



# FORM 10-K

## PANACOS PHARMACEUTICALS, INC. - PANC

**Filed: March 03, 2005 (period: December 31, 2004)**

Annual report which provides a comprehensive overview of the company for the past year

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-K**

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

For the fiscal year ended December 31, 2004

or

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

Commission File No. 0-24241

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**V.I. TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction  
of incorporation or organization)

**134 Coolidge Ave, Watertown, MA**  
(Address of principal executive offices)

**11-3238476**  
(I.R.S. Employer  
Identification No.)

**02472**  
(Zip code)

**Registrant's telephone number, including area code: (617) 926-1551**

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**Securities registered pursuant to Section 12(b) of the Act:**

**None**

**Securities registered pursuant to Section 12(g) of the Act:**

**Common stock, \$0.01 par value**  
(Title of class)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  No

The aggregate market value of voting common stock held by non-affiliates of the Registrant, based on the closing price of the common stock on June 26, 2004 as reported on the Nasdaq National Market, was approximately \$43,302,000. Shares of common stock held by each officer and director and by each person who owns 5 percent or more of the outstanding Common Stock have been excluded from this computation in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

**54,475,592**

(Number of shares of common stock outstanding as of March 2, 2005)

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Registrant's Annual Report to Stockholders for the fiscal year ended December 31, 2004 are incorporated by reference into Part II of this Report. Portions of the Registrant's Definitive Proxy Statement for the 2005 Annual Meeting of Stockholders (the Definitive Proxy Statement), to be filed with the SEC within 120 days of December 31, 2004, are incorporated by reference into Part III of this Report.

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## FORWARD LOOKING STATEMENTS

This document and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Also, our company management may make forward-looking statements orally to investors, analysts, the media and others. Forward-looking statements express our expectations or predictions of future events or results. They are not guarantees and are subject to many risks and uncertainties. There are a number of factors that could cause actual events or results to be significantly different from those described in the forward-looking statements. Forward-looking statements might include one or more of the following:

- anticipated results of financing activities;
- anticipated agreements with marketing partners;
- anticipated clinical trial timelines or results;
- anticipated research and product development results;
- projected regulatory timelines;
- descriptions of plans or objectives of management for future operations, products or services;
- forecasts of future economic performance; and
- descriptions or assumptions underlying or relating to any of the above items.

Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts or events. They use words such as “anticipate”, “estimate”, “expect”, “project”, “intend”, “opportunity”, “plan”, “potential”, “believe” or words of similar meaning. They may also use words such as “will”, “would”, “should”, “could” or “may”.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of such statements. We do not intend to update any of the forward-looking statements after the date of this report to conform such statements to actual results except as required by law. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should carefully consider that information before you make an investment decision. You should review carefully the risks and uncertainties identified in this report.

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**Item 1. BUSINESS**

**Overview**

V.I. Technologies, Inc. (“VITEX,” the “Company” or “we”) is a development stage biotechnology company developing novel anti-infective products. Our INACTINE™ Pathogen Reduction System for red cells, or INACTINE™ system, is designed to inactivate a wide range of viruses, bacteria, parasites and lymphocytes from red blood cells and to remove soluble prion proteins. Prion proteins in their pathogenic forms are the agents that cause “Mad Cow Disease”, or in humans, variant Creutzfeldt-Jakob Disease, or vCJD, which is 100% fatal, and for which no diagnostic test or therapy currently exists. Over 40 million red cell units are transfused annually in North America, Europe and Japan, making it one of the most frequently prescribed and important products in medicine. A pathogen reduction product for both acute and chronic patients could represent, according to our estimates as based on a report prepared for us by Easton Associates, an outside consultant, a \$4 billion market with acute indications representing approximately \$3 billion out of that total. We currently do not have any FDA approved products and have not made any commercial sales of our products under development.

On June 2, 2004, we entered into an Agreement and Plan of Merger with Panacos Pharmaceuticals, Inc., (“Panacos”). A special meeting of our stockholders to vote on the proposed merger has been scheduled for March 10, 2005. Upon obtaining stockholder approval, we expect to close the merger transaction on or about March 11, 2005. The proposed Panacos merger is discussed in greater detail below under “Proposed Merger with Panacos Pharmaceuticals”.

Blood safety and availability remain a significant concern as new pathogens are discovered and the demand for blood products continues to increase. To reduce the risk of contamination of the blood supply with pathogens, blood banks currently screen donors using detailed questionnaires and screen the donated blood for five known pathogens. Although these safety measures have increased the safety of blood products overall, the risk of transmitting pathogens remains. Our goal is to diminish this risk with our INACTINE™ system.

In November 2004, we suspended enrollment in our Phase III surgical, or acute, study for our lead product candidate, the INACTINE™ red cell system, following identification of an immune response to INACTINE™-treated red cells in one patient in the study during ongoing immunologic testing of subjects enrolled in the trial. As a result, both the Phase III trial of INACTINE™ for acute indications and the Phase III trial of INACTINE™ for chronic indications, described in more detail below, have been halted, in the case of the chronic trial, following a clinical hold by the FDA. Although no clinical consequences of the immune response are apparent based on review of available data, additional patients will not be enrolled in the acute trial pending full evaluation. We have notified the FDA that we have suspended enrollment in the study and that we intend to continue discussions with the FDA regarding the conditions, if any, under which the trial might be continued while we are completing our review of all relevant data. We intend to conduct these discussions as part of an ongoing dialogue with the FDA regarding conditions for licensure of the INACTINE™ system.

Our Phase III chronic study of the INACTINE™ system was placed on clinical hold by the FDA due to the availability of insufficient safety information, and was subsequently halted by us following a review by an independent data safety monitoring committee, or DSMC, in November 2003. The halting of the study by us was due to antibody formation in sickle cell anemia patients receiving repeat transfusions of INACTINE™-treated red cells. The Phase III trial of INACTINE™ for chronic indications was designed to be conducted in two sequential parts, Part A and Part B. The purpose of Part A was to allow assessment of the safety of INACTINE™-treated red cells in the patient population under study prior to proceeding to Part B. Enrollment in the chronic trial was stopped prior to initiation of Part B on the recommendation of the DSMC, which was charged with reviewing the data from Part A of the study following the FDA’s clinical hold on the trial due to availability of insufficient safety information.

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Prior to the suspension of the surgical trial, the FDA had expressed concerns regarding the licensing of the current INACTINE™ system for an acute indication in light of the presence of antibodies observed in the chronic trial, and has requested justification from us for pursuit of an acute-only indication in the context of these findings. The FDA has also indicated that a control system with respect to an acute-only indication would be required to ensure that patients who have previously received red cells treated by the current INACTINE™ system do not receive INACTINE™ red cells in subsequent hospitalizations. We have met with the FDA and presented proposals on supplemental clinical trials. However, the FDA has indicated that it will require the review of additional data, including the results of the Phase III trial for INACTINE™ in acute indications, before fully responding to our proposals for additional clinical trials. The occurrence of an immune response in the acute trial and the decision to suspend enrollment in it will require us to formulate and present to the FDA a regulatory plan for approval of INACTINE™ that takes into account all findings to date, which is likely to significantly delay determination of any acceptable regulatory pathway. The FDA has indicated that any such regulatory plan for the acute-only indication must address the development of a control system, as described above. In addition, we believe that modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells will also be required. At this time, we cannot determine the length of time required for us to develop such a regulatory plan, nor can we estimate the length of time required for the FDA to approve such a plan, or whether such a plan will be approved at all. Enrollment in the acute trial will continue to be suspended until such time as a regulatory plan is approved by the FDA and implemented by us, if ever. We have begun preclinical testing on the modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells. However, this work is preliminary and no assurance can be given that we will be able to develop a control system that will be technically feasible, approved by the FDA, and economically viable, or that the modifications to the current INACTINE™ process will succeed in reducing the likelihood of an immunologic response. Prior to the suspension of enrollment in the acute study, the FDA also directed us to implement additional patient safety monitoring procedures in the Phase III acute trial. We implemented these procedures and, until enrollment into the trial was suspended, were periodically updating the FDA on the trial data. While we believe that the steps taken addressed the FDA's recommendations prior to suspending enrollment in the acute trial, further steps could be required by the FDA. We also received from the FDA a written request for further information relating to an August 2004 amendment to our IND. The amendment included responses to questions raised by the FDA relating to procedures for patient safety monitoring used in the Phase III chronic study, which had been placed on clinical hold by the FDA due to the availability of insufficient safety information, and subsequently halted by us following a DSMC review. We have responded to the FDA's request and are awaiting further communications from the agency on this matter.

With the Phase III trial for INACTINE™ in chronic indications halted by us, following the clinical hold by the FDA and the subsequent review by the DSMC, and enrollment suspended in the Phase III trial for INACTINE™ in acute indications, our ongoing development plan for INACTINE™ for chronic, acute or other indications is highly uncertain. We cannot ensure that the acute trial will resume or complete enrollment in a timely manner. The exact nature, timing and estimated costs of the efforts necessary to bring to market the product resulting from our pathogen inactivation research and development projects involve a number of key variables which are either unpredictable or outside our control, including whether the likelihood of an immune response to INACTINE™-treated red cells can be adequately reduced, whether, and under what circumstances, the FDA will agree with our plan to proceed with clinical trials, the enrollment rates and results of the Phase III clinical trial in acute indications, should it be continued, the extent of further studies which could be required for filing a Biologics License Application with the FDA, the length of the FDA and foreign regulatory approval processes, the success of our fundraising efforts, our ability to establish and maintain relationships with marketing partners and strategic collaborators, and the timing of commencement of commercialization of our product. Inability to satisfy one or more of these conditions, or to do so in a commercially acceptable manner, may render continued development of our INACTINE™ system infeasible.

On December 10, 2004, we announced that we had implemented a restructuring to reduce expenses. The restructuring was intended to allow us to conserve cash until the completion of the proposed merger with Panacos. The restructuring included an immediate reduction in our research and development workforce by

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approximately 40%. We incurred a charge of \$0.1 million to research and development in the fourth quarter of 2004 in connection with the restructuring as each employee subject to the restructuring received severance pay equal to his or her one month salary. All payments were made prior to December 31, 2004.

We fund our operations primarily through sales of common stock and research and development grants.

As of February 28, 2005, we had cash on hand of approximately \$1.0 million. We expect to close on a \$20 million proposed financing concurrent with the proposed Panacos merger, described below. At present, after our recent restructuring in December 2004, we have been consuming approximately \$1.0 million in cash per month. Following completion of the proposed merger, the combined company expects to spend approximately \$2.6 million on average in cash per month in 2005. We believe that our present cash resources will be adequate to meet our requirements only through the first quarter of 2005.

We also believe that the sum of our present cash resources, Panacos' cash resources and the anticipated proceeds of \$20 million from the financing will be adequate to meet our cash requirements, post-merger, into the fourth quarter of 2005. However, there is no current guarantee that we will be able to successfully complete the merger transaction in March 2005 and close on the \$20 million financing shortly after closing the merger. The \$20 million financing is contingent on gaining shareholder approval for a reverse split of VITEX common shares and implementing the reverse split prior to closing the financing. In addition, we expect to commence a rights offering in March 2005, close in April 2005 and raise a maximum of \$5.5 million to increase that cash horizon. However, there is no guarantee that we will be able to successfully complete the rights offering. In the event that the merger, financing, or rights offering are not successful, we intend to delay or reduce expenditures so as to continue our operations on a limited scale and within our available resources.

Our office and research facilities are located in Watertown, Massachusetts.

### **Proposed Merger with Panacos Pharmaceuticals**

On June 2, 2004, VITEX signed a definitive merger agreement with Panacos Pharmaceuticals. The terms of the proposed merger were subsequently amended in November 2004, December 2004 and February 2005. We filed a final joint proxy statement – prospectus with the Securities and Exchange Commission, (the “SEC”), on February 14, 2005 and anticipate closing the merger shortly after our special meeting of shareholders on March 10, 2005, provided that our shareholders approve the merger and related proposals. We expect to receive \$20 million in gross proceeds from a private placement transaction with Great Point Partners, LLC, Ampersand Ventures, A.M. Pappas & Associates and other Panacos investors concurrently with the closing of the proposed merger.

### *Panacos*

Panacos Pharmaceuticals is a development stage company involved in the discovery and development of the next generation of small molecule, antiviral drugs for the treatment of Human Immunodeficiency Virus, or HIV, infection and other major virus diseases. Panacos is focusing exclusively on diseases with large markets, where there is a clear unmet need for more effective therapies. A major commercial advantage of the HIV market is the rapid clinical development and approval process for new drugs. The total time from initiation of clinical trials to market may be as little as four years, shorter than for many other disease indications.

The most urgent need in HIV therapy today is for new treatments that are effective against drug resistant strains of the virus. Drug resistance is a growing problem that occurs when an individual is treated with currently available drugs for an extended period, resulting in the emergence of virus strains that are no longer susceptible to those drugs. Recent studies have found that more than 50% of HIV-infected patients on antiretroviral therapy harbor drug-resistant virus. Furthermore, resistant viruses are often found in newly-infected people prior to initiating drug treatment, because they acquired these strains at the time of infection.

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By targeting different points in the virus life cycle than approved drugs, Panacos believes that its drug candidates can overcome the problem of resistance to current therapies. Panacos is focusing its attention on orally bioavailable, small molecule drugs in two new classes: Maturation Inhibitors and Fusion Inhibitors.

Panacos scientists recently identified Maturation Inhibition as a new target for antiviral intervention. Maturation occurs at the end of a virus life cycle as HIV buds from an infected cell. It involves the processing of a key viral protein called capsid, which is required for the viral core to assemble correctly, thereby allowing the virus to become infectious. Panacos' lead compound, PA-457, is the first in a new class of drugs called Maturation Inhibitors that block this process so that, following treatment, virus particles are defective and non-infectious.

Phase I clinical testing of PA-457 in uninfected volunteers is nearly complete. Single dose and multiple dose studies were performed and PA-457 was well tolerated, with good oral bioavailability and favorable pharmacokinetics that appear to support a once-a-day dosing regimen. Plasma concentrations of the drug were well above those predicted by Panacos scientists to provide therapeutic benefit in HIV-infected patients. Based on the positive Phase I data, Panacos carried out a Phase I/II study in HIV-infected patients to analyze pharmacokinetics and to determine the antiviral effect of a single oral dose of PA-457 in patients not on other therapy. Panacos has announced positive preliminary results from this proof-of-concept study. In the study, six patients received placebo, and eighteen patients received one of three dose levels of PA-457 (6 patients in each dose level). A reduction in the level of virus in the plasma, known as the viral load, of up to approximately 80%, was seen in 4 of 12 patients receiving the highest two dose levels (150 mg and 250 mg). The mean viral load reductions for these two dose levels were statistically significantly different than placebo at multiple time points following dosing ( $p < 0.05$ ). Because these results were based on a small sample, Panacos may have to conduct additional testing with respect to these results.

Panacos recently initiated a key multiple dose Phase IIa study in HIV-infected patients. Institutional Review Board, or IRB, and other approvals have been received and the study is open for enrollment. Panacos plans to complete dosing of all patients during the first quarter of 2005. The study is being performed at several sites in the U.S and is designed to demonstrate the antiviral potency of PA-457 following once-daily oral dosing of PA-457 for 10 days in HIV-infected patients who are not on other antiretroviral therapy.

The U.S. Food and Drug Administration has granted Fast Track Designation for PA-457, available for drugs designed to treat a serious or life-threatening condition with an unmet medical need. Developers of Fast Tracked products have greater access to FDA resources as well as eligibility for rolling NDA submissions. In addition, Fast Track designation may enable priority FDA review and accelerated approval.

Panacos' second drug discovery target is the initial step in the virus life cycle, virus fusion to a human cell. Panacos scientists have developed proprietary fusion drug screening technology and have used this successfully to identify novel HIV fusion inhibitors. These compounds are currently being optimized to generate a drug candidate for clinical testing.

All of Panacos' revenues have been generated from research grants and subcontract fees; Panacos has not generated any revenue from product sales. Panacos expects its primary revenue sources for the next few years to include research grants and collaboration payments under future arrangements. The timing and amounts of such revenues, if any, will likely fluctuate and depend upon the achievement of specified research and development milestones. Results of operations for any period may be unrelated to the results of operations for any other period.

Panacos' facilities are located in Gaithersburg, Maryland. Panacos is a privately-held Delaware corporation and as such its stock is not traded on established public market or exchange. As of February 11, 2005, Panacos had a total of 31 stockholders, of which 14 were holders solely of Panacos common stock, 12 were holders solely of Panacos preferred stock and 5 were holders of both common stock and preferred stock of Panacos.

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### *The Merger Agreement*

#### *Structure of the Merger*

Under the merger agreement, Panacos will merge into VITEX so that VITEX becomes the surviving corporation.

#### *Timing of Closing*

The closing will occur within two business days after the day on which the last of the conditions set forth in the merger agreement has been satisfied or waived, unless VITEX and Panacos agree to a different date. VITEX expects that, immediately upon the closing of the merger, the parties will file a merger certificate with the Secretary of State of Delaware, at which time the merger will be effective.

#### *Merger Consideration*

The merger agreement provides that each share of Panacos capital stock outstanding immediately prior to the effective time will, at the effective time, be converted into the right to receive a pro rata share of an aggregate of approximately 227,500,000 shares of VITEX common stock, or 6.75275 shares of VITEX common stock for each share of Panacos common and preferred stock held at the effective time.

