable securities, and long-term investments, including restricted	\$ 41,676	\$ 71,489	\$ 100,393
Working capital	30,144	64,642	97,289
Total assets	59,057	90,585	125,249
Long-term obligations, less current portion	2,469	2,565	2,973
Stockholders' equity	48,614	79,912	114,123

Dear Shareholders,

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*We are advancing selected key programs while managing our financial resources for success through a challenging economic period.*

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Through the second half of 2008, it became increasingly apparent that global financial markets were not likely to recover in the near term. We concluded that we needed to secure potential sources of revenue, rationalize our operational activities, and reduce our discretionary spending to make our available capital last as long as possible without compromising the scope or pace of our key development programs.

We announced in late November a strategic restructuring that included a 20% work force reduction and the early closure of a research facility. The primary benefit of the restructuring is a reduction of our cash burn by approximately \$4 million per year. We ended the year with \$42 million in cash and investments, which we believe is sufficient to last through 2010. We are now putting all of our energies behind our two promising late-stage product development programs, Allovectin-7<sup>®</sup> and our CMV vaccine, and we are advancing these programs toward the achievement of key milestones.

#### **Allovectin-7<sup>®</sup>**

Our lead independent product development program is our Phase 3 registration trial of Allovectin-7<sup>®</sup> as a front-line therapy for patients with metastatic melanoma. Funding of our Phase 3 trial is provided up to certain limits by AnGes MG, our partner for commercialization in Asia. To date, we have received cash payments and equity investments totaling \$17.6 million of the \$22.6 million committed by AnGes.

In December, we announced the first sales and marketing partnership for Allovectin-7<sup>®</sup> with Eczacibasi, a leading pharmaceutical company in Turkey. The agreement is a logical extension of our efforts overseas where we are making excellent progress recruiting patients as we continue to expand to clinical sites across Western and Eastern Europe and into Turkey and Israel. We are opening several sites in Brazil, and with our sites in the United States and Canada, we will have more than 100 sites recruiting in key locations worldwide as we advance towards the final months of enrollment. Based on the trends across these regions, we are confident that we will complete enrollment of the planned 375 subjects in this pivotal Phase 3 trial by the end of 2009.

After completion of the enrollment, the follow-up period is fixed and the trial endpoint of response rate at 24 weeks or beyond is well-defined under the terms of our Special Protocol Assessment. If we meet the agreed endpoint, we believe Allovectin-7<sup>®</sup> would qualify for fast track review by the U.S. Food and Drug Administration (FDA), which should minimize the post-trial time to product launch. The FDA has granted orphan drug designation to Allovectin-7<sup>®</sup> for metastatic melanoma, which could provide post-approval U.S. market exclusivity as well as certain tax benefits. We believe that Allovectin-7<sup>®</sup> has

the potential to become the next front-line therapy for metastatic melanoma, for which no new treatment has been approved in more than ten years.

### **CMV Vaccine**

Our lead infectious disease vaccine candidate is a DNA vaccine against cytomegalovirus (CMV), a common herpesvirus that poses significant risk for certain populations. Vical is among the few companies actively developing a CMV vaccine and the only one in an advanced clinical stage for transplant patients.

#### *Therapeutic vaccine*

Patients undergoing hematopoietic cell transplants, including bone marrow transplants, typically suffer from advanced cancers of the circulatory or lymphatic system. Patients undergoing solid organ transplants typically face organ failure due to underlying disease. Treatment with immunosuppressive drugs to prevent transplant rejection often allows latent CMV to reactivate causing serious medical complications during the recovery period. No vaccine is available to prevent or control CMV reactivation. The costly antiviral treatments in current use are not effective for all patients, and may cause severe side effects including rejection of the transplanted organ. Our therapeutic vaccine is intended to reduce or eliminate the need for toxic and expensive antiviral drugs to control CMV for this high-risk transplant patient population.

