



Delivering the promise of DNA vaccines

2005 ANNUAL REPORT

Vical

## 2005 HIGHLIGHTS

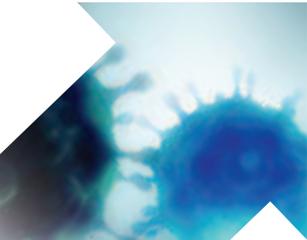
- Aqua Health (Novartis) vaccine for salmon received approval in Canada
- Merck advanced in cancer vaccine program
  - Exercise of cancer vaccine options
  - Expanded cancer vaccine options
  - Initiated cancer vaccine Phase 1 trial
- Merck received an option to sublicense electroporation for HIV vaccines
- We established an angiogenesis collaboration with AnGes MG
- We advanced CMV vaccine program
  - Completed Phase 1 trials and selected bivalent formulation for Phase 2
  - Received Orphan Drug designation for transplant indications from FDA
- We initiated IL-2 / electroporation Phase 1 trial
- NIH advanced in infectious disease vaccine collaboration
  - Initiated manufacturing for a \$12.1 million HIV vaccine production order
  - \$3 million grant for human vaccine against pandemic avian flu
  - Initiated HIV prime-boost vaccine Phase 2 trial
  - Initiated Phase 1 trial with West Nile virus vaccine
  - Established CRADA for HIV-electroporation program
- We completed Allovectin-7<sup>®</sup> Special Protocol Assessment

## CONDENSED FINANCIAL INFORMATION (UNAUDITED)

	2005	2004	2003
	(in thousands, except per share data)		
<b>Statement of Operations Data</b>			
Revenues	\$ 12,003	\$ 14,545	\$ 8,078
Operating expenses	37,654	39,688	34,182
Loss from operations	(25,651)	(25,143)	(26,104)
Net investment income	1,294	1,410	1,654
Net loss	(24,357)	(23,733)	(24,450)
Net loss per common share (basic and diluted)	\$ (0.99)	\$ (1.05)	\$ (1.22)
Shares used in per share calculation	24,581	22,695	20,091
<b>Balance Sheet Data</b>			
Cash, cash equivalents and marketable securities, including restricted	\$ 66,486	\$ 73,996	\$ 84,518
Working capital	63,484	67,300	76,983
Total assets	94,530	101,226	110,707
Long-term obligations	5,444	8,209	8,662
Stockholders' equity	80,306	82,909	89,822

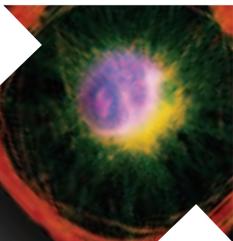
## VICAL'S DNA TECHNOLOGY

### INFECTIOUS DISEASE



Among the most promising applications of Vical's DNA technology are vaccines that can be developed rapidly for the prevention of diseases caused by emerging and persistent infectious pathogens such as cytomegalovirus and West Nile virus. Several DNA vaccines for infectious disease are already in clinical development.

### CANCER



DNA delivery technology can be used to deliver into tumor cells selected genes encoding specific proteins that help make cancer more visible to the immune system. This approach has advanced to late-stage clinical development at Vical. DNA cancer vaccines are also under development by our collaborators under license agreements with Vical.

### ANGIOGENESIS



The formation of new blood vessels can help alleviate disease in which narrowed blood vessels restrict blood flow. Vical's DNA technology is being evaluated in a Phase 3 clinical trial for gene-based delivery of a protein known to facilitate the growth of blood vessels. Applications include coronary artery disease and peripheral arterial disease.

### ANIMAL HEALTH



A veterinary vaccine using Vical's DNA technology for immunization of salmon against infectious disease received approval in Canada in 2005 and is currently being marketed there. It is the first DNA vaccine to reach the market. Our collaborators have additional DNA vaccines against infectious disease and for cancer therapy in animals currently under development.

## DEAR SHAREHOLDERS

I have spoken often about the promise of DNA vaccines. In July 2005, that promise became reality.