#### *Treatment of Panacos Stock Options and Warrants*

At the effective time, each outstanding option granted by Panacos to purchase shares of Panacos common stock and each outstanding warrant issued by Panacos to purchase shares of Panacos preferred stock will be converted into an option or warrant, as applicable, to acquire VITEX common stock or preferred stock, as applicable, having the same terms and conditions as the Panacos stock option or warrant had before the effective time. The number of shares that the new VITEX option or warrant will be exercisable for and the exercise price of the new VITEX option or warrant will reflect the exchange ratio in the merger. The Panacos options assumed by VITEX shall retain their existing vesting schedules following the effective time of the merger, except that the vesting of such assumed options, to the extent that they are not fully vested as of the effective time, shall be accelerated such that 57.29% of the portion of such assumed options that is unvested as of the effective time shall vest as of the effective time.

#### *Exchange of Shares*

Immediately prior to the closing, VITEX will provide to each holder of Panacos stock instructions explaining how to surrender Panacos stock certificates to VITEX. Holders of Panacos stock that surrender their certificates to VITEX, together with a properly completed letter of transmittal, will receive the appropriate merger consideration. Holders of unexchanged shares of Panacos stock will not be entitled to receive any dividends or other distributions payable by VITEX after the closing until their certificates are surrendered.

VITEX will not issue any fractional shares in the merger. Holders of Panacos stock will receive a cash payment in the amount of the fractional share amount multiplied by the average closing price of a share of VITEX common stock for the five (5) most recent trading days prior to the effective time, as reported on the Nasdaq National Market in the Wall Street Journal.

#### *VITEX Board and Related Matters*

VITEX has agreed to take the necessary corporate actions so that, as of the closing:

- The VITEX Board size will be increased from 8 to 9.
- Two directors of Panacos, Dr. Herbert H. Hooper and Mr. Eric W. Linsley, and one director nominated by the investors in the \$20 million financing, will become directors of VITEX.
- Dr. Samuel K. Ackerman will become Chief Executive Officer and will remain as Chairman of the Board of VITEX.

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- During the two-year period immediately following the closing of the merger, Dr. Hooper and Mr. Linsley will be appointed to the Compensation Committee of the VITEX Board and the Nominating and Governance Committee of the VITEX Board (provided that they are able to serve on such Committees under applicable Nasdaq and the Securities and Exchange Commission, or SEC, rules and regulations).
- The Charter of the Compensation Committee and the Charter of the Nominating and Governance Committee will be amended to require that any action of such Committees shall require the unanimous consent of such Committee's members.

### *Certain Covenants*

Each of VITEX and Panacos has undertaken certain covenants in the merger agreement, including those related to interim operations of the two companies. Each of VITEX and Panacos has undertaken a separate covenant that places restrictions on it until either the effective time or the merger agreement is terminated. In general, Panacos is required to conduct its business in the ordinary course consistent with past practice and to use its commercially reasonable efforts to preserve intact its business organization and relationships with third parties. VITEX has agreed to carry on its business in the ordinary course and consistent with past practice. The parties to the merger agreement also agreed to concur upon an operating plan for the combined company for the 2005 fiscal year. After the closing of the merger, any material deviation from the operating plan would require the consent of the Panacos representatives on the VITEX Board, which consent will not be unreasonably withheld. The companies have also agreed to some specific restrictions which are subject to exceptions described in the merger agreement, including those on amending their organizational documents, issuing or disposing of equity securities, options or other securities convertible into or exercisable for equity securities, except to a limited extent to employees or directors, and acquiring or disposing of assets.

### *Representations and Warranties*

The merger agreement contains representations and warranties made by VITEX and Panacos to each other, including those related to corporate authorization to enter into the contemplated transaction, capitalization, and intellectual property.

The representations and warranties in the merger agreement survive the closing of the merger agreement for a period of eighteen (18) months from the effective time of the merger, except with respect to the representations made by Panacos regarding tax and environmental matters, which shall survive until the expiration of the applicable statutes of limitations with respect to claims regarding such matters.

### *Escrow Arrangements*

At the effective time of the merger, fifteen percent (15%) of the aggregate number of shares of VITEX common stock to be issued to Panacos stockholders at the effective time will be placed into an escrow account to satisfy the indemnification obligations of those stockholders relating to representations and warranties made in the merger agreement, as described above.

### *Conditions to the Completion of the Merger*

The obligations of VITEX and Panacos to complete the merger are subject to the satisfaction or, to the extent legally permissible, waiver of a number of conditions, including approval of the merger by the VITEX and Panacos stockholders, entry by VITEX into a definitive agreement with respect to the provision of at least \$20 million in financing to the combined company following the merger, on terms that are mutually acceptable to Panacos and VITEX, and accuracy as of closing of the representations and warranties made by the other party to the extent specified in the merger agreement.

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Under the terms of the merger agreement, any of the conditions specified in the merger agreement, other than those that are required by the rules of the SEC, such as the requirement that the Registration Statement on Form S-4 be declared effective; by Delaware law, such as the requirement that the approval of the stockholders of VITEX and Panacos to the merger be obtained; or by the Securities Purchase Agreement for the \$20 million financing, such as the requirement that the financing have been approved by the stockholders of VITEX and Panacos, could be waived by the parties to the merger agreement. That waiver would be required to be mutual in the event of a condition that applies to both parties' obligations to complete the merger.

### *Termination of the Merger Agreement*

The merger agreement may be terminated at any time prior to the closing in any of the following ways:

- by mutual written consent of VITEX and Panacos;
- by either VITEX or Panacos upon the occurrence of certain events, including the merger not being completed by March 11, 2005, or such later date as VITEX and Panacos may mutually agree upon due to SEC regulatory or other considerations, and VITEX or Panacos stockholders failing to give the necessary approval at a duly held meeting, provided that the party terminating may not be the party whose conduct was responsible for the failure to receive such vote.

### *Voting Agreement*

Each Panacos stockholder who will receive ten percent (10%) or more of the shares of VITEX common stock to be issued in the merger will enter into a voting agreement with VITEX, under which the stockholder has agreed to vote his, her or its shares of Panacos common or preferred stock:

- in favor of the adoption of the merger agreement and approval of the merger,
- in favor of the other transactions contemplated by the merger agreement,
- in favor of other matters relating to the consummation of the merger, and
- against any merger, liquidation or sale or transfer of any material assets of Panacos, other than the merger with VITEX.

Holders of an aggregate of 60.3% of the outstanding Panacos common stock (assuming the conversion of preferred stock) are parties to the merger agreement. Holders of an aggregate of 68.6% of the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock taken together as a single class have signed voting agreements.

### *Amendments and Waivers*

Any provision of the merger agreement may be amended or waived prior to closing if the amendment or waiver is in writing and signed, in the case of an amendment, by Panacos and VITEX or, in the case of a waiver, by the party against whom the waiver is to be effective. After the approval of the merger agreement by the stockholders of Panacos, no amendment or waiver that by law requires further approval by stockholders may be made without the further approval of such stockholders.

## **The Securities Purchase Agreement with Great Point Partners and Other Purchasers**

### *Structure of the Financing*

Under the terms of the private placement, VITEX will issue \$20,000,000 worth of shares of its common stock, at a per share price equal to the lower of (i) \$0.20 per share and (ii) a 10 day average of the stock price prior to closing, and warrants to purchase 0.45 times the number of shares of its common stock issued in the financing, exercisable for a five-year period from the date of issuance at a price of \$0.24 per share. The private placement

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investors will have the right to appoint a member to the VITEX Board. The \$20 million financing is led by Great Point Partners LLC of Greenwich, Connecticut, Ampersand Ventures and A.M. Pappas, the two largest investors in Panacos, will also participate. Ampersand Ventures is also the largest investor in VITEX.

The \$20 million private placement is designed to fund simultaneously with the closing of the Panacos merger, and is a condition to the closing of the merger. As required by the regulations of the Nasdaq Stock Market, VITEX stockholders will be asked to vote their approval of the financing as well as the Panacos merger.

### *Timing of Closing*

The closing will occur within three business days after the day on which the last of the conditions set forth in the Securities Purchase Agreement has been satisfied or waived.

### *Conditions to the Completion of the Financing*

The obligations of VITEX and the purchasers to complete the financing are subject to the satisfaction or, to the extent legally permissible, waiver of certain conditions, including approval of the financing by the VITEX stockholders, approval by the VITEX and Panacos stockholders and closing of the merger between VITEX and Panacos, increase in the number of authorized shares of VITEX common stock to 550,000,000, and a reverse split of VITEX common stock on the terms generally described in the joint proxy statement – prospectus for the special meeting of stockholders scheduled for March 10, 2005.

### *Certain Covenants*

Each of VITEX and the investors has undertaken certain covenants in the Securities Purchase Agreement. The following summarizes the more significant of these covenants.

*Listing of Common Stock.* VITEX has agreed to use commercially reasonable efforts to maintain the listing of its common stock on the Nasdaq National Market, and to list the securities issued in the financing in the time frame described in the Securities Purchase Agreement.

*Panacos Transaction.* VITEX has agreed not to agree to any amendment of the Panacos merger agreement or any other document or agreement entered into in connection with the merger transaction without the prior consent of the purchasers, if such an amendment (i) would have the effect of a change in the capitalization of the combined company following the merger from what is reflected in the merger agreement as in effect on the date of the Securities Purchase Agreement or (ii) would have a material adverse effect on the combined company following the merger. VITEX also agreed not to effect the merger unless the closing of the financing occurs concurrently or substantially concurrently with the consummation of the merger, unless the Securities Purchase Agreement is terminated as described therein.

*Voting Agreements.* VITEX has delivered executed voting agreements, relating to the stockholder meeting to be held to approve the merger and the financing, from stockholders representing an aggregate of 17% or more of the voting rights in respect of the capital stock of VITEX and from stockholders representing an aggregate of 30% or more of the voting rights in respect of the capital stock of Panacos prior to the merger at the time of signing the Securities Purchase Agreement. In addition, VITEX provided the purchasers affiliated with Great Point Partners, LLC with a true and correct copy of a voting agreement dated as of June 2, 2004, between VITEX and each of Ampersand Ventures, A.M. Pappas & Associates, and New England Capital Partners, L.P., entered into in connection with the Panacos merger agreement, and VITEX agreed that the Panacos merger-related voting agreement shall not be amended or terminated, nor shall the obligations under that voting agreement be waived by VITEX, without the consent of the purchasers affiliated with Great Point Partners, LLC.

*Break-up Fee.* In the event that the closing of the financing does not occur for any reason within one hundred twenty (120) days of December 9, 2004, with certain exceptions, including if the closing of the financing does not occur by reason of the termination of the merger agreement or the non-consummation of the

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merger, VITEX will pay to the purchasers affiliated with Great Point Partners, LLC a fee equal to \$1,670,000 in the aggregate and will reimburse all unreimbursed expenses of Great Point Partners, LLC related to the Securities Purchase Agreement and transactions contemplated thereby.

### *Representations and Warranties*

The Securities Purchase Agreement contains representations and warranties made by VITEX to the investors, including those related to corporate authorization to enter into the contemplated transaction, capitalization and intellectual property.

### *Amendments and Waivers*

Any provision of the Securities Purchase Agreement may be amended or waived prior to closing if the amendment or waiver is in writing and signed, in the case of an amendment, by VITEX and each purchaser or, in the case of a waiver, by the party against whom the waiver is to be effective.

### **Market Opportunity for Pathogen Reduction Systems**

The global market for blood products is large and growing. Over 40 million units of whole blood are collected each year in the United States, Europe and Japan, yielding over 40 million units of red blood cells for transfusion. A 2001 study commissioned by us and performed by Easton Associates, an outside consulting group, estimated that over 80% of red blood cells are transfused in an acute setting. We estimate the worldwide opportunity for the INACTINE™ system for red blood cells in acute indications is in excess of \$3 billion dollars and in excess of \$4 billion for combined acute and chronic red cell transfusions. Over one-third of all transfusions occur in the United States, where it is estimated that one out of every three Americans will receive a transfusion at some point during his or her lifetime. Driven by an aging population susceptible to illness, increased prevalence of new disease and a rise in the number of major surgeries performed, blood use in the United States grew more than 10% between 1999 and 2001. From 2001 to 2003, the average price paid by a hospital in the U.S. for a leukoreduced unit of red cells increased to over \$200 or over 30%. This increase was largely driven by new safety mandates under which new tests were required to screen for pathogens, and also by restrictions on donor eligibility, thereby increasing donor recruiting cost at a time of rising red cell demand. Reports of supply shortages continue to increase on a regional and national basis. The continued tightening of the donor exclusion criteria for individuals has exacerbated shortages.

### **Industry Background**

In the United States, the American Red Cross collects nearly half of the country's blood supply. The next two largest blood banks are United Blood Services and the New York Blood Center. The rest of the industry consists of smaller independent blood banks. The Japanese and European blood markets are even more concentrated. For example, in Japan, which collects 15% of the world's transfusion blood supply, the Japanese Red Cross collects and distributes all blood components transfused in that country.

Blood banks collect, separate and process whole blood from donors at either mobile or fixed collection sites. After collection, whole blood is separated into the components identified below, which are then distributed to hospitals for storage and transfusion. An increasing number of red cells are collected via apheresis in an automated process that limits collection only to the blood component desired (e.g., two units of red cells) and returns other components to the donor. Red cell apheresis represents a growing but still small proportion of total red cell units collected and transfused. The INACTINE™ system has been designed to work with red cells collected as part of a whole blood donation or through an automated apheresis procedure.

The components of whole blood are:

- *Red Blood Cells.* Red blood cells transport oxygen and carbon dioxide throughout the body. Red blood cells are frequently administered to patients who have anemia, trauma, surgical bleeding or genetic disorders and

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account for the majority of transfusions. Red blood cells have a shelf life of 42 days. We estimate the average price paid by hospitals in the United States in 2003 for leukoreduced red blood cells was \$200 per unit.

- *Plasma.* Plasma is the liquid part of the blood and contains a large number of proteins with important therapeutic applications. Plasma is frequently administered to patients to mediate and control blood clotting, provide immune protection, and treat several rare and life-threatening diseases. Plasma can be frozen after collection and stored for up to one year in the form of fresh frozen plasma. We estimate the average price paid by hospitals in the United States in 2002 for plasma was \$50 per unit.
- *Platelets.* Platelets initiate blood clotting and facilitate the repair of damaged blood vessels. Platelets are often administered to cancer patients following chemotherapy and to other patients who have lost large volumes of blood as a result of trauma or during surgery. Platelets have a shelf life of five days. We estimate the average price paid by hospitals in the United States in 2002 for platelets was \$50 per unit. A typical therapeutic platelet transfusion involves 4 to 6 units of platelets.
- *White Blood Cells.* White blood cells, or leukocytes, are comprised of many different types of cells that form part of the body's immune system and play a major role in wound repair. White blood cells are rarely transfused as a separate component because of the potential for an adverse immune response by the recipient.

The demand for blood products is ultimately driven by hospital-based physicians, particularly surgeons, in the acute care setting. Hematologists and oncologists also prescribe most of the blood used to treat chronic diseases such as sickle cell anemia or thalassemia.

Maintaining adequate supplies of safe blood products is an increasing challenge for blood centers around the world. While collections increased in 2001 by 7.1% over 2000, the most recent period for which data has been reported by the National Blood Data Resource Center, this increase reflected the spike in collections immediately following September 11, 2001. Subsequently, collections have returned to previous levels and inventories are again becoming dangerously low.

Most blood centers rely on volunteer donors to donate blood for transfusion, but less than 5% of healthy Americans eligible to donate blood do so each year. More rigorous screening and stricter donor exclusion criteria have reduced the number of previously eligible donors. For example, due to fears of vCJD, which has resulted in over 100 deaths in the United Kingdom alone, the FDA guidelines currently exclude potential donors who have spent a total of three months or more in the United Kingdom between 1980 and 1996, or a cumulative five years in other countries in Europe. The FDA estimates that approximately 5% of currently eligible donors are excluded due to these rules. That concern heightened in 2003 with the first suspected case of transfusion-related vCJD reported in the U.K. and the first case of Mad Cow Disease reported in the U.S.

In 2002, the FDA and the Center for Disease Control (CDC) reported on 13 cases of suspected transmission of West Nile Virus via blood transfusion. As a result, NAT testing for West Nile Virus was implemented in 2004 under an investigational exemption by blood banks in the U.S. Early reports suggest that the sensitivity of existing tests will need to be improved significantly to approach the sensitivity of NAT for HIV and HCV. The West Nile Virus (WNV) is an example of the vulnerability of the blood supply to emerging pathogens. Year 2003 also saw the emergence of additional new deadly pathogens such as SARS and avian flu although there have not yet been confirmed cases of transmission of these pathogens by blood transfusion.

### **Current Approaches to Blood Safety**

The following approaches are currently being used or are under development to reduce the risk of having the blood supply contaminated by pathogens and to maintain an adequate supply of blood products.

*Donor Exclusions.* Regulatory agencies increasingly rely on tightened donor exclusion criteria to reduce the risk of transmitting infections caused by viruses, bacteria, parasites and prions. In the United States, all donors are screened confidentially immediately prior to donation. A trained healthcare professional questions the prospective donor regarding his or her current health, health history, sexual habits, drug usage and travel outside the United States.