In November 2008, we completed enrollment of the full 80 subjects in the recipient-only arm of our Phase 2 trial for patients undergoing bone marrow transplants and we reported statistically significant interim immunogenicity data from the first group of 33 transplant recipients. The results indicated significant ( $p < 0.05$ ) enhancement of CMV-specific T-cell immune responses in the vaccine group compared with the placebo group. These results are encouraging because independent publications have shown that increased CMV-specific T-cell responses following bone marrow transplants are predictive of favorable clinical outcome as measured by endpoints such as limited levels of active CMV and reduced CMV disease.

In the second quarter of 2009, we plan to report expanded immunogenicity results and initial clinical efficacy results on the full cohort of transplant recipients after a four-month follow up. The efficacy analysis will compare vaccine versus placebo groups using multiple efficacy markers including a) frequency of viral reactivation, b) total antiviral therapy, and c) viral load. We believe these endpoints are key indicators of patient benefit for transplant recipients.

#### *Prophylactic vaccine*

Mothers who initially become infected with CMV during pregnancy, particularly during the first trimester, can transmit the virus to their unborn children. Infants born with CMV infection can be affected by blindness, deafness, and mental retardation, which are frequently undiagnosed until the child reaches several years of age. Our prophylactic vaccine is designed to prevent infection of women before or during pregnancy, thereby preventing viral transmission to the fetus.

We believe the best approach for this market segment is an antibody focused DNA vaccine encoding at least the gB antigen, one of the two antigens currently used in our transplant vaccine. We intend to formulate this vaccine with the same Vaxfectin<sup>®</sup> adjuvant used in our successful pandemic influenza vaccine trial. We are actively evaluating opportunities to move forward with such a program and are currently in discussions with CMV experts for the development of an appropriate clinical trial design.

### **Pandemic Influenza Vaccine**

Global concerns of pandemic influenza are currently fueled by the transmission of several H5N1 influenza virus strains from birds to humans in recent years leading to hundreds of infections with high death rates. We believe our DNA delivery technology is ideally suited to address such emerging diseases because of its rapid development and manufacturing potential.

Beginning in July 2008, we reported breakthrough H5 antibody response data for our monovalent vaccine, demonstrating for the first time that DNA vaccines achieved potentially protective levels of antibody responses in up to 67% of evaluable subjects in the higher dose cohorts. Using the same immunogenicity test, the conventional pandemic influenza vaccine currently stockpiled by the U.S. government achieved protective levels of antibody responses in 44% of subjects.

Additional data presented later in the year showed that our vaccine produced sustained antibody responses up to six months, cross-clade antibody responses, T-cell responses against H5 with our monovalent vaccine, and both antibody and T-cell responses against all three targets with our trivalent vaccine. We are currently exploring potential funding sources for further development of this program.

### **Partnered Programs**

Our lead partnered programs for human health address angiogenesis—one of the largest potential markets for our technology with near-term commercialization opportunity. Our two angiogenesis partners, AnGes and sanofi-aventis, use our technology to deliver genes that promote the growth of new blood vessels to circumvent blocked arteries in patients with peripheral arterial disease. We are entitled to receive milestone payments from both programs if and when they advance through development, and we could receive substantial royalties if they advance to marketing approval.

In March 2008, our Japanese partner AnGes filed for marketing approval in Japan of its angiogenesis product Collategene<sup>™</sup>. We are hopeful that the approval will occur this year.

Our European partner sanofi-aventis is conducting a large, multinational, double-blind, placebo-controlled Phase 3 trial designed to support approval of its angiogenesis product in major global markets. Assuming successful completion of the trial, sanofi-aventis expects to file for marketing approval in 2010.

In December 2008, we announced the receipt of a \$1.0 million milestone payment from Merck related to the initiation of a Phase 1 cancer vaccine trial. The new DNA vaccine encodes hTERT, a form of human telomerase and is being evaluated in patients with broad range of solid tumors. Merck has another active cancer vaccine program evaluating a DNA vaccine encoding HER-2 and CEA.

We are collaborating with the U.S. Navy and the U.S. Army to develop a dengue DNA vaccine formulated with our Vaxfectin<sup>®</sup> adjuvant to protect troops being deployed in dengue-endemic regions. We are manufacturing the vaccine and adjuvant under a \$1.3 million contract and providing regulatory and clinical expertise.