We reached a significant milestone for our DNA vaccine technology when our licensee Aqua Health (Novartis) received marketing approval for a DNA vaccine for salmon in Canadian fish farms. We believe this approval is an important validation of our technology in the animal health area. Aqua Health developed its novel DNA vaccine to protect farm-raised salmon against Infectious Hematopoietic Necrosis Virus, or IHNV, a highly lethal and commercially devastating infectious disease. When the young salmon are transferred from the protected environment of fish farms into pens in the ocean, as many as 90% can be lost to this disease.

Aqua Health licensed Vical's technology for this vaccine because conventional vaccine approaches did not provide effective protection. The large numbers of fish that must be vaccinated and the competitive profit margins in this industry demanded a vaccine that is economical as well as effective. Very low doses of DNA are providing the needed protection on a highly cost-effective basis. We are truly excited to have reached this landmark approval for our technology.

Our partner Merial, a joint venture of Merck and Sanofi-Aventis, has advised us that it expects to receive USDA conditional approval in 2006 of a gene-based melanoma vaccine for dogs. This would be a significant milestone for our technology in the cancer vaccine area, and our first opportunity to address the substantial market for companion animals.

These product launches provide important validation of our technology in diverse animal applications as we approach validation in humans.



## INFECTIOUS DISEASE VACCINES

### CMV

Our lead program in the human infectious disease vaccine area is the development of an immunotherapeutic vaccine candidate against cytomegalovirus (CMV). We announced in January 2006 that we had opened enrollment in our placebo-controlled, randomized Phase 2 CMV vaccine trial, the only CMV vaccine trial in hematopoietic cell transplant (HCT) patients we know of that is currently enrolling in the United States.

The design of this Phase 2 trial was based on results from our Phase 1 trials in a total of 84 subjects. Our bivalent vaccine, which combines genes for a surface protein, glycoprotein B, and an internal protein, phosphoprotein 65, was found generally to be safe and well-tolerated and at the 5 mg dose elicited cellular and/or antibody responses in 50% of CMV-seronegative volunteers and detectable responses in many of the other subjects. We believe this relatively small human Phase 2 trial will allow us to evaluate safety in immunocompetent donors and immunosuppressed recipients. Protective efficacy of the vaccine will be compared against placebo in the transplant recipients.

In addition to this trial in HCT patients, we also are exploring options for a Phase 2 trial in solid organ transplant patients, including potential funding from government sources. Both the HCT and solid organ (e.g., liver, kidney, heart-lung) transplant indications for our CMV vaccine have Orphan Drug Status designation by FDA.

An important long-term goal of our CMV vaccine program is to evaluate the potential for the much larger commercial opportunity to protect against congenital CMV infection. The goal here is to protect females of childbearing age from infection with CMV to prevent transmission to the unborn fetus. Clearly, a protective vaccine for the target population would address a significant unmet medical need.

### Pandemic Influenza

We launched a new initiative in 2005 with the support of NIH funding to develop a vaccine to protect against pandemic forms of influenza, potentially leading to more effective vaccines for seasonal flu as well. Our approach for pandemic



flu is similar to our approach to seasonal flu. We are focused on human and avian forms of the conserved NP and M2 proteins as well as the HA surface protein to drive both antibody and cellular immune responses, unlike conventional killed flu vaccines that elicit only an antibody response against HA. The conventional killed vaccine is least effective in the elderly, and annual revaccination is required to address HA variations in circulating strains. Our goal is to develop a vaccine that provides enhanced effectiveness for the elderly and cross-strain immunity.

We have completed the first milestone in our \$2.9 million NIH grant pandemic flu program by demonstrating that our DNA-based avian flu HA surface protein vaccine is immunogenic in animals. We are now working towards the second milestone in this program that includes challenging vaccinated mice and ferrets with a virulent Vietnam strain of H5N1 avian flu. Ferrets are a widely accepted animal model for influenza vaccines. This work is being conducted by St. Jude Children's Research Hospital at its BSL-3 facilities. We expect data from the challenge studies in 2006.

### **National Institutes of Health (NIH)**

We are collaborating with the NIH on multiple infectious disease vaccine development programs, which have become significant sources of contract manufacturing revenues, and some of which offer potential commercialization rights.