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*Screening Donated Blood.* In the United States, Europe, and Japan, donated blood undergoes screening for five or six (in the U.S. and Canada) different infectious disease-causing pathogens:

- viruses (four in Europe and Japan and five in the U.S.):
  - Hepatitis B, or HBV;
  - Hepatitis C, or HCV;
  - human immuno-deficiency virus, or HIV;
  - human T-cell lymphotropic, or HTLV, and
  - West Nile Virus or WNV (U.S. and Canada only)
- one bacteria, syphilis.

Three types of screening tests are currently used – antibody, antigen, and nucleic acid testing. Antibody tests detect the body’s response to a virus. Antigen tests detect antigens on the surface of the virus itself. Nucleic acid testing, or NAT, used in Europe to screen for the presence of HIV and Hepatitis C, employs a relatively new technology that directly tests for evidence of the pathogen itself. NAT enables earlier detection of a pathogen because it detects genetic material of a virus, its DNA or RNA, instead of waiting for the human body to mount a detectable response to a virus.

*Donation Strategies.* Autologous, or self, donation is a strategy that can be used by patients undergoing scheduled surgery to avoid the risk of receiving contaminated blood. Prior to a scheduled surgery, the patient can arrange to have his or her own blood taken and stored for later transfusion. A related strategy, quarantining, a method used for plasma, requires that blood be stored for three to six months after donation, at which time the donor must return to the blood bank to undergo additional testing. If there are no detectable pathogens in the donor’s blood after this additional testing, the donated blood may be used for transfusion.

*Leukocyte Reduction and Gamma Irradiation.* Leukocyte reduction, which is used to remove leukocytes, or white blood cells, from blood, is a standard of care in many European countries where all donated blood is filtered to remove leukocytes prior to transfusion. We estimate that 65% of all red blood cell units, and greater than 90% of red blood cell units collected by the American Red Cross, in the United States are currently leukoreduced. Gamma irradiation, which is a method of destroying white blood cells, has been used more frequently over the past few years. Gamma irradiation involves exposing blood products to radioactive isotopes which inactivate leukocytes. We estimate that 10% of red blood cells in the United States are gamma irradiated, while 100 % of red blood cells are gamma irradiated in Japan. Currently, gamma irradiation is used primarily to destroy lymphocytes, a type of leukocyte that can cause graft versus host disease, which is the body’s rejection of transfused blood, after transfusion.

*Blood Substitutes or Temporary Oxygen Carriers.* Several companies are developing blood substitutes designed to mimic the therapeutic properties of blood components. These products fall into two general categories: those that are based on the blood’s own hemoglobins and those that are synthetic substitutes. Hemoglobin-based substitutes require donated blood from either people or cows; synthetic substitutes, generally oxygen carriers, are designed to dissolve gases, moving oxygen from the lungs to organs and removing carbon dioxide.

*Pathogen Inactivation.* Pathogen inactivation depletes or inactivates a limited number of pathogens in blood, which improves the safety of the blood product instead of simply testing for the presence of pathogens. Current pathogen inactivation approaches are only applicable for plasma derivatives and transfusion plasma.

### Limitations of Current Approaches to the Safety of the Blood Supply

Each of the current approaches is limited in its scope, effectiveness, or practicality.

*Donor Exclusions.* Although donor screening has been used for decades, it remains limited because it relies heavily on the honesty and the cooperation of the donor. In addition, it is only designed to exclude donors who are more likely to be at risk for diseases known to be transmissible through blood. In a time when maintaining

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adequate supplies of safe blood products is increasingly challenging, donor exclusions can inadvertently increase the magnitude of that challenge. There is also no guarantee that the donor will return once the required deferral period has lapsed.

*Screening Donated Blood.* The principal limitation on current screening procedures is their limited scope in that only 4 or 5 viruses, HIV, HBV, HCV, HTLV and WNV, and the bacteria that causes syphilis are routinely screened in the United States. Europe and Japan routinely screen for the same pathogens with the exception of WNV. Therefore, current screening methods are not used to detect other known pathogens. In addition, they cannot detect unknown or emerging pathogens, which have historically presented a threat to the blood supply. For example, scientists estimate that HIV was present in the blood supply for at least seven years before it was identified as the agent that causes AIDS and at least eight years before a test was commercially available to detect the presence of HIV antibodies in donated blood. During those years, many transfusion recipients were infected with HIV, including approximately 70% of patients with severe hemophilia. Similarly, of the four million Americans infected with HCV, the most common chronic blood borne viral infection in the United States, more than one million were infected through HCV infected blood products. Although HCV was first identified in 1988, donated blood was not screened for HCV until 1992. In 2002, the FDA and the CDC reported on 13 cases of suspected transmission of West Nile Virus via blood transfusion. In 2003 West Nile Virus testing was implemented in all U.S. blood banks under an FDA investigational exemption.

In addition, most tests for known pathogens cannot detect the presence of viruses during the infectivity window, the period during which viruses are present in the blood but are not yet detectable. NAT provides only limited incremental benefits, because it is effective only for specific viruses for which the testing is performed.

No tests have been implemented for certain pathogens that are known to be prevalent in the blood supply, such as SEN V and parvo B-19 virus. The latter virus has been reported to cause rashes and arthritis, and has also been implicated in miscarriages in pregnant women. Moreover, there are no practical tests available to detect the presence of pathogenic prions. In addition, bacteria and many other agents are known to transmit disease during transfusion, including the bacteria which can cause sepsis or other systemic infections which can result in serious illness or even death. The parasites that cause malaria and Chagas' disease may also be transmitted by transfusion; however, there are no practical tests used for these pathogens. Animal studies have indicated that the pathogenic prions known to cause Mad Cow Disease and vCJD can be transmitted by blood but no diagnostic tests exist to determine the presence of these specific prions in blood. The first case of a suspected transmission of vCJD through blood transfusion was reported in the UK in December 2003.

*Donation Strategies.* Autologous donation is impractical for most patients and impossible when a transfusion is required due to trauma or emergency surgery. Quarantining depends on the donor's timely return for additional testing, cannot be applied to red blood cells or platelets because of their limited shelf life and remains subject to limitations associated with blood screening.

*Leukocyte Reduction and Gamma Irradiation.* Leukocyte reduction is effective at removing white blood cells, but does little to reduce the existence of pathogens other than cytomegalovirus in blood products.

Gamma irradiation provides a narrow range of efficacy – insufficient treatment can leave white blood cells in the blood, while excessive treatment can impair the therapeutic function of the desirable blood components being transfused. In addition, irradiated red blood cells have a decreased survival rate, resulting in a reduced shelf life. Gamma irradiation may also have the unintended side effect of activating latent cytomegalovirus, a potential threat to immune compromised recipients of a blood transfusion.

*Blood Substitutes or Temporary Oxygen Carriers.* Blood substitutes are being developed to simulate specific therapeutic characteristics of blood and are not intended to replace whole blood components, such as red blood cells, for most conditions. The few substitutes available today remain effective only for approximately 24 to 48 hours in the blood, making the substitutes inadequate for treatment of indications requiring chronic transfusion.

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*Pathogen Inactivation.* There is currently no pathogen inactivation process available for red blood cells. Existing pathogen inactivation approaches are only applicable to plasma and platelets. These are limited in the scope of pathogens they can inactivate.

### Our Solution

We believe that our proprietary INACTINE™ Pathogen Reduction System for red cells, or INACTINE™ system, offers the following advantages over current approaches to blood safety:

- *Inactivates known pathogens.* Our INACTINE™ system, using the processing parameters tested in human clinical trials to date, inactivates a broad range of pathogens known to be transmitted through donated red blood cells, such as HIV and Hepatitis C, as well as pathogens for which screening is not currently conducted, such as parvo B-19 virus and West Nile Virus. The INACTINE™ system also inactivates other classes of pathogens for which no practical technologies exist to screen the red blood cells. This includes gram negative and gram positive bacteria and parasites such as those that cause Malaria and Chagas Disease.
- *May inactivate new or emerging pathogens.* Based on preclinical testing which demonstrates its broad effectiveness in inactivating known pathogens, the INACTINE™ system, using the processing parameters tested in human clinical trials to date, has the potential to inactivate emerging pathogens in red blood cells. In 2002, we demonstrated the inactivation of West Nile Virus in units of red blood cells and in 2003 reported the inactivation of SARS in units of red blood cells.
- *May reduce the need for new blood screening tests to be added in the future.* The potential effectiveness of the INACTINE™ system, using the processing parameters tested in human clinical trials to date, against both known and unknown pathogens for which blood donations are not currently screened may result in the avoidance of some new screening tests becoming necessary. For instance, the FDA allowed in 2003 an investigational version of a test for West Nile Virus to be implemented in all U.S. blood centers while clinical trials were underway. Broad use of the INACTINE™ system could affect the decision to move ahead with a new diagnostic test.
- *May reduce transfusion reactions.* Our INACTINE™ system reduces the amount of impurities such as cytokines in red blood cell units which may lead to fewer allergic reactions from patients receiving blood transfusions.
- *May reduce soluble prion proteins.* Our INACTINE™ system has demonstrated the ability to remove prion proteins from red blood cells in research studies. This ability could lead to the relaxing of current donor exclusion criteria implemented in an effort to reduce the spread of Mad Cow Disease.

### Our Strategy for INACTINE™

Our objective is to establish our proprietary INACTINE™ system as the industry standard for blood product safety. The key elements of our strategy include:

- *Reduce the likelihood of an immune response to INACTINE™ red cells that was observed in the Phase III trials.* We are focusing our INACTINE™ system on red blood cells, the largest segment of transfusion blood components in the United States, Europe and Japan. On November 23, 2004, we announced that we suspended enrollment in our Phase III surgical, or acute, study for our lead product candidate, the INACTINE™ system, following identification of an immune response to INACTINE™-treated red cells in one patient during ongoing immunologic testing of subjects enrolled in the trial. As a result, both the Phase III trial of INACTINE™ for acute indications and the Phase III trial of INACTINE™ for chronic indications have been halted. Although no clinical consequences of the immune response are apparent based on review of available data, additional patients will not be enrolled in the trial pending full evaluation. The Phase III chronic study of INACTINE™ was placed on clinical hold by the FDA due the availability of insufficient safety information, and was subsequently halted by us, following a review by an independent DSMC, in November of 2003. With the Phase III trial for INACTINE™ in chronic indications halted and enrollment

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suspended in the Phase III trial for INACTINE™ in acute indications, our ongoing development plan for INACTINE™ for chronic, acute or other indications is highly uncertain. VITEX is currently focusing our R&D resources on modifications to the INACTINE™ system to reduce the likelihood of an immune response that was observed in the Phase III trials. As a consequence, we cannot ensure that the acute trial will resume or complete enrollment in a timely manner. The exact nature, timing and estimated costs of the efforts necessary to bring to market the product resulting from our pathogen inactivation research and development projects involve a number of key variables which are either unpredictable or outside our control, including whether the likelihood of an immune response to INACTINE™-treated red cells can be adequately reduced, whether, and under what circumstances, the FDA will agree with our plan to proceed with clinical trials, the enrollment rates and results of the Phase III clinical trial, should it be continued, the extent of further studies which could be required for filing a Biologics License Application with the FDA, the length of the FDA and foreign regulatory approval processes, the success of our fundraising efforts, our ability to establish and maintain relationships with marketing partners and strategic collaborators, and the timing of commencement of commercialization of our product. Inability to satisfy one or more of these conditions, or to do so in a commercially acceptable manner, may render continued development of the INACTINE™ system infeasible.

- *Expand our strategic alliances.* If we can successfully reduce the likelihood of an immune response that was observed in the Phase III trials and develop a strategy for continued clinical development of the INACTINE™ system that is acceptable to the FDA, we intend to pursue new strategic alliances to commercialize the INACTINE™ system with companies whose technologies and business strengths complement ours. We have established important contract development and manufacturing relationships with well respected medical device engineering and development firms for adapting the INACTINE™ system for ease of implementation in blood banks.
- *Promote the benefits of our INACTINE™ system.* We intend to work closely with regulatory agencies, third party payors, the medical community and healthcare consumers to build awareness about the benefits of using our pathogen reduction technology for blood products.
- *Simplify implementation by the blood center.* The INACTINE™ system is being designed to be implemented into the existing blood collection manufacturing infrastructure. The INACTINE™ system is currently designed for use with red cells collected with currently licensed storage solutions and sets. With the help of an engineering firm, we are developing a highly automated device to add the appropriate concentration of INACTINE™ to a unit of red cells. The removal of INACTINE™ is accomplished via a highly automated cell wash device. Units treated with the INACTINE™ system, using the processing parameter tested to date in human clinical trials, can be stored for up to 42 days and safely reinfused based on Phase I and Phase II clinical trial results. The current limit for red cell storage is 42 days.

## Our Technology

### INACTINE™

We have identified a family of small molecular compounds that penetrate blood-borne viruses, bacteria, and other pathogens. Our INACTINE™ compound for red blood cells, referred to as PEN110, is a highly water soluble, stable and low-molecular weight compound. This compound selectively binds and irreversibly modifies nucleic acids, including both DNA and RNA. The compound is activated when it forms a weak bond with the negatively-charged sites within DNA and RNA, after which the compound forms a permanent bond with its guanine in DNA, or guanidine in RNA, the key building blocks of nucleic acid. This bond prevents the replication of the nucleic acid. As the vast majority of pathogens have DNA and RNA, and pathogens need to replicate to survive and grow, preventing the replication of the nucleic acid effectively kills the pathogens. Blood components, such as red blood cells, plasma and platelets, do not contain nucleic acid. In addition to its pathogen reduction capabilities, because PEN110 is a stable and small molecule, it can penetrate the tight protein coat of non-enveloped viruses, such as parvo B-19 virus, which are small, difficult to kill viruses that do not have an outer lipid envelope surrounding them.

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The following basic steps are involved in our INACTINE™ Pathogen Reduction System for red cells using the processing parameters tested in human clinical trials to date:

- PEN110 is manually added to the unit of red cells in an aseptic fashion; however, an automated device is in advanced stages of development and the Company plans to test the device as part of future clinical studies for the INACTINE™ system.
- Using the current processing parameters tested in human clinical trials to date, the mixture is incubated for 18 to 24 hours at room temperature; and
- the mixture is transferred to a fully-automated cell washing system, which we exclusively license from Haemonetics Corporation, to remove inactivated pathogens, cell debris, proteins, including prion proteins, and PEN110.

The result is a unit of pathogen-inactivated washed red blood cells that is ready for transfusion.

Our preclinical research indicates that the cell washing process we use to remove PEN110 has the potential to remove substantial levels of proteins, including prion proteins, immunoglobulins and cytokines from red blood cells. This feature of our INACTINE™ system could provide an important competitive advantage over other approaches by further reducing pathogen levels.

### ***INACTINE™ System Development Status***

Our INACTINE™ Pathogen Reduction System for red cells is in clinical trials. Below is a summary of our INACTINE™ clinical program to date:

### ***INACTINE™ Clinical Program***

	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III</b>
Goal	To establish 28-day storage and safety of 10ml of INACTINE™ red blood cells treated for 6 hours.	To establish maximum storage and safety of full unit of INACTINE™ red blood cells treated for 24 hours.	To establish effectiveness and safety of INACTINE™ red blood cells in a transfusion
Source of red blood cells	Autologous	Autologous	Donor
INACTINE™ treatment time	6 hours	24 hours	24 hours
Storage time	28 days	35 days and 42 days	Up to 42 days
Status	Completed	Completed	Suspended

### ***Research Studies***

Our current research studies focus on identifying changes to the INACTINE™ system that will reduce the likelihood of an immune response that was observed in the Phase III trials. We will also determine the range of viruses and bacteria that the modified INACTINE™ system could inactivate, as well as the ability to inactivate other pathogens, such as parasites, and the ability to inactivate and remove lymphocytes.

### ***Phase I Clinical Study***

We designed our Phase I clinical study of our INACTINE™ system to further evaluate the effect of INACTINE™ on the therapeutic properties of red blood cells and blood storage time after a six-hour INACTINE™ treatment of red blood cells followed by a 28-day storage period. This study involved 12 healthy adults using a randomized

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crossover design, meaning that each participant received a treatment of the INACTINE™ treated red blood cells and standard red blood cells sequentially. In the study, we collected a red blood cell unit from each participant. We then treated half of these units with 0.1% INACTINE™ for six hours followed by cell washing. We stored the INACTINE™ treated and untreated red blood cells for 28 days. This study effectively demonstrated a 28-day shelf life for INACTINE™ treated red blood cells and equivalent functionality or recovery of INACTINE™ treated red blood cells compared to control red blood cells in healthy participants. In addition, the participants had no adverse reactions to the transfusions.

### *Phase II Clinical Study*

We designed our Phase II clinical study for our INACTINE™ system to evaluate a 24-hour INACTINE™ treatment of red blood cells, a maximum storage period and full unit transfusion safety. This study involved 72 healthy adults divided into three groups based on the storage time of the INACTINE™-treated red blood cells: 28 days, 35 days and 42 days. This study effectively demonstrated that a 24-hour treatment period and a 42-day storage life for INACTINE™ treated red blood cells is possible and that this treatment period and storage time did not affect the 24-hour survival of the red blood cells. In addition, the participants had no adverse reactions to the transfusions.

### *Phase III Clinical Studies*

We designed our Phase III clinical studies for our INACTINE™ system to evaluate the safety and effectiveness of INACTINE™-treated red blood cells. One study involved cardiac surgical patients requiring acute transfusion support, and a second study involved patients requiring chronic transfusion support. Enrollment in the surgical study was temporarily suspended in November 2004 when an immune response was observed in a single patient in the trial. No clinical consequences of this response were apparent. Enrollment in a second Phase III study, referred to as the chronic study, was previously halted in November of 2003 after the trial was placed on clinical hold by the FDA due to the availability of insufficient safety information following a review of an independent data safety monitoring committee due to a concern regarding antibody responses observed in patients. No serious adverse reactions were observed.