In the animal health arena, our partner Merial received conditional approval in 2007 of its canine melanoma vaccine and is awaiting full approval. This is the first vaccine ever approved for therapeutic use in any species.

### **Outlook**

We look back on 2008 as a year of great progress for the company, and look forward to the remainder of 2009 for a series of significant milestones in both our independent and partnered programs. We have positioned the company to sustain the scope and pace of development in our key programs. We are managing the business to conserve our cash through this difficult economic climate while continuing to drive our key programs forward.

We thank our collaborative partners, our employees, our customers and suppliers, and our long-term investors for their continuing support.

Sincerely,

A handwritten signature in black ink, appearing to read "V.B. Samant". The signature is fluid and cursive, with a large initial "V" and a long, sweeping tail.

Vijay B. Samant  
President and Chief Executive Officer

April 3, 2009

## Board of Directors

### **R. Gordon Douglas, M.D., Chairman**

Retired President  
Merck Vaccine Division

### **Robert H. Campbell**

Retired President and  
Chief Executive Officer  
Sunoco, Inc.

### **Gary A. Lyons**

Boards of Directors  
Neurocrine Biosciences  
Rigel Pharmaceuticals

### **Robert C. Merton, Ph.D.**

John and Natty McArthur  
University Professor  
Harvard Business School

### **Vijay B. Samant**

President and  
Chief Executive Officer  
Vical Incorporated

## Executives

### **Vijay B. Samant**

President and  
Chief Executive Officer

### **Jill M. Broadfoot**

Senior Vice President,  
Chief Financial Officer and  
Secretary

### **Alain P. Rolland, Pharm. D., Ph.D.**

Executive Vice President,  
Product Development

### **Robin M. Jackman, Ph.D.**

Senior Vice President,  
Business Operations

### **Kevin R. Bracken**

Vice President, Manufacturing

### **Andrew R. de Guttadauro**

Vice President,  
Corporate Development

### **Larry R. Smith, Ph.D.**

Vice President, Vaccine Research

## Contact

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## Transfer Agent

### **BNY Mellon Shareowner Services**

P.O. Box 358015

Pittsburgh, PA 15252-8015

Tel: (800) 522-6645

TDD for Hearing Impaired:

800-231-5469

Foreign Shareowners:

201-680-6578

TDD Foreign Shareowners:

201-680-6610

Web site:

[www.bnymellon.com/shareowner/isd](http://www.bnymellon.com/shareowner/isd)

## Attorneys

### **Cooley Godward Kronish LLP**

4401 Eastgate Mall

San Diego, CA 92121-9109

Tel: (858) 550-6000

Web site: [www.cooley.com](http://www.cooley.com)

## Independent Registered Public Accounting Firm

### **Ernst & Young LLP**

4370 La Jolla Village Drive, Suite 500

San Diego, CA 92122-1249

Tel: (858) 535-7200

Web site: [www.ey.com](http://www.ey.com)

## Annual Meeting of Stockholders

### **Hilton Times Square**

234 West 42nd Street

New York, NY 10036

Thursday, May 21, 2009

7:30 a.m.

## Corporate Information

Vical's common stock is traded on the Nasdaq Global Market under the symbol VICAL.

Vical's Annual Report on Form 10-K contains additional information about our business, including our full financial statements and related notes, and is therefore an integral part of this report. In addition, this report contains statements that discuss our future expectations, contain projections of our results of operations and 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 significantly and materially from those expressed in these forward-looking statements as a result of risks and uncertainties, including those detailed in our Annual Report on Form 10-K. We disclaim any intent or obligation to update these forward-looking statements, and you should not unduly rely on them.

## SEC Form 10-K

A copy of the exhibits to Vical's Annual Report on Form 10-K filed with the Securities and Exchange Commission is available, upon payment of our reasonable expenses in furnishing such exhibits, upon written request to:

Investor Relations

Vical Incorporated

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San Diego, CA 92121-4340