The NIH started a multinational Phase 2 HIV vaccine trial in October 2005 that will enroll about 480 healthy volunteers. The trial uses a prime-boost approach combining three doses of a DNA vaccine followed by a single boost with an adenoviral vector vaccine. DNA vaccines continue to be a key component in a number of active HIV vaccine development programs.

In addition, the NIH has placed a \$12.1 million production order for additional supplies of DNA vaccines against HIV in support of a second, much larger, Phase 2 trial. We have begun production and expect to complete shipments under this order in 2006, and this large trial is expected to start in early 2007.

In February 2006, the NIH presented Phase 1 data from its Ebola DNA vaccine program, indicating that the vaccine was safe and well tolerated, and produced Ebola-specific

antibody and cellular immune responses in all 20 healthy volunteers who received all 3 doses of vaccine. We believe this is the only clinical-stage Ebola vaccine. Ebola has been allocated \$90 million for initial stockpiling and \$260 million for long-term procurement under Project BioShield, and the Ebola DNA vaccine under development by the NIH may be eligible for this stockpiling program.

The NIH also has conducted Phase 1 trials of DNA vaccines against SARS and West Nile virus. Data from those trials should be available in 2006.

## **CANCER**

### **IL-2 / Electroporation**

Our first clinical trial using electroporation-enhanced DNA delivery technology licensed from Inovio Biomedical Corporation began in July 2005, with a gene-based IL-2 product candidate for solid tumors and an initial application in metastatic melanoma patients. The goal is to surpass the clinical benefits of IL-2 protein therapy and avoid the toxicity associated with systemic protein delivery. We have progressed through the initial dose-escalation stages, and expect to complete enrollment later in 2006.

### **Merck**

We saw significant progress in our collaboration with Merck in 2005. Merck exercised its option on three cancer vaccine targets in the second quarter. In the third quarter, we granted Merck an option for additional cancer vaccine targets in exchange for non-exclusive, sublicenseable rights for vaccines against HIV, giving both companies freedom to operate in the HIV field. Merck also received an option to exclusively sublicense electroporation-enhanced delivery technology for use with HIV vaccines. In the fourth quarter, Merck initiated a Phase 1 clinical trial of a cancer vaccine encoding two of its three licensed targets, HER-2 and CEA. The third licensed target has not yet been disclosed. These activities resulted in license and milestone payments to Vical of \$4 million in 2005. We are excited by Merck's advancement of this program into the initial human study, and we look forward to continued progress.

## ANGIOGENESIS

### AnGes MG

We signed on a new angiogenesis partner last year, AnGes MG, a Japanese company, who is using our technology to deliver the gene encoding Hepatocyte Growth Factor (HGF). AnGes has advised us that it expects to present results from its Phase 2 trial in the United States and to complete enrollment in its Phase 3 trial in Japan in 2006, both for peripheral arterial disease (PAD). It also is conducting a U.S. Phase 1 trial for ischemic heart disease. AnGes' marketing partner, Daiichi, a large Japanese pharmaceutical company, has projected the launch of the PAD product in Japan in 2007.

### Sanofi-Aventis

Our angiogenesis partner Centelion, a part of the Sanofi-Aventis Group, has conducted Phase 2 trials in Europe and in the United States. This program is targeting PAD using the gene for Fibroblast Growth Factor 1 (FGF-1). Results from the Phase 2 trials were presented in March 2006, and demonstrated improved amputation-free survival. Sanofi-Aventis separately announced plans to begin a Phase 3 trial of its FGF-1 product candidate in the fourth quarter of 2006.

### Corautus Genetics

Corautus Genetics is working with the strong support of Boston Scientific on the gene-based delivery of Vascular Endothelial Growth Factor 2 (VEGF-2) as a treatment for severe cardiovascular disease. In 2004, Corautus initiated a Phase 2b clinical trial. That trial was placed on clinical hold in March 2006 following a cluster of three reported cases of fluid buildup around the heart, which did not appear to be related to the VEGF-2 biologic. Patient enrollment in the trial was terminated in April 2006 on the recommendation of an independent Data Monitoring Committee.

### Universities

In January 2006, we announced academic licenses of our core technology to three leading research institutions:

Stanford, Harvard and Yale. A fourth institution, the Massachusetts Institute of Technology (MIT), also has signed our academic license agreement.