### *International Clinical and Regulatory Status*

If we can successfully modify the INACTINE™ system to reduce the likelihood of the immune response observed in the Phase III studies and gain concurrence of the FDA on a clinical development plan for the system, we intend to discuss our clinical and regulatory plans in Europe and Japan with the relevant regulatory agencies.

### **Strategic Alliances**

We believe that we can accelerate the commercialization of our products by entering into new strategic alliances for sales, marketing, distribution and complementary technologies. To date, the collaborations we have entered into for the development and commercialization of the INACTINE™ system are as follows:

#### ***Pall Corporation***

In February 1998, we entered into a series of agreements with Pall Corporation (“Pall”) to collaborate on the development and marketing of systems employing our pathogen reduction technologies for red blood cell and platelet concentrates. Pall is a leading manufacturer and distributor of filtration products, including those relating to the collection, preservation, processing, manipulation, storage and treatment of blood and blood components.

In August 2002, we modified our worldwide collaboration with Pall for the INACTINE™ system. Driven by our commencement of the pivotal Phase III clinical trials in the United States, this modification sought to accelerate our clinical development and broaden geographic distribution in the United States and other international markets through the establishment of agreements with new distribution partners.

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As part of this modification,

- Pall relinquished its exclusive worldwide distribution rights in return for a cap on its financial commitments to the program and a royalty per unit sold following commercialization.
- We will continue to work aggressively on the research and development and clinical program. We will ensure that INACTINE™ technology and Pall filters, solutions and blood bags are compatible in each country where the technology is licensed. Pall filters will be used exclusively in the INACTINE™ system.
- Pall funded a \$4,000,000 equity milestone in 2003 related to the initial use of the INACTINE™ system in the Phase III trials.
- Pall extended to us a \$5,000,000 revolving credit facility which approximated Pall's financial support from August 2001 through the date of the modification in August 2002. The credit facility terminated in 2003.
- We will retain all proceeds from new partnerships including upfront rights fees, milestone payments and ongoing royalties or profit sharing. Pall will be paid a royalty per unit upon successful commercialization of the INACTINE™ system for red blood cells. The total royalty payment is capped and the obligation to pay royalties will cease upon achieving the royalty cap. There are no material payments due by either party in the event of termination of the agreement. VITEX will continue to be obligated to include Pall filters in the INACTINE™ system following the termination of royalty payments due to achieving the royalty cap.

Pall remains a significant shareholder and, as of February 28, 2005, owned approximately 11.3% of our outstanding shares. To date Pall has invested \$20 million in VITEX equity and reimbursed us \$17.4 million of our development costs. To date, we have purchased products worth approximately \$1.6 million from Pall, principally filters used in the INACTINE™ system.

### ***Haemonetics Corporation***

In January 2000, we entered into a development and manufacturing agreement with Haemonetics Corporation. Haemonetics is one of the leading developers of automated blood collection equipment and disposables. The Haemonetics system is the only "closed" cell washing system approved by the FDA. This closed system allows the cells to be either immediately transfused or stored for later transfusion, similar to untreated red blood cells. We secured exclusive worldwide rights to use the Haemonetics cell washing system as part of our INACTINE™ Pathogen Reduction System for red cells. When and if our INACTINE™ system is commercialized, Haemonetics will provide contract manufacturing services for the cell wash equipment and disposables. The contract establishes maximum prices for equipment and disposables and target prices following the commercial launch of the system and disposables. We are paying Haemonetics for modifications to the cell wash system to adapt it for use as part of our INACTINE™ red blood cell system. To date we have paid Haemonetics \$3.2 million as part of this development effort. This agreement will terminate in 2010 unless extended by mutual agreement. The agreement can convert to a non-exclusive one at the end of 2005, if we have not received regulatory approval for the INACTINE™ system in at least one market. It is highly unlikely that VITEX will secure regulatory approval by the end of 2005, but we are not aware of any other company developing a pathogen inactivation system for red blood cells that uses cell washing technology as part of their system. The contract can also convert to a non-exclusive one at the end of 2006 if VITEX does not meet minimum purchase levels specified in the agreement. If we choose not to use cell washing as part of the system, we will owe Haemonetics a royalty on sales of the system for the first five years of market launch or until this agreement terminates, whichever occurs first. There are no material payments due by either party upon termination of the agreement.

### **Patents, Licenses and Proprietary Rights**

Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We believe that the protection of our proprietary technologies may create competitive barriers to entry into the pathogen reduction market. We intend to continue to pursue our patent filing strategy and to vigorously defend our intellectual property position against infringement.

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As of December 31, 2004, our INACTINE™ patent portfolio consisted of seventeen issued United States patents, twenty-six issued foreign patents and fifty-nine pending United States and foreign patent applications. Our issued patents expire at various dates between 2015 and 2020. Our INACTINE™ portfolio includes patents and/or patent applications that generally relate to methods comprising the use of pathogen reduction and/or inactivating agents, methods of removing and/or quenching pathogen inactivating agents, methods of synthesizing pathogen reduction agents, a blood collecting device comprising a pathogen inactivating agent, and therapeutic uses for pathogen inactivating agents.

Our patent portfolio also consists of twelve other pending United States and foreign patent applications, covering applications relating to methods of affinity purification, prion detection and virus detection.

It is worth noting that:

- patent applications filed in the United States on or before November 29, 2000 generally are currently maintained in secrecy until United States patents are issued;
- patent applications filed in the United States after November 29, 2000 and patent applications filed in other countries generally are not published until 18 months after they are first filed in any country;
- publication of technology developments in the scientific or patent literature often lags behind the date of the actual developments; and,
- searches of prior art may not reveal all relevant prior inventions.

We cannot be certain that we were the first to invent the subject matter covered by our patents and patent applications or that we were the first to file patent applications for our inventions or that a court or patent authority will not determine that our patent rights are invalid or unpatentable.

We believe that several elements of our pathogen inactivation program involve unpatented proprietary technology, processes, know-how, or data, including fermentation and production process and purification technology. With respect to proprietary technology, know-how and data which are not patentable or potentially patentable or processes other than production processes for which patents are difficult to enforce, we have chosen to protect our interests by relying on trade secret protection and confidentiality agreements with our employees, consultants and certain strategic partners. All of our key employees and scientific researchers are parties to confidentiality agreements. The confidentiality agreements and other trade secret protection may not provide meaningful protection to us and may be breached. We may not have adequate remedies for any breach. Our trade secrets may otherwise become known or be independently developed by competitors.

## **Competition**

Our products under development will compete with current approaches to enhance blood safety, as well as with future products under development by others, including medical technology, biotechnology, pharmaceutical and hospital supply companies, national and regional blood centers, governmental organizations and agencies, academic institutions and other agencies. The industries in which we compete are characterized by rapid and significant technological changes. Accordingly, our success will depend in part on our ability to respond quickly to medical and technological changes through the development and introduction of new products. Until the decision in November of 2004 to temporarily suspend the enrollment in the Phase III acute study, we were the only company with a pathogen reduction system for red cells in human clinical trials. Many companies and organizations, including our principal competitors, Cerus Corporation and Gambro BCT, and those that may be or may become competitors, have substantially greater financial and other resources than we do and may have greater experience in conducting non-clinical studies and clinical trials and obtaining regulatory approvals. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, or that might render our technology and products obsolete. Furthermore, we cannot be certain that our competitors will not obtain patent protection or other intellectual property rights that would limit our ability to use our technology or commercialize products that may be developed.

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Competition for INACTINE™-treated red blood cells may come from alternative approaches to the problem of improving the safety of blood and blood products and from alternative pathogen reduction technologies. There is no licensed technology for the pathogen reduction of red cells in any market in the world. There is currently no pathogen reduction system for red blood cells in human clinical trials. Cerus Corporation stopped two Phase III trials in September of 2003 following the detection of an antibody response in patients in those trials. Cerus has announced that they are attempting to develop modifications to the system to eliminate this response and has not publicly disclosed plans to resume clinical trials with a modified system. Gambro BCT has publicly stated that their red cell pathogen reduction system is in pre-clinical development. Neither company has disclosed enough detail of their pathogen inactivation systems for red blood cells to discuss the relative strengths and weaknesses when compared to the INACTINE™ system for red blood cells. We believe that the primary competitive factors in the market for pathogen inactivation systems will include the breadth and effectiveness of pathogen inactivation processes, compatibility of processes with cells and proteins, ease of use, the scope and enforceability of patent or other proprietary rights, product price, product supply and marketing and sales capability. In addition, the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval is an important competitive factor.

The alternative approaches to achieving safer blood component products include the introduction of new donor tests using nucleic acid testing, the use of leukoreduction filters and blood substitutes. Screening and leukocyte filtering are currently available, and blood substitutes are in late stage clinical testing.

Pall Corporation and Baxter Healthcare are the major suppliers of leukoreduction filters. Approximately 60% of the approximately 14 million red cell units transfused annually in the U.S. are leukoreduced (reduction in concentration of white blood cells) prior to transfusion based on industry estimates. Neither company breaks out the revenue from the sales of leukoreduction filters from their total corporate or healthcare sales. Both companies have considerably more resources than VITEX. The leukoreduction process can add as much as \$50 to the price paid by the hospital when compared to the price for non-leukoreduced red blood cells for transfusion. The INACTINE™ system could potentially eliminate the need for leukoreduction in addition to providing other benefits such as pathogen reduction of viruses and other pathogens.

Each new pathogen detected in the blood supply can trigger the requirement for a new blood screening test, using nucleic acid testing, for each unit of blood collected and prior to transfusion. A recent example was the implementation of an experimental screening test for West Nile Virus in 2004 for all units of blood collected in the U.S. The FDA took this step following multiple confirmed transmissions of WNV by a blood transfusion in 2003. Each new test adds cost to the unit of blood and this cost may increase depending on the sensitivity of the screening test for a particular pathogen. Incremental testing cost for the most sensitive screening method, can add \$15 to \$70 dollars to the cost of a unit of red cells depending on how many patient samples are screened using a single test. Implementation of the INACTINE™ system could reduce the need to add new screening tests for each new pathogen demonstrated to be transmissible by a blood transfusion. Companies that provide blood screening tests include Chiron, Roche, Abbott and Johnson and Johnson. Chiron reported \$494 million in blood testing revenue for 2004. The other companies do not break out sales of blood testing in their financial reports. All of these companies have considerably more resources than VITEX.

In the area of blood substitutes, also referred to as temporary oxygen carriers, several companies such as Northfield Laboratories and Biopure are developing temporary oxygen carriers. The most advanced product from Northfield Laboratories is in Phase III testing for an indication for use in trauma. No temporary oxygen carrier has been licensed in any country in the world. The temporary oxygen carriers may cost significantly more than a unit of red blood cells and due to their product characteristics may only be licensed for a subset of the indications for red blood cells potentially limiting their use as a substitute for red blood cell transfusions. We plan to seek a broader indication for use for red cells treated by the INACTINE™ system and believe the cost of INACTINE™-treated red cells could be significantly less than a comparable therapeutic unit of a temporary oxygen carrier.

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### **Government Regulation**

Our products under development will be comprehensively regulated by the FDA and, in some instances, by state and local governments, and by foreign regulatory authorities. The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and pre-market approval of these products.

We believe that our red blood cell system incorporating our INACTINE™ system will be treated as a biologic regulated by the FDA's Center for Biologics Evaluation and Research.

Before a biologic may be marketed in the United States, the FDA must approve a biologics license application, or BLA, covering both the product and the facility. Before a medical device may be marketed in the United States, the FDA must clear a pre-market notification known as a 510(k) notice or approve a pre-market application or PMA for the product. Before a combination product may be marketed in the United States, it must have an approved BLA (or PLA/ELA) or PMA.

The steps required before a biologic or medical device may be approved for marketing in the United States generally include:

- non-clinical laboratory and animal tests;
- submission to the FDA of an investigational new drug exemption, or IND, for biologics, or an investigational device exemption, or IDE, for medical devices, for human clinical trials, which must become effective before such trials may begin;
- appropriate tests in humans to show the product's safety;
- adequate and well-controlled human clinical trials to establish the product's efficacy for intended indications;
- submission to the FDA of a BLA or PMA, as appropriate; and
- FDA review of the BLA or PMA in order to determine whether the product is safe and effective for its intended uses.

In addition, the FDA inspects the facilities at which the product is manufactured and will not approve the product unless the facilities and the process used to manufacture the product comply with current good manufacturing practices, or cGMP.

We believe that, in deciding whether a pathogen inactivation system is safe and effective, the FDA will consider the therapeutic efficacy of treated blood components as compared to blood components which are untreated by the system and that system safety and any other risks in the use of treated components will be weighed against system benefits.

Generally, similar regulatory requirements apply to products intended for marketing outside the United States.

The FDA could significantly limit the indicated use for which one of our products can be marketed. The testing and review process requires substantial time, effort and financial resources, and is generally lengthy, expensive and uncertain. The approval process may be affected by a number of factors, including the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review period and may delay marketing approval. Even if we are granted regulatory approval or clearance from the FDA, we and our products will be subject to continuing review. After FDA approval for the initial indications, further clinical trials may be necessary to obtain approval for the use of the product for additional indications. The FDA may also require post-marketing testing which can involve significant expense. Later discovery of previously unknown problems with a product may result in

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labeling changes and other restrictions on the product, including withdrawal of the product from the market. In addition, the policies of the FDA may change, and additional regulations may be promulgated which could prevent or delay regulatory approval of our planned products.

In addition to the regulatory requirements applicable to us, there are also regulatory requirements applicable to our prospective customers, which are primarily entities that ship blood and blood products in interstate commerce. Such entities are regulated by the FDA pursuant to the Food, Drug and Cosmetic Act and the Public Health Service Act and implementing regulations. Blood centers and others that ship blood and blood products interstate will likely be required to obtain approved license supplements or BLAs from the FDA before shipping products processed with our pathogen reduction systems. This requirement and/or FDA delays in approving such supplements may deter some blood centers from using our products, and blood centers that do submit supplements may face disapproval or delays in approval that could provide further disincentives to use of the systems.

### **Organization and Operating History**

We are headquartered in Watertown, Massachusetts and were incorporated in Delaware in 1992.

Our total costs over the last three fiscal years in our research and development activities were as follows: fiscal year 2004 – \$13.3 million, fiscal year 2003 – \$18.5 million, and fiscal year 2002 – \$20.4 million.

### **Employees**

As of December 31, 2004, we had twenty-five employees, of whom fifteen were engaged in research and development and ten were engaged in general and administrative activities. We consider our employee relations to be good.

### **Website Access to Reports**

Our website address is [www.Vitechnologies.com](http://www.Vitechnologies.com).

We make available on our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, any current reports on Form 8-K and any such amendments to those reports as soon as reasonably practicable after this material is electronically filed with or furnished to the Securities and Exchange Commission.

In addition, we provide paper copies of our filings free of charge upon request.

### **Item 2. PROPERTIES**

We currently lease 37,400 square feet of space in Watertown, Massachusetts to accommodate our research and development activities. This lease expires in December 2009 with two options to extend the lease term by five years each. We believe that this facility is adequate for present and foreseeable future uses.

### **Item 3. LEGAL PROCEEDINGS**

We entered into a lease in 2002 for 16,500 square feet of space near Boston, Massachusetts intended for use as a processing site for INACTINE™-treated red blood cells. In 2003 we concluded that this second site was not required and took steps to terminate our obligations under the lease, which would expire in 2008. In the fourth quarter of 2004, the landlord of that space filed a complaint in Middlesex Superior Court of the Commonwealth of Massachusetts against VITEX seeking damages of not less than \$531,905, plus attorneys' fees, representing a claim for damages relating to re-rental of the facility at a lower rental rate plus associated costs. While we have received limited explanations concerning the landlord's calculation of damages, certain calculations remain

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unexplained and we have not received supporting documentation for any of the calculations, many of which we dispute. However, based on the evidence provided, namely the landlord's affidavits, the trial court issued an order preventing us from using up to \$300,000 of our assets except in the ordinary course of business, and further has allowed an attachment of \$250,000 of our funds as security for a potential future judgment in the landlord's favor. VITEX is vigorously defending against this claim.

In February 2005, we were served with a complaint filed in the United States District Court for the Eastern District of New York by a former employee of the Melville plant which was divested to Precision Pharma Services, Inc., or Precision, in August 2001. The complaint alleges that we underpaid overtime pay to this employee while he was employed by us in our Melville plant. We currently intend to file a motion to dismiss the claim and, based on a review of the employee's payroll records, believe that any overtime pay due to this employee will be less than \$1,000.

In February 2005, we were served with a second complaint by another employee of the Melville, New York plant. This suit, to which Precision Pharma Services is also a party, has been filed in the Supreme Court of the State of New York, County of Suffolk. The suit is a class action in which the lead plaintiff, representing the class, claims that we underpaid overtime due to employees of the processing plant. The complaint alleges an amount in excess of \$125,000 in unpaid overtime pay plus the costs of the action and reasonable attorney's fees due from the two defendants. We are in the process of analyzing employee payroll records for the period in question, which based on the statute of limitations, we believe to be from February 1999 to August, 2001, and we intend to contest the claim vigorously.

### **Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

On December 10, 2004, we held our Annual Meeting of Stockholders. The following matters were approved at that meeting:

1. The election of Dr. Doros Platika as Class II Director to serve until the 2006 Annual Meeting of Stockholders or until a successor is elected and qualified. There were 31,355,448 shares of common stock voted for the election of Dr. Platika and 1,137,321 shares of common stock withheld.
2. The election of Dr. Samuel Ackerman, Mr. David Tendler and Mr. Joseph Limber as Class III Directors to serve until the 2007 Annual Meeting of Stockholders or until successors are elected and qualified. There were 31,267,048 shares of common stock voted for the election of Dr. Samuel Ackerman and 1,225,721 shares of common stock withheld. There were 31,350,698 shares of common stock voted for the election of Mr. David Tendler and 1,142,071 shares of common stock withheld. There were 30,843,950 shares of common stock voted for the election of Mr. Joseph Limber and 1,648,819 shares of common stock withheld.

In addition, the terms in office of Mr. John Barr, Dr. Richard Charpie, Mr. Irwin Lerner and Mr. Jeremy Hayward-Surry continued after the meeting.

3. The ratification of the appointment of KPMG LLP as the Company's independent accountants for the current fiscal year. There were 31,366,484 shares of common stock voted for such ratification, 1,107,067 shares of common stock voted against such ratification, holders of 19,218 shares of common stock abstained from the vote, and there were no broker non-votes.

## PART II

**Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock trades on the Nasdaq National Market under the symbol "VITX." The following table sets forth the reported high and low bid prices of our common stock for each fiscal quarter during the period from December 30, 2002 through December 31, 2004. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2004:</b>		
First Quarter	\$1.78	\$0.95
Second Quarter	1.55	1.00
Third Quarter	1.20	0.67
Fourth Quarter	0.98	0.51
<b>Year Ending December 27, 2003 (fiscal 2003):</b>		
First Quarter	\$1.20	\$0.55
Second Quarter	3.98	0.70
Third Quarter	3.32	1.86
Fourth Quarter	3.10	0.55

The closing price of our common stock on February 28, 2005, as reported on the Nasdaq National Market was \$0.87 per share. As of February 28, 2005, there were 100 holders of record of the 54,475,592 outstanding shares of our common stock.

We have not paid any dividends on our common stock to date. We intend to retain future earnings for use in the development of our business and do not anticipate paying dividends in the foreseeable future. The payment of any dividends will be at the discretion of our Board of Directors and will depend on, among other things, future earnings, business outlook, capital requirements, contractual restrictions, and the general health of our Company.

We did not repurchase any of our securities in 2004.

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**Item 6. SELECTED FINANCIAL DATA (in thousands, except per share data)**

The following table sets forth consolidated financial data with respect to the Company for each of the five years in the period ended December 31, 2004. The selected financial data for each of the five years in the period ended December 31, 2004 have been derived from the consolidated financial statements of the Company, which consolidated financial statements have been audited by KPMG LLP, independent registered public accounting firm.

	<u>2004(1)</u>	<u>2003(2)</u>	<u>2002(3)</u>	<u>2001(3)</u>	<u>2000(4)</u>
<b>Statement of Operations Data:</b>					
Revenues:					
Research funding (5)	\$ 1,682	\$ 716	\$ 4,225	\$ 6,264	\$ 4,030
Processing revenues	—	—	—	20,628	35,445
ARC Incentive Program credit	—	—	—	—	1,235
<b>Total revenues</b>	<b>1,682</b>	<b>716</b>	<b>4,225</b>	<b>26,892</b>	<b>40,710</b>
Costs, expenses and charges:					
Research and development, gross	13,289	18,508	20,351	19,224	16,966
Selling, general and administrative	6,456	4,334	5,942	8,725	10,882
Cost of sales (5)	—	—	—	15,697	28,107
Plasma Operations divestiture (credit) charge	—	—	(1,628)	6,801	—
<b>Total costs and expenses</b>	<b>19,745</b>	<b>22,842</b>	<b>24,665</b>	<b>50,447</b>	<b>55,955</b>
<b>Loss from operations</b>	<b>(18,063)</b>	<b>(22,126)</b>	<b>(20,440)</b>	<b>(23,555)</b>	<b>(15,245)</b>
Interest (expense) income, net	(99)	(227)	400	135	(138)
Discount on customer advance, net	—	—	—	—	402
<b>Total other income (expense)</b>	<b>(99)</b>	<b>(227)</b>	<b>400</b>	<b>135</b>	<b>264</b>
<b>Net loss</b>	<b>\$(18,162)</b>	<b>\$(22,353)</b>	<b>\$(20,040)</b>	<b>\$(23,420)</b>	<b>\$(14,981)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.35)</b>	<b>\$ (0.67)</b>	<b>\$ (0.88)</b>	<b>\$ (1.05)</b>	<b>\$ (0.75)</b>
Weighted average common shares used in computing basic and diluted net loss per share	52,489	33,360	22,752	22,316	19,860
	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Balance Sheet Data:</b>					
Cash and cash equivalents, including restricted cash	\$ 3,632	\$ 4,848	\$ 7,249	\$ 21,949	\$ 7,768
Short-term investments	—	—	—	3,332	—
Working capital (deficit)	(252)	6,357	5,454	23,331	4,432
<b>Total assets</b>	<b>7,938</b>	<b>17,656</b>	<b>23,468</b>	<b>43,672</b>	<b>64,203</b>
Long-term obligations, less current portion	1,165	2,526	1,628	4,901	5,233
<b>Stockholders' equity</b>	<b>2,360</b>	<b>12,245</b>	<b>12,858</b>	<b>32,788</b>	<b>45,157</b>

Note: For presentation purposes, years ended December 27, 2003, December 28, 2002, December 29, 2001 and December 30, 2000 are presented as fiscal years 2003, 2002, 2001 and 2000, respectively. In 2004, we changed our fiscal year end to December 31, a calendar year end.

- (1) In fiscal year 2004, we recorded a \$2.5 million charge within research and development costs to write off certain core technology which we determined was impaired. We also recorded \$1.2 million of merger-related charges in 2004 within general and administrative expenses. Also in 2004 we recorded \$0.52 million and \$0.08 million to research and development and general and administrative expenses, respectively,

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representing a non-cash charge to reflect the cumulative effect of a change in leased property accounting over the past five years that was not material to our reported results in any one year.

- (2) In fiscal year 2003, we recorded a \$1.4 million charge within research and development costs to write off capitalized build-out costs and to provide for estimated lease and associated carrying costs until the facility was sublet or the lease was terminated.
- (3) During 2002 and 2001, we incurred a \$1.6 million credit and \$6.8 million charge, respectively, on the divestiture of our Plasma Operations (see Note 4 to the consolidated financial statements). Included in the \$1.6 million credit in 2002 is a \$1.2 million credit to recognize a settlement with the Bureau of Alcohol, Tobacco and Firearms of a dispute over ethanol usage taxes.
- (4) During 2000, we recorded a \$1.2 million incentive sales credit reflecting unused sales incentives from a program which commenced in 1999.
- (5) Research funding includes collaborator reimbursement amounts received from related parties in the amounts of \$3.6 million, \$5.8 million and \$4.0 million in 2002, 2001 and 2000, respectively. Cost of sales includes royalties and materials used in the production of PLAS+<sup>®</sup>SD which were paid or owed to related parties in the amounts of \$0.9 million and \$0.4 million in 2001 and 2000, respectively.

### **Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

#### **Executive Overview**

VITEX is a development stage biotechnology company developing novel anti-infective products. Our INACTINE<sup>™</sup> Pathogen Reduction System for red cells, or INACTINE<sup>™</sup> system, is designed to inactivate a wide range of viruses, bacteria, parasites and lymphocytes from red blood cells and to remove soluble prion proteins. Prion proteins in their pathogenic forms are the agents that cause "Mad Cow Disease", or in humans, variant Creutzfeldt-Jakob Disease, or vCJD, which is 100% fatal, and for which no diagnostic test or therapy currently exists. Over 40 million red cell units are transfused annually in North America, Europe and Japan, making it one of the most frequently prescribed and important products in medicine. A pathogen reduction product for both acute and chronic patients could represent, according to our estimates as based on a report prepared for us by Easton Associates, an outside consultant, a \$4 billion market with acute indications representing approximately \$3 billion out of that total. We currently do not have any FDA approved products and have not made any commercial sales of our products under development.

In November 2004, we suspended enrollment in our Phase III surgical, or acute, study for our lead product candidate, the INACTINE<sup>™</sup> red cell system, following identification of an immune response to INACTINE<sup>™</sup>-treated red cells in one patient in the study during ongoing immunologic testing of subjects enrolled in the trial. As a result, both the Phase III trial of INACTINE<sup>™</sup> for acute indications and the Phase III trial of INACTINE<sup>™</sup> for chronic indications, described in more detail below, have been halted, in the case of the chronic trial, following a clinical hold by the FDA. Although no clinical consequences of the immune response are apparent based on review of available data, additional patients will not be enrolled in the acute trial pending full evaluation. We have notified the FDA that we have suspended enrollment in the study and that we intend to continue discussions with the FDA regarding the conditions, if any, under which the trial might be continued while we are completing our review of all relevant data. We intend to conduct these discussions as part of an ongoing dialogue with the FDA regarding conditions for licensure of the INACTINE<sup>™</sup> system.

Our Phase III chronic study of the INACTINE<sup>™</sup> system was placed on clinical hold by the FDA due to the availability of insufficient safety information, and was subsequently halted by us following a review by an independent data safety monitoring committee, or DSMC, in November 2003. The halting of the study by us was due to antibody formation in sickle cell anemia patients receiving repeat transfusions of INACTINE<sup>™</sup>-treated red cells. The Phase III trial of INACTINE<sup>™</sup> for chronic indications was designed to be conducted in two sequential parts, Part A and Part B. The purpose of Part A was to allow assessment of the safety of INACTINE<sup>™</sup>-treated red cells in the patient population under study prior to proceeding to Part B. Enrollment in the chronic trial was

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stopped prior to initiation of Part B on the recommendation of the DSMC, which was charged with reviewing the data from Part A of the study following the FDA's clinical hold on the trial due to availability of insufficient safety information.

Prior to the suspension of the surgical trial, the FDA had expressed concerns regarding the licensing of the current INACTINE™ system for an acute indication in light of the presence of antibodies observed in the chronic trial, and has requested justification from us for pursuit of an acute-only indication in the context of these findings. The FDA has also indicated that a control system with respect to an acute-only indication would be required to ensure that patients who have previously received red cells treated by the current INACTINE™ system do not receive INACTINE™ red cells in subsequent hospitalizations. We have met with the FDA and presented proposals on supplemental clinical trials. However, the FDA has indicated that it will require the review of additional data, including the results of the Phase III trial for INACTINE™ in acute indications, before fully responding to our proposals for additional clinical trials. The occurrence of an immune response in the acute trial and the decision to suspend enrollment in it will require us to formulate and present to the FDA a regulatory plan for approval of INACTINE™ that takes into account all findings to date, which is likely to significantly delay determination of any acceptable regulatory pathway. The FDA has indicated that any such regulatory plan for the acute-only indication must address the development of a control system, as described above. In addition, we believe that modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells will also be required. At this time, we cannot determine the length of time required for us to develop such a regulatory plan, nor can we estimate the length of time required for the FDA to approve such a plan, or whether such a plan will be approved at all. Enrollment in the acute trial will continue to be suspended until such time as a regulatory plan is approved by the FDA and implemented by us, if ever. We have begun preclinical testing on the modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells. However, this work is preliminary and no assurance can be given that we will be able to develop a control system that will be technically feasible, approved by the FDA, and economically viable, or that the modifications to the current INACTINE™ process will succeed in reducing the likelihood of an immunologic response. Prior to the suspension of enrollment in the acute study, the FDA also directed us to implement additional patient safety monitoring procedures in the Phase III acute trial. We implemented these procedures and, until enrollment into the trial was suspended, were periodically updating the FDA on the trial data. While we believe that the steps taken addressed the FDA's recommendations prior to suspending enrollment in the acute trial, further steps could be required by the FDA. We also received from the FDA a written request for further information relating to an August 2004 amendment to our IND. The amendment included responses to questions raised by the FDA relating to procedures for patient safety monitoring used in the Phase III chronic study, which had been placed on clinical hold by the FDA due to the availability of insufficient safety information, and subsequently halted by us following a DSMC review. We have responded to the FDA's request and are awaiting further communications from the agency on this matter.

Our ongoing development plan for INACTINE™ for chronic, acute or other indications is highly uncertain, with the Phase III trial for INACTINE™ in chronic indications halted by us following the clinical hold by the FDA and the subsequent review by the DSMC, and enrollment suspended in the Phase III trial for INACTINE™ in acute indications. We cannot ensure that the acute trial will resume or complete enrollment in a timely manner. The exact nature, timing and estimated costs of the efforts necessary to bring to market the product resulting from our pathogen inactivation research and development projects involve a number of key variables which are either unpredictable or outside our control, including whether the likelihood of an immune response to INACTINE™-treated red cells can be adequately reduced, whether, and under what circumstances, the FDA will agree with our plan to proceed with clinical trials, the enrollment rates and results of the Phase III clinical trial, should it be continued, the extent of further studies which could be required for filing a Biologics License Application with the FDA, the length of the FDA and foreign regulatory approval processes, the success of our fundraising efforts, our ability to establish and maintain relationships with marketing partners and strategic collaborators, and the timing of commencement of commercialization of our product. Inability to satisfy one or more of these conditions, or to do so in a commercially acceptable manner, may render continued development of our INACTINE™ system infeasible.

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The development of the INACTINE™ system is our most significant current activity. With the proposed merger with Panacos further described below under “Recent Developments” anticipated to close in mid-March 2005, our continuing significant activities will include the Panacos clinical trials and development work.

We fund our operations primarily through sale of common stock and research and development grants. As of February 28, 2005, we had cash on hand of approximately \$1.0 million. We expect to close on a proposed financing with anticipated proceeds of \$20 million concurrently with the closing of the proposed merger with Panacos. At present, after our recent restructuring in December 2004, we are consuming approximately \$1.0 million in cash per month. Following the proposed merger, the combined company expects to spend approximately \$2.6 million on average in cash per month in 2005. We believe that our present cash resources will be adequate to meet our requirements only through the first quarter of 2005.

We believe that the sum of our present cash resources, Panacos’ cash resources and the anticipated proceeds of \$20 million from the financing will be adequate to meet our requirements, post-merger, into the fourth quarter of 2005. However, there is no current guarantee that we will be able to successfully complete the merger transaction and close on the \$20 million financing. Our special meeting of shareholders to vote on the merger and financing is scheduled for March 10, 2005. We expect to commence a rights offering in March 2005, close in April 2005 and raise a maximum of \$5.5 million to increase that cash horizon. However, there is no guarantee that we will be able to successfully complete the rights offering. In the event that the merger, financing, or rights offering are not successful, we intend to delay or reduce expenditures so as to continue our operations on a limited scale and within our available resources.

### **Recent Developments**

#### *Proposed Merger with Panacos Pharmaceuticals*

On June 2, 2004, we signed a definitive merger agreement with Panacos Pharmaceuticals. The terms of the proposed merger were subsequently amended in November 2004, December 2004 and February 2005. We filed a final joint proxy statement – prospectus with the Securities and Exchange Commission on February 14, 2005 and anticipate closing the merger shortly after our special meeting of shareholders on March 10, 2005.

Panacos Pharmaceuticals is a development stage company involved in the discovery and development of the next generation of small molecule, antiviral drugs for the treatment of Human Immunodeficiency Virus, or HIV, infection and other major virus diseases. Panacos is focusing exclusively on diseases with large markets, where there is a clear unmet need for more effective therapies. A major commercial advantage of the HIV market is the rapid clinical development and approval process for new drugs. The total time from initiation of clinical trials to market may be as little as four years, shorter than for many other disease indications.

Panacos completed its pre-clinical program for its lead candidate to treat HIV, PA-457, at the end of 2003 and filed an IND with the FDA in December 2003. Panacos entered Phase I clinical testing of PA-457 in March 2004. It has completed the Phase I programs and begun the Phase II program. PA-457 is the first in a new class of drugs called maturation inhibitors discovered by Panacos scientists. The FDA has granted fast track status, available for drugs designed to treat a serious or life threatening condition with an unmet medical need, to PA-457.

The merger, if completed, would expand VITEX into anti-infective therapeutics and will add additional pre-clinical and clinical drug candidates to our product portfolio.

#### *Rights Offering*

We plan to file a registration statement with the SEC for a proposed offering of our common stock with a maximum value of approximately \$5.5 million through the distribution of subscription rights to our shareholders in early March 2005. Under terms of the rights offering our shareholders will receive a certain number of subscription rights for each share of VITEX common stock owned at the record date of March 4, 2005 thereby entitling them to purchase shares of our common stock representing a total maximum of 27.5 million shares, prior to the anticipated reverse split. Our largest shareholder, Ampersand Ventures, held 9.3 million shares of

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VITEX common stock as of February 28, 2005, prior to the anticipated reverse split. Ampersand agreed not to participate in the rights offering as a condition to their participation in the \$20 million private placement. The exercise price for the rights will be \$0.20 per share, the same as the price paid for our common stock by Great Point Partners and affiliates in the \$20 million private placement, which we expect to close concurrently with the proposed Panacos merger in March 2005. There is no guarantee that we will be able to successfully complete any of these transactions.