These non-exclusive licenses allow the universities to use our technology for academic research purposes, not for company-sponsored research. In exchange, we have the option to exclusively license resulting commercial applications. We are offering identical terms to other universities to encourage broader use of our technology while protecting our intellectual property.

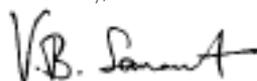
## FINANCIAL POSITION

We ended the year with about \$66 million in cash and investments. We completed a registered direct placement of stock under our shelf registration during the fourth quarter of 2005, generating net proceeds of approximately \$21 million, and we filed a new \$70 million shelf registration in January 2006.

## OUTLOOK

The milestones achieved in 2005, particularly the first commercial applications of a DNA vaccine, encourage our ongoing efforts to develop human vaccines. As we continue advancing with each of our programs, we rely on the continued support of our collaborative partners, our employees, our customers and suppliers, and of course, our long-term investors. I look forward to another year of progress for our technology and our company.

Sincerely,



Vijay B. Samant

President and Chief Executive Officer

April 11, 2006

**BELOW, FROM LEFT TO RIGHT:**  
Kevin R. Bracken, Vice President, Manufacturing; David C. Kaslow, M.D., Chief Scientific Officer; Vijay B. Samant, President and Chief Executive Officer; Robin M. Jackman, Ph.D., Vice President, Business Development; Jill M. Church, Vice President, Chief Financial Officer and Secretary; Alain P. Rolland, Pharm. D., Ph.D., Senior Vice President, Product Development



# DNA VACCINES AND EMERGING DISEASES

The continuing spread of avian influenza is the latest in a series of infectious diseases that have aroused global



concerns about emerging pathogens. The anthrax threat of 2001 was limited to a handful of cases because of the highly selective and visible targeting of just a few locations, combined with rapid detection and lock-downs of the affected buildings. The periodic outbreaks of

Ebola in Africa have severely impacted populations in the affected villages, but have been contained through geographic isolation. The SARS threat of 2002 resulted in more than 750 deaths worldwide before it was halted primarily through aggressive quarantines of potential carriers.

Conventional vaccines offered no help against these diseases, and offer little hope for protection of large populations against other emerging disease threats. The shortcomings of conventional vaccines center on the long development times after isolation and characterization of a new pathogen, long manufacturing cycles and limited capacity in highly customized manufacturing facilities.

## Pandemic Influenza Case Study

The threat of pandemic influenza drew a flurry of media attention during 2005. Vical's DNA vaccine technology may be viewed as an emerging disease platform with the potential to overcome the shortcomings of the conventional killed virus or subunit protein vaccines:

- **First**, there are serious limitations to egg-based manufacturing, including purity, consistency and capacity. Eggs may not be available on short notice, if at all, if avian flu continues to spread. In addition, the pandemic strains of flu may be toxic to eggs even if they are available. The long manufacturing process for the flu shot requires substantial lead time. But selection of a potential pandemic strain in advance of its emergence is merely a guess.

Whether it will be based on H5 or H9 or some other variation is unknown.

- **Second**, alternative cell culture manufacturing methods can eliminate the reliance on eggs, and potentially speed up production, but the inherent complexities of cell-based production restrict its potential for rapid response to an emerging disease, and the resulting vaccine is still limited to antibody responses against the surface protein.
- **Third**, conventional flu vaccines for seasonal flu provide protection via antibody responses against the selected surface protein, and have little ability to provide cross-protection against different strains of flu. The pandemic flu shot will still only provide antibody-mediated protection, which may not be enough, especially if the guess on the strain is not precisely on target. Early data suggests that the egg-based H5 vaccine requires six times the current amount per dose, times two injections. An adjuvant could help, but it is unlikely that current technology can meet the demand even if the correct strain is chosen.

**Vical's approach** may be able to overcome these problems for pandemic influenza, and the same methods and facilities could be easily converted to address other emerging pathogens. The goal is to develop a vaccine that provides cross-strain antibody and cellular immunity.