### **Critical Accounting Estimates and Policies**

We prepare our consolidated financial statements in conformity with generally accepted accounting principles in the United States of America. The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements as well as reported revenues and expenses during the reporting periods. Our actual results could differ from these estimates.

The significant accounting policies that we believe are most critical to aid in fully understanding and evaluating our reported financial results and the accounting policies most critical to the preparation of our consolidated financial statements include the following:

#### *Research and Development Revenue and Cost Recognition*

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements". We recognize revenues under research collaborations, including grants received from the government and minimum royalty payments, as we incur research costs eligible for reimbursement under the collaboration agreements. Non-refundable up-front and milestone payments related to license and distribution agreements are deferred and amortized over the period in which the licensee has distribution rights. We continually review these estimates for any events which could result in a change in the deferral period. Amounts received in advance of the incurrence of reimbursable research expenses are deferred and recognized when the related expenses have been incurred.

Research and development costs are charged to operations as incurred.

#### *Long-Lived Assets*

Our long-lived assets, which consist primarily of property and equipment, are recorded at cost and amortized over the estimated useful life of the asset. We generally depreciate property and equipment using the straight-line method over their economic life, which ranges from 3 to 15 years. Determining the economic lives of our long-lived assets requires us to make significant judgments and estimates, and can materially impact our operating results. Our estimates of the useful lives of these assets are based on industry standards and our specific business. We believe our estimates are reasonable for all material purposes and that our estimates are not likely to change in the near future.

#### *Asset Impairments*

We review the valuation of long-lived assets, including property and equipment and intangible assets, under the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). We are required to assess the recoverability of long-lived assets on an interim basis whenever events and circumstances indicate that the carrying value may not be recoverable. Factors we consider important that could trigger an interim impairment review include the following:

- significant changes in the manner of our use of the assets or the strategy of our overall business;
- significant decrease in the market value of an asset;
- significant adverse change in our business or industry; and
- significant decline in our stock price for a sustained period.

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In accordance with SFAS No. 144, when we determine that the carrying value of applicable long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we evaluate whether the carrying amount of the asset exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of that asset. If such a circumstance were to exist, we would measure an impairment loss to the extent the carrying amount of the particular long-lived asset or group of assets exceeds its fair value. We would determine the fair value based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model. Use of different estimates and judgments on any of these factors could yield materially different results in our analysis, and could result in significantly different asset impairment charges.

We follow the provisions of SFAS No. 142, "*Goodwill and Other Intangible Assets*" ("SFAS No. 142"). Under SFAS No. 142, goodwill is required to be tested for impairment annually in lieu of being amortized. We have selected the fourth quarter as the period to perform the annual test. Furthermore, goodwill is required to be tested for impairment on an interim basis if an event or circumstance indicates that it is more likely than not that an impairment loss has been incurred. An impairment loss shall be recognized to the extent that the carrying amount of goodwill exceeds its implied fair value. Impairment losses shall be recognized in operations.

On November 23, 2004, we announced that we had temporarily suspended enrollment in our Phase III surgical, or acute, study for our lead product candidate, the INACTINE™ system, following identification of an immune or antibody response to INACTINE™-treated red cells in one patient during ongoing immunologic testing of subjects enrolled in the trial. As a result, both the Phase III trial of INACTINE™ for acute indications and the Phase III trial of INACTINE™ for chronic indications have been halted. The Phase III chronic study was placed on clinical hold by the FDA due to the availability of insufficient safety information and subsequently halted following the review of an independent data safety monitoring committee. These developments triggered an impairment review of long-lived assets and goodwill under the provisions of SFAS No. 144 and SFAS No. 142, respectively. Based on the results of our review of long-lived assets, we wrote off certain core technology acquired in our 1999 acquisition of Pentose Pharmaceuticals, Inc. The intangible asset had a remaining net book value of \$2.5 million. The charge was booked in the fourth quarter of 2004 to research and development costs. Based on the results of our review for goodwill, which totaled \$0.4 million at December 31, 2004, no impairment charge was indicated as the Company's market capitalization exceeded the book value of its net assets.

### *Contingencies*

Contingencies are addressed by assessing the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of losses. A determination of the amount of reserves required, if any, for these contingencies is made after reviewing the relevant facts and circumstances, seeking outside professional advice of lawyers or accountants where appropriate, and then making and recording our best judgment of potential loss under the guidance of Statement of Financial Accounting Standards No. 5, "*Contingencies*". This process is repeated in each reporting period as circumstances evolve and are reevaluated. Any changes in our assumptions or estimates that impact our estimates of loss will be recorded in operations immediately in the period of the change. As discussed in Item 3 above, we are currently involved in certain legal proceedings. After consulting with our attorneys regarding these proceedings, we have recorded our best judgment of potential costs in the fourth quarter of 2004.

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**Table of Contents****Results of Operations****Fiscal Year 2004 as Compared to Fiscal Year 2003***Net Revenues- Research Funding*

<u>Fiscal Year 2004</u>	<u>Fiscal Year 2003</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$1.7 million	\$0.7 million	1.0 million	135%

The increase in research funding is attributed to the recognition in revenue of non-refundable up-front and milestone payments from Amersham Pharmacia Biotech, which were previously deferred and are being amortized over the life of the related agreement, or approximately ten years. We terminated the agreement with Amersham Pharmacia Biotech during the fourth quarter of 2004 and, as a result, recognized the balance of the unamortized deferred revenue of approximately \$0.8 million. This agreement covered the development and marketing of INACTINE™ for use as a pathogen reduction step in the manufacture of biopharmaceuticals. We made the decision to terminate the agreement based on the result of joint development efforts suggesting that the chance of material commercial success were relatively low. Further, the development and regulatory process was likely to be lengthy and expensive. Total Amersham Pharmacia Biotech revenue totaled \$1.0 million for fiscal year 2004 and \$0.25 million for fiscal year 2003. Research funding also includes grants received from governmental agencies in the amount of \$0.7 and \$0.5 million in fiscal years 2004 and 2003, respectively. We expect revenues earned from existing government grants to total approximately \$0.5 million in 2005.

*Research and Development*

<u>Fiscal Year 2004</u>	<u>Fiscal Year 2003</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$13.3 million	\$18.5 million	\$(5.2 million)	(28)%

Our current research and development activities all relate to the development of pathogen inactivation technologies for blood products of which our INACTINE™ chemistry is currently the core technology and our INACTINE™ system for red cells is the lead product candidate. Our research and development spending on pathogen inactivation technologies have principally included our internal research efforts, clinical trials conducted by medical institutions and scientific and development work under contract to independent vendors. We have completed Phase I and Phase II clinical trials in human subjects. In January 2003, we commenced two Phase III trials, a surgical, or acute, study for patients requiring acute transfusions of red blood cells and a chronic study for patients with sickle cell anemia requiring repeat transfusions of red blood cells.

In the fourth quarter of 2003, we halted our Phase III chronic study of INACTINE™ red cells due to antibody formation in sickle cell anemia patients. Following this decision to halt our INACTINE™ system Phase III chronic clinical trial, we restructured our operations to reduce spending and to concentrate our efforts on the acute trial. We reduced staffing by over 50%, eliminating over 40 positions, and curtailed non-essential activities. There were no restructuring expenses related to these actions.

In November 2004, we suspended enrollment in our Phase III surgical, or acute, study for our lead product candidate, the INACTINE™ red cell system, following identification of an immune response to INACTINE™-treated red cells in one patient in the study during ongoing immunologic testing of subjects enrolled in the trial. Following this decision, in December 2004, we announced that we had implemented another restructuring to reduce expenses. The restructuring was intended to allow us to conserve cash until the completion of the proposed merger with Panacos. The restructuring included an immediate reduction in our research and development workforce by approximately 40%, or 15 positions. We incurred a charge of \$0.1 million to research and development in the fourth quarter of 2004 in connection with this restructuring as each employee subject to the restructuring received severance pay equal to his or her one month salary. All payments were made prior to December 31, 2004.

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Following the decision to halt the chronic trial in November 2003, research and development operations were restructured resulting in a reduction in head count. A significant portion of the decrease in research and development costs from fiscal year 2003 to 2004 occurred as a result of that reduction in head count and development activity. Labor costs decreased by \$2.2 million from 2003 to 2004 and consumption of lab supplies decreased by \$0.8 million. Development spending decreased by \$3.1 million from the prior year due to the reduction in investment in the development of equipment and disposables for use in the INACTINE™ system. Spending in this area in 2003 included major investments in construction of prototype equipment and disposables for use in the clinical trials for the INACTINE™ system. The work in 2004 centered on validation of the equipment and disposables at a much reduced level of investment when compared to 2003. Research and development spending in fiscal year 2003 also included a non-cash charge to write off \$1.4 million capitalized build-out and other costs of a processing facility which we decided not to place in service (see Item 3. "Legal Proceedings"). These decreases from the prior year are offset by a non-cash charge of \$2.5 million to write-off certain core technology after we performed an impairment review on our long-lived assets, triggered by the halting of enrollment in the acute Phase III trial during the fourth quarter of 2004. Also in 2004 we recorded a one-time non-cash charge of \$0.52 million reflecting a cumulative effect of a change in leased property accounting over the past five years that was not material to our reported results in any one year.

The restructuring in 2004 lowered our spending rate in December 2004 into the range of approximately \$1.0 million per month and decreased research and development costs from a monthly average of \$0.8 million into the range of approximately \$0.5 million per month. Due to the proposed merger with Panacos expected to close in mid-March 2005, we expect research and development costs to increase to approximately \$7 million on a quarterly basis beginning in the second quarter of 2005 primarily due to the significant costs of Panacos' ongoing Phase II clinical trials.

Cumulatively, we have invested \$160.0 million in research and development of pathogen inactivation technologies for blood products since 1995, including the cost of in-process research and development resulting from our 1999 merger with Pentose Pharmaceuticals, Inc.

### *General and Administrative Expenses*

<u>Fiscal Year 2004</u>	<u>Fiscal Year 2003</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$6.5 million	\$4.3 million	\$2.1 million	49%

The majority of the increase from 2003 to 2004 is due to merger-related costs of \$1.2 million for our proposed merger with Panacos, the agreement for which was signed in 2004. Additionally, we established legal contingencies in 2004 in the amount of \$0.7 million for pending litigation (see Item 3. "Legal Proceedings"). We allocate various corporate charges based on certain indicators, including headcount. A greater proportion of the headcount reduction due to our restructuring in November 2003 was in research and development rather than in the general and administrative functions. Primarily as a result of this, allocation of charges to general and administrative expenses increased \$0.5 million from 2003 to 2004. Significant reductions in expense from 2003 to 2004 include \$0.2 million in investor relations costs and \$0.2 million in general administrative costs as a result of our restructuring in 2003. The Company reduced the use of outside consultants and took on direct responsibility for these activities.

### *Interest (Expense) Income, Net*

<u>Fiscal Year 2004</u>	<u>Fiscal Year 2003</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$(0.1) million	\$(0.2) million	\$(0.1) million	(56)%

Fiscal year 2004 interest expense reflects a \$0.2 million decrease due to the repayment of advances to Pall Corporation in fiscal year 2003. Interest income decreased by \$0.1 million from fiscal year 2003 to fiscal year 2004 resulting from a lower level of invested cash and cash equivalents during the year.

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### *Provision for Income Taxes*

For fiscal years 2004 and 2003, we have recorded no income tax expense or benefit. At December 31, 2004 and December 27, 2003, we established a full valuation allowance against our net deferred tax asset positions of \$62.3 million and \$55.1 million, respectively. Realization of these net deferred tax assets will be based on, among other things, our ability to generate future taxable profits and utilize our net operating loss carry-forwards and tax credits before they expire. Our ability to utilize all of our net operating loss carryforwards may be limited if there is a change in ownership, as defined by Section 382 of the Internal Revenue Code, in connection with the proposed merger with Panacos.

### **Fiscal Year 2003 as Compared to Fiscal Year 2002**

#### *Net Revenues- Research Funding*

<u>Fiscal Year 2003</u>	<u>Fiscal Year 2002</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$0.7 million	\$4.2 million	\$(3.5 million)	(83)%

The decrease in research funding is primarily a result of our August 2002 modification of the Pall collaboration, under the terms of which we assumed responsibility from Pall for funding of the INACTINE™ red cell program. Prior to August 2002, research funding received was principally from Pall Corporation.

Also included within research funding is amortized revenue related to non-refundable up-front and milestone payments from Amersham Pharmacia Biotech, which are amortized over the life of the related agreement. These amounts totaled \$0.15 million for each of fiscal years 2003 and 2002. In addition, we recorded minimal royalty payments from Amersham Pharmacia Biotech of \$0.1 million and \$0.2 in fiscal years 2003 and 2002, respectively. Finally, research funding includes grants received from governmental agencies in the amount of \$0.46 million and \$0.3 million in fiscal years 2003 and 2002, respectively.

#### *Research and Development*

<u>Fiscal Year 2003</u>	<u>Fiscal Year 2002</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$18.5 million	\$20.4 million	\$(1.9 million)	(9)%

Our research and development activities all relate to the development of pathogen inactivation technologies for blood products of which our INACTINE™ chemistry is currently the core technology and our INACTINE™ system for red cells is the lead product candidate. The INACTINE™ system has completed Phase I and Phase II clinical trials in human subjects and, until suspension in November 2004, was in a Phase III trial with patients requiring acute transfusions of red blood cells.

Our research and development spending on pathogen inactivation technologies principally includes our internal research efforts, clinical trials conducted by medical institutions and scientific and development work under contract to independent vendors.

Fiscal year 2003 includes a \$1.4 million non-cash charge to write off capitalized build-out and other costs of a processing facility which we have decided not to place in service. In fiscal year 2003, Phase III clinical costs were higher than in the prior year by \$0.9 million as our Phase III trials commenced in January 2003.

Fiscal year 2002 includes a non-recurring \$1.0 million royalty payment for engineering services on the INACTINE™ delivery system. This payment was required under our agreement for engineering services to maintain exclusivity for the INACTINE™ delivery system. Toxicology program costs were \$1.0 million higher in fiscal year 2002 than in fiscal year 2003 as our INACTINE™ system toxicology studies were significantly completed in fiscal year 2002. Fiscal 2002 includes \$1.3 million higher spending than 2003 on a prion diagnostic research program which was phased out by the end of 2002. This program was terminated to allow to focus

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ongoing development resources on INACTINE™ development efforts. Costs for laboratory supplies decreased by \$0.8 million from fiscal year 2002 to 2003 as our R&D emphasis shifted toward clinical trials and away from pre-clinical development and validation of the technology.

In the fourth quarter of 2003, following the decision to halt our INACTINE™ system Phase III chronic clinical trial after it was placed on clinical hold by the FDA due to the availability of insufficient safety information and review by an independent data safety monitoring committee, we restructured our operations to reduce spending and to concentrate our efforts on the acute trial. We reduced staffing by over 50%, eliminating over 40 positions, and curtailed non-essential activities. There were no restructuring expenses related to these actions.

### General and Administrative Expenses

<u>Fiscal Year 2003</u>	<u>Fiscal Year 2002</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$4.3 million	\$5.9 million	\$(1.6 million)	(27)%

The decrease in general and administrative expenses is due to lower staffing needs, lower discretionary consulting expenditures and lower costs related to the protection of intellectual property.

### Plasma Operations Impairment

<u>Fiscal Year 2003</u>	<u>Fiscal Year 2002</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$—	\$1.6 million credit	\$(1.6 million)	(100)%

In 2002, we recorded credits on the divestiture of our Plasma Operations primarily related to the \$1.2 million settlement of an ethanol tax dispute with the U.S. Bureau of Alcohol, Tobacco and Firearms, as well as the settlement of certain liabilities below recorded amounts.

### Interest (Expense) Income, Net

<u>Fiscal Year 2003</u>	<u>Fiscal Year 2002</u>	<u>Increase/(Decrease)</u>	<u>%</u>
\$0.2 million expense	\$0.4 million income	\$(0.6 million)	(157)%

Fiscal year 2003 net interest expense reflects a \$0.3 million charge on remeasurement to net present value of the \$3.0 million receivable from Precision on which payment was rescheduled by one year to December 2004. Additionally, we had lower average cash balances in fiscal year 2003 versus 2002.

### Provision for Income Taxes

For fiscal years 2003 and 2002, we have recorded no income tax expense or benefit. At December 27, 2003 and December 28, 2002, we established a full valuation allowance against our net deferred tax asset positions of \$55.1 million and \$47.2 million, respectively. Realization of these net deferred tax assets will be based on, among other things, our ability to generate future taxable profits and utilize our net operating loss carryforwards and tax credits before they expire.

### Liquidity and Capital Resources

We finance our operations primarily through sales of our common stock and research and development grants. At December 31, 2004, we had a working capital deficit of \$0.3 million, including unrestricted cash of \$3.0 million, in comparison with working capital of \$6.4 million, including unrestricted cash of \$4.3 million at the prior year end. Our cash balances are invested with the primary objectives of safety of principal and liquidity. Our available unrestricted cash balances on February 28, 2005 were approximately \$1.0 million. We believe that our present cash resources will be adequate to meet our requirements only through the first quarter of 2005.

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We expect to close on a proposed financing with anticipated proceeds of \$20 million concurrently with the closing of the proposed Panacos merger. At present, after our recent restructuring in December 2004, we have been consuming approximately \$1.0 million in cash per month. Following the proposed merger, the combined company expects to spend approximately \$2.6 million on average in cash per month during 2005. VITEX believes that our present cash resources, in addition to Panacos' cash resources and the anticipated proceeds of the \$20 million financing will be adequate to meet our requirements, post-merger, into the fourth quarter of 2005. However, there is no guarantee that we will be able to successfully complete the merger transaction and close on the \$20 million financing. Our special meeting of shareholders to vote on the merger and the financing is scheduled for March 10, 2005. We also expect to commence a rights offering in March 2005, close in April 2005 and raise a maximum of \$5.5 million to increase that cash horizon. However, there is no guarantee that we will be able to successfully complete the rights offering. In the event that the merger, financing, or rights offering are not successful, we intend to delay or reduce expenditures so as to continue our operations on a limited scale and within our available resources.

Beyond 2005, we anticipate cash requirements of between \$30 million and \$40 million annually. The level of cash resources required will depend on the continuing progress of clinical trials for PA-457, the ongoing investment in the clinical development of the INACTINE™ red cell system and the level of investment in any other therapeutic products under development by the Company. We plan to fund operations through a combination of additional sales of VITEX stock and debt securities, grants from government agencies, such as the National Institutes of Health, and partnerships for the clinical development and distribution of products, such as PA-457. Development partnerships can include license fees and reimbursement of the cost to conduct clinical trials required to commercialize the product in return for distribution rights following licensing of the product by regulatory authorities. There is no guarantee that we will be able to close new financings, secure additional grants, or enter into commercial partnerships. Other than grants, proceeds from financings and partnerships, we do not anticipate generating cash flow from operations until the licensing and launch of PA-457 in a major market, such as the U.S. or Europe.

In fiscal 2004 and 2003, we generated cash primarily from equity transactions and the receipt of partner research funding. Our cash activity during 2004 was comprised of the following (in millions):

Net proceeds from equity transactions	\$ 11.6
Settlement of Plasma Operations receivables (see Note 4 to the consolidated financial statements)	1.7
Cash used in operating activities	(12.9)
Net repayment of advances and financed insurance costs	(1.0)
Transfers to restricted cash	(0.3)
Payment of financing-related costs	(0.2)
Purchase of property and equipment	(0.2)
	<hr/>
Decrease in cash position	\$ (1.3)

## Contractual Obligations

The following table represents our outstanding contractual obligations at December 31, 2004, in thousands:

Contractual Obligations	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating Leases	\$5,131	\$ 942	\$3,142	\$1,047	—
Repayment of Advances (1)	1,467	1,257	210	—	—
Financed insurance costs (2)	116	116	—	—	—
<b>Total</b>	<b>\$6,714</b>	<b>\$ 2,315</b>	<b>\$3,352</b>	<b>\$1,047</b>	<b>—</b>

(1) Includes interest at annual rate of 10.0%

(2) Includes interest at annual rate 4.69%

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### **New Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board (“FASB”) issued FASB Statement No. 123 (revised 2004), “*Shared-Based Payment*” (“Statement 123(R)”). Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise’s equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, “*Accounting for Stock Issued to Employees*”, which was permitted under Statement No. 123, as originally issued. The revised Statement requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements. All public companies must use either the modified prospective or the modified retrospective transition method. The Company has not yet evaluated the impact of this pronouncement which must be adopted in the third quarter of 2005. See Note 2 to the consolidated financial statements for information related to the pro forma effect on our reported net loss and net loss per share of applying the fair value recognition provisions of the previous SFAS No. 123 to stock-based employee compensation.

Also in December 2004, as part of its short-term international convergence project with the International Accounting Standards Board, the FASB issued Statement 153 to address the accounting for nonmonetary exchanges of productive assets. Statement 153 amends APB No. 29, “*Accounting for Nonmonetary Exchanges*”, which established a narrow exception for nonmonetary exchanges of similar productive assets from fair value measurement. This Statement eliminates that exception and replaces it with an exception for exchanges that do not have commercial substance. Under Statement 153 nonmonetary exchanges are required to be accounted for at fair value, recognizing any gains or losses, if their fair value is determinable within reasonable limits and the transaction has commercial substance. The Statement specifies that a nonmonetary exchange has commercial substance if future cash flows of the entity are expected to change significantly as a result of the exchange. We plan to adopt this Statement in fiscal 2005, and its adoption is not expected to impact our financial position or results of operations.

### **Risk Factors**

Our business faces significant risks. These risks include those described below and may include additional risks of which we are not currently aware or which we do not currently believe are material. These statements relate to future events or the future financial performance of VITEX. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimated”, “predicts”, “potential”, or “continue” or the negative of such terms and other comparable terminology. These statements only reflect management’s expectations and estimates. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined below. The risks described below are the risks that we believe to be the most significant at this time to the combined company post-merger of VITEX and Panacos as the proposed merger is anticipated to close in mid-March, 2005. These factors may cause our actual results to differ materially from any forward-looking statements. These risks should be read in conjunction with the other information set forth in this report.

#### ***Risks Relating to the Merger***

##### **The ability of VITEX and Panacos to successfully integrate their businesses is uncertain.**

After closing the merger, VITEX and Panacos, each of which previously operated independently, will have to integrate their operations. The integration will require efforts from each company, including the coordination of their general and administrative functions. For example, integration of administrative functions includes coordinating employee benefits, payroll, financial reporting, purchasing and disclosure functions. Delays in successfully integrating and managing employee benefits could lead to dissatisfaction and employee turnover.

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Problems in integrating purchasing and financial reporting could result in control issues, including unplanned costs. Diversion of management attention could result in delays in clinical programs. The combination of VITEX's and Panacos' organizations may result in greater competition for resources and elimination of research and development programs that might otherwise be successfully completed. VITEX management may have their attention diverted while trying to integrate the two companies, one of which is located in Watertown, Massachusetts and one of which is located in Gaithersburg, Maryland. Such diversion of management's attention or difficulties in the transition process could have an adverse impact on VITEX. VITEX will have approximately 23 employees and Panacos will have approximately 21 employees at the time the merger is closed. Virtually all of the employees in the merged company will work at either the Watertown, MA or the Gaithersburg, MD facility. The majority of VITEX personnel in Watertown, MA are scientists, clinical and regulatory professionals, engineers and individuals who process blood for experimental and clinical use. Panacos is principally engaged in the development of innovative drugs to treat HIV and other serious viral diseases. The VITEX workforce in Gaithersburg, MD (formerly the Panacos workforce) consists largely of scientists, clinical and regulatory professionals. The companies share a focus in innovative anti-infective technologies including extensive knowledge of how to kill or inactivate viruses and other agents such as bacteria that can cause disease in humans. The management team of the combined company has experience in attracting and retaining the technical personnel that will represent the majority of employees in the combined company. However, no assurance can be given that the combined company will succeed in its efforts to integrate the VITEX and Panacos operations successfully. The transition period is expected to be largely complete within the fiscal quarter following the closing of the merger.

### **Failure to integrate the companies' operations successfully could result in delays in the companies' clinical trial programs.**

VITEX and Panacos have entered into the merger agreement with the expectation that the merger will result in beneficial synergies, including:

- improved ability to raise new capital through access to new classes of investors focused on public companies engaged in anti-infective drug development;
- shared expertise in developing innovative anti-infective technologies and the potential for technology collaboration;
- a broader pipeline of products;
- greater ability to attract commercial partners;
- larger combined commercial opportunities; and
- a broader portfolio of patents and trademarks.

Achieving these anticipated synergies and the potential benefits underlying the two companies' reasons for the merger will depend on a number of factors, some of which include:

- retention of scientific staff;
- significant litigation, if any, adverse to Panacos and VITEX, including, particularly, product liability litigation and patent and trademark litigation; and
- the ability of the combined company to continue development of VITEX and Panacos product candidates.

Patent litigation is costly, highly uncertain and can require a significant amount of management time and the time of key technical staff to prosecute or defend. An adverse patent ruling could affect the ability of the company to successfully develop a product and affect the return on investment with the earlier introduction of competitive products should patent protection be ruled invalid or unenforceable. Litigation associated with a clinical trial could adversely affect the progress of the trial, consume significant resources in defending the claim and negatively affect the successful commercialization of the product. The consideration to be paid in the merger is

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based on the expectation of continued clinical and commercial development of the combined company's products, and the associated protection provided by related intellectual property rights. In addition, significant litigation could impact the ability of the merged company to raise capital to fund the clinical development programs due to the associated cost and uncertainty.

Even if the two companies are able to integrate their operations, there can be no assurance that these anticipated synergies will be achieved. The failure to achieve such synergies could have a material adverse effect on the business, results of operations and financial condition of the combined company.

### **The value of the shares of VITEX common stock to be received is not fixed and may decline from its current value.**

The number of shares of VITEX common stock to be issued in the merger is fixed and each stockholder of Panacos will receive a fixed number of shares of VITEX common stock in exchange for their Panacos common stock and preferred stock in the merger. However, because VITEX common stock is publicly traded, the value of a share of VITEX common stock may change on a daily basis. Therefore, the value of the shares of VITEX common stock each Panacos stockholder is to receive in the merger may decline from the value as of the date of the joint proxy statement – prospectus for the special meeting of stockholders scheduled for March 10, 2005.

### **VITEX's and Panacos' directors and executive officers have interests that are or in addition to those of other shareholders, which may influence them to support the merger.**

The directors and executive officers of VITEX and Panacos participate in arrangements that provide them with interests in the merger that are in addition to those of other shareholders. For example, VITEX has agreed that, as of the closing of the merger, it will cause Dr. Ackerman, the Chairman of the Board and Interim Chief Executive Officer of Panacos and the Chairman of the Board of VITEX, to become the Chief Executive Officer of the surviving company. VITEX has also agreed that Dr. Herbert H. Hooper, a General Partner of Ampersand and a current director of Panacos, and Mr. Eric W. Linsley, a Partner with A.M. Pappas and also a current director of Panacos, will be appointed to the surviving company's Board of Directors. Further, as a result of the merger, options to purchase an aggregate of 1,922,644 shares of Panacos common stock that are held by officers and directors of Panacos will immediately vest. The exercise prices of these options range from \$0.112 to \$0.38 per share of Panacos common stock, with a weighted average exercise price of approximately \$0.15 per share. In accordance with the terms of the merger agreement, these options will convert into options to purchase an aggregate of 12,987,921 shares of VITEX common stock and will have exercise prices ranging from \$0.017 to \$0.056 per share, with a weighted average exercise price of \$0.022 per share, immediately following the consummation of the merger. As a result, you should consider whether these directors and executive officers could be more likely to support approval of the merger than if they did not hold these interests.

### **VITEX has been notified by Nasdaq that it is not in compliance with continued listing standards, which may result in a delisting of the common stock if VITEX cannot regain compliance.**

On September 2, 2004, VITEX reported that it had received a notice from the Nasdaq Stock Market, Inc. that the bid price of its common stock had closed below \$1.00 per share for the previous 30 consecutive trading days and that, in accordance with Nasdaq rules, VITEX would be provided 180 calendar days to regain compliance with the minimum bid price requirement under the rules for continued listing. VITEX has until February 28, 2005 to regain compliance with the minimum bid price requirement. In the event that at any time before February 28, 2005, the bid price of VITEX common stock closes at \$1.00 per share or more for a minimum of 10 consecutive trading days, Nasdaq staff will notify VITEX that it has achieved compliance with the rule. However, VITEX cannot assure you that it will be able to achieve compliance with this requirement. In addition, on November 10, 2004, VITEX reported that it had received a notice from the Nasdaq Stock Market, Inc. that its stockholders' equity as of September 25, 2004 had fallen below the Nasdaq requirement for continued listing of \$10.0 million. VITEX's stockholders' equity as of December 31, 2004 was \$2.4 million. Nasdaq noted that it is reviewing VITEX's eligibility for continued listing on The Nasdaq National Market and, to facilitate this review, requested

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that VITEX provide Nasdaq with its plan to achieve and sustain compliance with all listing requirements. VITEX submitted its plan to regain compliance on November 19, 2004. As a condition to the closing of the financing with Great Point Partners, LLC, VITEX has agreed, subject to stockholder approval, to effect a reverse stock split generally on the terms described in the joint proxy statement – prospectus for its special meetings of stockholders scheduled for March 10, 2005. VITEX anticipates that the reverse split will result in the per share price of VITEX common stock exceeding \$1.00 per share immediately following the split, but there can be no assurance that the price will close above \$1.00 per share for the time required to be in compliance with the Nasdaq stock price requirement. On December 9, 2004, Nasdaq notified VITEX that, on the basis of the plan submitted on November 19, 2004, it was granting VITEX an extension of time until February 17, 2005 to regain compliance with the stockholders' equity requirement for continued listing, and until February 28, 2004 to regain compliance with the stock price requirement. On February 18, 2005, VITEX received from Nasdaq a notice of extension of the deadline for reaching compliance with the minimum stockholders' equity requirement until March 15, 2005. VITEX believes that the merger and financing transactions will be sufficient to meet that requirement. We have requested an extension of the deadline until March 31, 2005 to achieve compliance with the minimum bid price requirement from Nasdaq in order to allow us to complete the merger and financing, although there can be no assurance that Nasdaq will grant our request.

### **Following the merger, the combined company may be required to qualify for listing on Nasdaq under Nasdaq's initial listing criteria, and we cannot assure you that Nasdaq will accept the combined company's application.**

Under applicable Nasdaq listing requirements, as a result of the ownership structure of the combined company after the merger, the combined company may be required to apply for listing to Nasdaq under Nasdaq's initial listing criteria. Under Nasdaq rules governing reverse mergers, under certain circumstances, a surviving company resulting from the merger of a private company and a Nasdaq-listed public company may be required to apply for a new listing if Nasdaq determines that the combination results in a change in control of the listed company. Factors that Nasdaq will consider when determining whether a combination results in a change in control of the listed company include changes in management, board of directors, voting power, ownership and financial structure of the listed company as well as the similarity in the nature of the businesses of the combining companies and the relative size of the listed company and the private company. Following the closing of the merger, and without giving effect to any financing, Panacos shareholders will own approximately 80.6% of the combined company, which alone could lead Nasdaq to conclude that VITEX has undergone a change in control. While VITEX currently believes that, following the merger, the combined company will qualify for initial listing under those criteria, it cannot assure you that Nasdaq will accept the combined company's listing. If VITEX were required to apply for initial listing of its securities on the Nasdaq National Market as of February 11, 2005, it would not meet the minimum bid price per share requirement for initial listings of \$5.00. If Nasdaq did not accept the listing application, the combined company would be required to apply for listing of its common stock on another market, which could have an adverse effect on the trading volume and liquidity of the common stock.

### ***Risks Relating to VITEX and Panacos as a Combined Company***

#### **VITEX and Panacos have historically incurred operating losses and these losses will continue after the merger.**

VITEX and Panacos have each historically incurred substantial operating losses due to their research and development activities and expect these losses to continue after the merger for the foreseeable future. As of December 31, 2004, VITEX and Panacos had an accumulated deficit of approximately \$169.3 million and \$25.1 million, respectively. VITEX's fiscal year 2002, 2003 and 2004 net losses were \$20.0 million, \$22.4 million, and \$18.2 million, respectively. Panacos' fiscal year 2002, 2003 and 2004 net losses were \$4.5 million, \$4.5 million, and \$12.0 million, respectively. VITEX's fiscal year 2002, 2003 and 2004 operating losses were \$20.4 million, \$22.1 million, and \$18.1 million, respectively. Panacos' fiscal year 2002, 2003 and 2004 operating losses were \$4.5 million, \$4.3 million and \$12.0 million, respectively. VITEX currently expects to continue research and development activities. The combined company will expend significant amounts on the research and

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development programs previously undertaken by Panacos, including those relating to PA-457. The INACTINE™ red blood cell Phase III clinical trial program for acute indications, though enrollment is currently suspended, and the PA-457 clinical trial program are being conducted in various geographic locations, and clinical studies may occur in other geographic markets. In addition, prior to the end of 2005, PA-457 is expected to progress to late stage Phase II trials. In parallel to the clinical development activities, the combined company would increase expenditures for pre-commercial activities, such as planning for, and preliminary investments in, the scale-up of manufacturing of the drug, and marketing and distribution of the drug both in the U.S. and internationally. The combined company would also plan to evaluate marketing partnerships for distribution as well as to fund a portion of the late stage clinical development of the drug. These activities will take time and expense, both to identify the best partners and reach agreement on terms, and to negotiate and sign definitive agreements. VITEX will actively seek new financing from time to time to provide financial support for new activities. However, at this time VITEX is not able to assess the probability of success in its fundraising efforts or the terms, if any, under which it may secure financial support from strategic partners. It is expected that VITEX will continue to incur operating losses for the foreseeable future.