Vical's vaccines are manufactured by fermentation in *E. coli* bacteria, a process that does not rely in any way on chicken



eggs or cell culture. The process is the same for any pathogen, and significantly faster than conventional methods.

Vical's vaccine will encode for the HA surface protein, and encode for the NP and M2 conserved proteins, with the goal of engaging both arms of the immune system and hopefully improving cross protection. This ability to target

Vical's DNA vaccine technology may be viewed as an emerging disease platform with the potential to overcome the shortcomings of the conventional killed virus or subunit protein vaccines.



# VICAL'S NON-VIRAL DNA DELIVERY TECHNOLOGY

The key discovery leading to our patented core technology was that muscle tissues can take up polynucleotide genetic material, such as DNA or RNA, directly *in vivo*, without the use of viral components or other delivery vehicles, and subsequently express the proteins encoded by the genetic material.

Vical's DNA delivery technology typically uses closed loops of DNA called plasmids (pDNAs) that encode a protein of interest as well as short segments of DNA that control protein expression. After being reproduced in large quantities, the plasmids are formulated for the specific application and delivered to the appropriate tissue. Proteins encoded by the DNA are then expressed by cells in the body for periods ranging from days to weeks. These proteins can trigger the specific desired biological activity, such as tracking down and destroying cancer cells, fighting off infectious pathogens, or promoting the growth of blood vessels.



## Plasmid

A segment of DNA encoding a protein associated with a specific gene or target infectious organism is spliced into a plasmid, which is then produced by bacterial fermentation.

## Formulation

Once the plasmid is constructed, it is formulated for optimal delivery and effectiveness. The formulation of the plasmid allows for more efficient uptake of the DNA by the cells and may provide additional immune stimulation.

## Delivery

Vical delivers its plasmid DNA immunotherapeutics and vaccines via injection with or without electroporation, however, other methods that could be adopted in the future include inhalation, patch delivery and oral delivery.

## ADVANTAGES OF VICAL'S NON-VIRAL DNA TECHNOLOGY

Traditional vaccines, cancer therapies and protein delivery therapies are limited in their breadth of use by safety concerns and in their production efficiency by manufacturing difficulties. Vical's DNA technologies offer significant improvements in safety and manufacturing over other technologies while

enabling accelerated development of new vaccines and stimulating antibody and T-cell immune responses.

Benefits of our DNA delivery technologies may include the following, which may enable us to offer novel treatment alternatives for diseases that are currently poorly addressed:

- **Broad Applicability.** Our DNA delivery technologies may be useful in developing vaccines for infectious diseases, in which the expressed protein induces an immune response; novel therapies for cancer, in which the expressed protein is an immune system stimulant or tumor antagonist; and therapeutic protein delivery, in which the expressed protein is a therapeutic agent.
- **Convenience.** Our DNA-based biopharmaceutical product candidates are designed to be administered on an outpatient basis, allowing patients to continue living at home and in many cases, functioning well in their jobs and personal lives while undergoing treatment.
- **Safety.** Unlike traditional vaccines and viral gene delivery methods, Vical's non-viral DNA technology does not require the use of viral components for delivery into cells or stimulation of immune response. No live, attenuated or killed pathogens are used in making vaccines developed from Vical's DNA technology, so there is no risk of an infectious agent causing unwanted immune responses, infections or malignant changes.
- **Repeat Administration.** Our product candidates do not use viral components that can cause immune responses against the product itself, potentially precluding multiple dosing with a single product or use of the same viral components in multiple products. We have substantial experience involving repeat administration of DNA-based vaccines and immunotherapeutics in humans.
- **Ease of Manufacturing.** Our product candidates are manufactured using uniform fermentation and purification procedures that allow products to be manufactured in large quantities in a relatively short period of time and released after uniform analyses.
- **Cost-Effectiveness.** Our DNA delivery technologies may be more cost-effective than other approaches. The ease and safety of manufacturing and production of Vical's DNA technology offers potential cost efficiencies when compared to other therapies. It may also cause fewer potential side effects, which itself may reduce per patient treatment costs.

## WHY DNA VACCINES?

Vaccines are a powerful tool in the effort to prevent or treat infectious diseases. Our DNA delivery technology may offer both technical and economic advantages that would allow development of vaccines not feasible with conventional vaccine approaches. Made up of DNA that encodes certain proteins associated with a target pathogen, rather than the pathogen itself, these DNA vaccines can induce potent antibody and T-cell immune responses. Critically, our vaccines contain no viral particles, are non-infectious, and can be administered on a repeat basis without unwanted immune responses or side effects. Additionally, our DNA vaccines have the potential to achieve proof of concept in humans more quickly and cost-effectively than conventional vaccines. This is especially important because it enables the rapid and economical development of vaccines for small populations and for new threats, such as those posed by bioterrorism.

In fact, we believe infectious disease vaccines represent our most promising independent product development opportunities. Already, our technology is being harnessed to develop a new approach to vaccines against diseases such as CMV, influenza, HIV, Ebola, West Nile virus, anthrax and SARS. We have several novel product candidates in development with major pharmaceutical partners. We are leveraging that expertise, together with vaccine industry leadership, a proficient research staff and integrated manufacturing capabilities, to fuel the growth of our independent vaccine programs.

## FUTURE OF NON-VIRAL DNA TECHNOLOGY

Already validated by the recent approval of a DNA vaccine against infectious disease in animal populations, Vical's DNA technology is currently in advanced stages of human clinical testing against cancer and for angiogenesis. The broad applicability of Vical's DNA technology and its demonstrated ability to advance quickly from concept to human testing are among its most compelling advantages as a powerful platform for vaccines against emerging infectious diseases.

DNA-based infectious disease vaccines, immunotherapies, and protein delivery drugs have the potential to become the

standard of care in treating and preventing some of the world's most challenging health concerns—from heart disease to bioterror.



## PATENTS

Patents and other proprietary rights are essential to our business. We believe that our patent portfolio is the most comprehensive of any company in the non-viral DNA delivery sector. In addition to our protected technologies, we also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We and our exclusive licensors have received U.S. and foreign patents covering various aspects of our proprietary technology including:

- **Core DNA Delivery Technology.** We own rights to issued patents covering our core DNA delivery technology, including patents on methods of administering DNA sequences for the purposes of expressing therapeutic proteins or for inducing immune responses. Other issued patents specifically cover the administration of DNA sequences into blood vessels and the heart.
- **Core Lipid Technology.** We have received issued patents covering numerous examples of cationic lipid compounds that are used to facilitate delivery of gene therapies to some tissues. These patented compounds include the lipids contained in some of our product candidates.
- **Specific DNA Therapeutics.** We have supplemented the broad patent coverage described above with patents covering specific product applications of our technology. To date, we have received patents issued in the United States covering our lead product candidates and other patents related to gene delivery to the heart, including delivery of a vascular endothelial growth factor, or VEGF.
- **DNA Process Technology.** As a result of our pioneering efforts to develop the use of pure plasmid DNA as a therapeutic agent, we have also developed manufacturing processes for producing pharmaceutical-grade DNA. We have received issued patents covering various steps involved in the process of economically producing pure plasmids for pharmaceutical use.

Vical's Annual Report on Form 10-K contains additional information about our business, including our 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.

## CONTACT

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## CORPORATE INFORMATION

Vical common stock is traded on the Nasdaq National Market under the symbol VICL.

## EXECUTIVES

Vijay B. Samant  
President and Chief Executive Officer

David C. Kaslow, M.D.  
Chief Scientific Officer

Jill M. Church  
Vice President,  
Chief Financial Officer and Secretary

Alain P. Rolland, Pharm. D., Ph.D.  
Senior Vice President,  
Product Development

Kevin R. Bracken  
Vice President, Manufacturing

Robin M. Jackman, Ph.D.  
Vice President,  
Business Development

## BOARD OF DIRECTORS

R. Gordon Douglas, M.D., Chairman  
Robert H. Campbell  
M. Blake Ingle, Ph.D.  
Gary A. Lyons  
Robert C. Merton, Ph.D.  
Vijay B. Samant

## TRANSFER AGENT

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## ANNUAL MEETING

Friday, May 19, 2006  
9:00 a.m.  
Country Inn & Suites  
5975 Lusk Boulevard  
San Diego, California 92121

## 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:

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