### **The combined company will need additional capital in the future, but its access to such capital is uncertain.**

VITEX's current resources are insufficient to fund all of its and, following the merger, the combined company's, commercialization efforts. As of February 28, 2005, VITEX had cash on hand of approximately \$1.0 million, and Panacos had cash on hand of approximately \$3.2 million. As described elsewhere in this Proxy Statement-Prospectus, VITEX has recently entered into definitive agreements with respect to \$20 million in financing, the closing of which is to occur upon closing of the merger. At present, after its recent restructuring, VITEX is consuming approximately \$1.0 million in cash per month and expects this spending rate to continue into early 2005. Following the merger, the combined company expects to spend approximately \$2.6 million on average in cash per month in 2005. VITEX believes that its present cash resources will be adequate to meet its requirements through the first quarter of 2005. VITEX's capital needs beyond fiscal 2004 will depend on many factors, including its research and development activities, the scope of its clinical trial program, the completion of the merger with Panacos, the timing of regulatory approval for its products under development and the successful commercialization of its products. VITEX's needs may also depend on the magnitude and scope of these activities, the progress and the level of success in its clinical trials, the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in or terminations of existing collaboration and licensing arrangements, the establishment of collaboration and licensing arrangements and the cost of manufacturing scale-up and development of marketing activities, if undertaken by the combined company. Other than the financing described in this document which is contingent on the merger, VITEX does not have committed external sources of funding. Should the merger not close, VITEX may not be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, the combined company may be required to:

- delay, reduce the scope of or eliminate one or more of its development programs;
- obtain funds through arrangements with collaboration partners or others that may require it to relinquish rights to technologies, product candidates or products that it would otherwise seek to develop or commercialize itself;
- license rights to technologies, product candidates or products on terms that are less favorable to it than might otherwise be available; or
- seek a buyer for all or a portion of its business, or wind down its operations and liquidate its assets.

If VITEX raises additional funds by issuing additional stock, further dilution to its stockholders may result, and new investors could have rights superior to existing stockholders. If funding is insufficient at any time in the future, VITEX may be unable to develop or commercialize its products, take advantage of business opportunities or respond to competitive pressures.

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### **VITEX's ability to continue as a going concern is dependent on future financing.**

KPMG LLP, VITEX's independent registered public accounting firm, has included an explanatory paragraph in their report on VITEX's consolidated financial statements for the fiscal year ended December 31, 2004, which highlights that current cash balances are insufficient to support operations until the end of 2005, thereby raising substantial doubt about the Company's ability to continue as a going concern. Ernst & Young LLP, Panacos' independent registered public accounting firm, is also expected to include a similar explanatory paragraph in their report on Panacos' financial statements for the year ended December 31, 2004. The inclusion of a going concern explanatory paragraph in KPMG LLP's report on the consolidated financial statements of VITEX and in Ernst & Young LLP's report on the financial statements of Panacos could have a detrimental effect on VITEX's stock price, the proposed rights offering and ability to raise additional capital.

VITEX's consolidated financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. VITEX has not made any adjustments to the consolidated financial statements as a result of the outcome of the uncertainty described above.

### **The success of the combined company will depend on the products and systems which it is and will be developing, including the INACTINE™ system, but may be unable to commercialize due to numerous factors, including regulatory requirements on both the combined company and its customers.**

The success of the combined company's business will depend on its successful development and commercialization of its products and systems, including products based on the INACTINE™ system. Successful commercialization of the combined company's products and systems under development depends, in significant part, on its ability to:

- complete their development in a timely fashion;
- demonstrate their safety and efficacy in clinical trials;
- obtain and maintain patents or other proprietary protections;
- obtain required regulatory approvals;
- implement efficient, commercial-scale manufacturing processes;
- obtain approval for reimbursement under health care systems; and
- establish and maintain development, sales, marketing, and distribution collaborations.

VITEX's pathogen inactivation system for red blood cells is currently the only product being developed by VITEX, and together with Panacos' product candidate PA-457, will be the only two clinical stage products of the combined company when the merger closes. The INACTINE™ system is under development and has not been approved by the Food and Drug Administration for marketing in the United States or by regulatory authorities in other countries. The process of obtaining regulatory approvals is generally lengthy, expensive and uncertain. Satisfaction of pre-market approval or other regulatory requirements of the FDA, or similar requirements of non-United States regulatory agencies, typically takes several years, depending upon the type, complexity, novelty and intended purpose of the product. The regulatory process includes pre-clinical (animal) studies and clinical (human) trials of each product to establish its safety and efficacy. During fiscal years 2004, 2003 and 2002, VITEX spent approximately \$13.3 million, \$18.5 million and \$20.4 million on research and development, respectively.

The combined company must provide the FDA and foreign regulatory authorities with pre-clinical and clinical data that demonstrate its products are safe and effective before they can be approved for commercial sale. In November 2004, VITEX suspended enrollment in its Phase III surgical, or acute, study for its lead product candidate, the INACTINE™ red cell system, following identification of an immune response to INACTINE™-treated red cells in one patient during ongoing immunologic testing of subjects enrolled in the trial. As a result, both the Phase III trial of INACTINE™ for acute indications and the Phase III trial of INACTINE™ for chronic

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indications, described in more detail below, have been halted, in the case of the chronic trial, following a clinical hold by the FDA. Although no clinical consequences of the immune response were apparent based on review of available data, additional patients will not be enrolled in the acute trial pending full evaluation. VITEX has notified the FDA that it has voluntarily suspended enrollment in the study and it intends to continue discussions with FDA regarding the conditions, if any, under which the trial might be continued while VITEX is completing its review of all relevant data. VITEX intends to conduct these discussions as part of an ongoing dialogue with the FDA regarding conditions for licensure of the INACTINE™ system.

VITEX's Phase III chronic study of INACTINE™ red cells was placed on clinical hold by the FDA due to the availability of insufficient safety information, and was subsequently halted by VITEX following a review by an independent data safety monitoring committee, or DSMC, in November 2003. The halting of the study by VITEX was due to antibody formation in sickle cell anemia patients receiving repeat transfusions of INACTINE™-treated red cells. The Phase III trial of INACTINE™ for chronic indications was designed to be conducted in two sequential parts, Part A and Part B. The purpose of Part A was to allow assessment of the safety of INACTINE™-treated red cells in the patient population under study prior to proceeding to Part B. Enrollment in the chronic trial was stopped prior to initiation of Part B on the recommendation in November 2003 of the DSMC, which was charged with reviewing the data from Part A of the study, following the FDA's clinical hold on the trial due to availability of insufficient safety information.

Prior to the suspension of the surgical trial, the FDA had expressed concerns regarding the licensing of the current INACTINE™ system for an acute indication in light of the presence of antibodies observed in the chronic trial, and had requested justification from the Company for pursuit of an acute-only indication in the context of these findings. The FDA had also indicated that a control system with respect to an acute-only indication would be required to ensure that patients who have previously received red cells treated by the current INACTINE™ system do not receive INACTINE™ red cells in subsequent hospitalizations. VITEX has met with the FDA and presented proposals on supplemental clinical trials. However, the FDA has indicated that it will require the review of additional data, including the results of the Phase III trial for INACTINE™ in acute indications, before fully responding to VITEX's proposals for additional clinical trials. The occurrence of an immune response in the acute trial and the decision to suspend enrollment in it will require VITEX to formulate and present to the FDA a regulatory plan for approval of INACTINE™ that takes into account all findings to date, which is likely to significantly delay determination of any acceptable regulatory pathway. The FDA has indicated that any such regulatory plan for the acute-only indication must address the development of a control system, as described above. In addition, VITEX believes that modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells will also be required. At this time, VITEX cannot determine the length of time required for it to develop such a regulatory plan, nor can VITEX estimate the length of time required for the FDA to approve such a plan, or whether such a plan will be approved at all. Enrollment in the acute trial will continue to be suspended until such time as a regulatory plan is approved by the FDA and implemented by VITEX, if ever. VITEX has begun preclinical testing on the modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells. However, this work is preliminary and no assurance can be given that VITEX will be able to develop an INACTINE™ process that will be technically feasible, approved by the FDA, and economically viable, or that the modifications to the current INACTINE™ process will succeed in reducing the likelihood of an immunologic response. Prior to the suspension of enrollment in the acute study, the FDA also directed VITEX to implement additional patient safety monitoring procedures in the now-suspended Phase III acute trial. VITEX implemented these procedures and, until accrual into the trial was suspended, was periodically updating the FDA on the trial data. While VITEX believes that the steps taken addressed the FDA recommendations prior to suspension of enrollment in the acute trial, further steps could be required by the FDA. VITEX also received from the FDA a written request for further information relating to an August 2004 amendment to its IND. The amendment included responses to questions raised by the FDA relating to procedures for patient safety monitoring used in the Phase III chronic study, which had been placed on clinical hold by the FDA due to the availability of insufficient safety information, and subsequently halted by VITEX following a DSMC review. VITEX has responded to the FDA's request and is awaiting further communications from the agency on this matter.

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With the Phase III trial for INACTINE™ in chronic indications halted by VITEX, following the clinical hold by the FDA and the subsequent review by the DSMC, and enrollment suspended in the Phase III trial for INACTINE™ in acute indications, VITEX's ongoing development plan for INACTINE™ for chronic, acute or other indications is highly uncertain. VITEX cannot ensure that the acute trial will resume or complete enrollment in a timely manner, if ever. The exact nature, timing and estimated costs of the efforts necessary to bring to market the product resulting from VITEX's pathogen inactivation research and development projects involve a number of key variables which are either unpredictable or outside VITEX's control, including whether the likelihood of an immune response to INACTINE™-treated red cells can be adequately reduced, whether, and under what circumstances, the FDA will agree with a plan by VITEX to proceed with clinical trials, the enrollment rates and results of the Phase III clinical trial, should it be continued, the extent of further studies which could be required for filing a Biologics License Application with the FDA, the length of the FDA and foreign regulatory approval processes, the success of VITEX's fundraising efforts, its ability to establish and maintain relationships with marketing partners and strategic collaborators, and the timing of commencement of commercialization of its product. Inability to satisfy one or more of these conditions, or to do so in a commercially acceptable manner, may render continued development of the INACTINE™ system infeasible.

Delays in the combined company's clinical testing or approval from government authorities will increase its product development costs and may impair its ability to commercialize its products and allow competitors to bring products to market before the combined company does. VITEX's clinical development plan for cellular products, including INACTINE™, assumes that only data from laboratory studies, not from human clinical trials, will be required to demonstrate efficacy in reducing pathogens and that clinical trials for these products will instead focus on demonstrating therapeutic efficacy, safety and tolerability of treated blood components. Although VITEX has held discussions with the FDA concerning the proposed clinical plan for these products, this plan of demonstrating safety and efficacy may not ultimately be acceptable to the FDA or the FDA may reconsider any decision that this clinical plan is appropriate.

Even if the combined company's products receive approval for commercial sale, their manufacture, storage, marketing and distribution are and will be subject to extensive and continuing regulation in the United States by the federal government, especially the FDA, and state and local governments. The failure to comply with these regulatory requirements could result in enforcement action, including, without limitation, withdrawal of approval, which would harm the combined company's business. Later discovery of problems with the combined company's products may result in additional restriction on the product, including withdrawal of the product from the market. Regulatory authorities may also require post-marketing testing, which can involve significant expenses. Additionally, governments may impose new regulations, which could further delay or preclude regulatory approval of the combined company's products or result in significantly increased compliance costs.

In similar fashion to the FDA, foreign regulatory authorities require demonstration of product quality, safety and efficacy prior to granting authorization for product registration which allows for distribution of the product for commercial sale. International organizations, such as the World Health Organization, and foreign government agencies including those for the Americas, Middle East, Europe, and Asia and the Pacific, have laws, regulations and guidelines for reporting and evaluating the data on safety, quality and efficacy of new drug products. Although most of these laws, regulations and guidelines are very similar, each of the individual nations reviews all of the information available on the new drug product and makes an independent determination for product registration.

In addition to the regulatory requirements applicable to the combined company and its products and systems, there are regulatory requirements applicable to its prospective customers for the INACTINE™ system, which are the blood banks that process and distribute both blood and blood products. Blood banks, such as the American Red Cross and the New York Blood Center, will be required to obtain approved license supplements from the FDA before using products processed with VITEX pathogen reduction systems. FDA delays in approving these supplements may deter some blood centers from using VITEX products. In addition, blood centers that do submit supplements may face disapproval or delays in approval that could in turn cause further delay or deter them from using VITEX products.

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**The success of the combined company will also depend on the antiviral therapeutics being developed, including PA-457, and we cannot assure you that the efforts to commercialize PA-457, which is still in early-stage clinical trials, will succeed.**

Together with the INACTINE™ system, PA-457 will be the only clinical stage product to be developed by VITEX following the completion of the merger.

PA-457 and the other compounds being developed by VITEX are still in early stage clinical trials and involve a high degree of development, technical, regulatory and other risks. The results from pre-clinical studies and early clinical trials conducted by Panacos prior to the merger do not ensure that results obtained in later stage clinical studies of PA-457 will be satisfactory to the FDA or foreign regulatory authorities. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Completion of clinical trials may also be delayed by slower than anticipated patient enrollment, negative or inconclusive clinical results or other adverse circumstances occurring during the clinical trials. Therefore, the combined company cannot ensure that clinical trials will demonstrate sufficient safety and efficacy to obtain required marketing approvals on a timely basis, if at all.

Positive results from preclinical studies or early clinical trials should not be relied upon as evidence that later or larger-scale clinical trials will succeed. Initial clinical trials of PA-457 have been conducted only in small numbers of patients that may not fully represent the diversity present in larger populations infected with HIV or the results of long-term drug administration, and thus the limited results Panacos has obtained prior to the merger may not predict results from more prolonged studies in larger numbers of patients drawn from more diverse populations. These initial trials are not designed to assess the long-term efficacy of PA-457. VITEX will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before it can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. If PA-457 or any other product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, the combined company would experience potentially significant delays in, or be required to abandon, development of that product candidate. If the combined company delays or abandons its development efforts related to PA-457, it may not be able to generate sufficient revenues to become profitable, and its reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause the stock price to decrease significantly.

**If the combined company fails to establish relationships with strategic collaborators and distributors, it may be unable to market its products.**

The combined company intends to enlist strategic collaborators for sales, marketing and distribution support and for financial support in the development of its products. The combined company will require marketing and distribution partners for the commercialization of its products. If the combined company fails to develop new strategic partnerships for these purposes, the failure could delay or possibly inhibit the commercialization of its products.

For example, in order to effectively market its products outside the United States, the combined company may need to secure foreign marketing partners who have a strong presence in such foreign markets. Securing new corporate collaborators is a time-consuming process, and VITEX cannot guarantee that the negotiations with new collaborators will yield positive results. Even if it finds additional corporate collaborators to assist in the commercialization of existing or new product candidates, the terms of the arrangements may not be favorable or acceptable to the combined company.

**A small number of customers will determine market acceptance of some of VITEX's products.**

A defined number of blood collection services will dominate any market for the INACTINE™ system. In the United States, the American Red Cross and the America's Blood Centers collect and distribute the vast majority of the nation's supply of blood and blood components. Major United States blood centers include the New York Blood Center and the United Blood Services, which together distributes approximately 9 percent of the nation's

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supply of blood and blood components. In Europe and Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. Failure to properly market, price or sell VITEX products to any of these large customers could significantly diminish the combined company's potential product revenue.

### **VITEX relies on a limited number of suppliers to manufacture its inactivation compound and other components of its INACTINE™ system for red cells.**

VITEX's INACTINE™ system uses a small molecule compound known as PEN110 to inactivate pathogens. VITEX has a contract with one manufacturer for PEN110 and will seek to qualify additional manufacturers to produce this compound to meet its anticipated commercialization requirements. If any of these additional manufacturers, which have not yet been identified, or its existing manufacturer cannot produce and deliver this compound in the required quantities, to the required standards, or in a timely manner, the combined company may face delays in the commercialization of the INACTINE™ system before it is able to identify alternate or additional manufacturers to meet these requirements.

The procedure for inactivating pathogens using the INACTINE™ system requires the use of an automated INACTINE™ system to deliver the compound into the red cell unit and a cell washing system to remove PEN110, plasma proteins and other impurities. VITEX worked with an engineering firm to develop the automated delivery system which is now being qualified for use in its clinical trials. This system and related system disposables could be manufactured by several suppliers and VITEX has not yet entered commercial supply agreements.

VITEX is currently using a cell washing system manufactured by Haemonetics, which it exclusively licenses from Haemonetics pursuant to a development and manufacturing agreement. When and if VITEX's INACTINE™ system is commercialized, Haemonetics will provide contract manufacturing services for the cell washing equipment and associated disposables. If Haemonetics fails to deliver an adequate supply of the cell washing systems and disposables, the combined company would be required to identify other third-party manufacturers.

VITEX may not be able to identify manufacturers for the delivery system and disposables or to replace Haemonetics for the wash system and disposables on a timely basis or enter into contracts with such manufacturers on reasonable terms, if at all. Any delay in the availability of these systems and disposables could delay commercialization and subsequent sales of the INACTINE™ system. Furthermore, the inclusion of delivery and cell washing systems by new manufacturers could require the combined company to seek new approvals from governmental regulatory authorities, which could result in delays in product delivery. VITEX may not be able to receive any such required regulatory approvals.

### **If the combined company does not successfully distinguish and commercialize its technology, it may be unable to compete successfully or to generate revenue significant to sustain its operations.**

The biotechnology industry, including the fields of transfusion medicine, therapeutic use of blood products, and therapeutic products to treat HIV and serious infections, is highly competitive and subject to significant and rapid technological change. Accordingly, VITEX's success will depend, in part, on its ability to respond quickly to such change through the development and introduction of new products and systems.

Many of the combined company's competitors or potential competitors have substantially greater financial and other resources than VITEX has and may also have for the viral inactivation of red cells, greater experience in conducting pre-clinical studies, clinical trials and other regulatory approval procedures as well as in marketing their products. Major competitors in the market for HIV drugs include large, publicly-traded pharmaceutical companies, such as GlaxoSmithKline, Bristol Myers Squibb, Pfizer, Roche, Johnson & Johnson, and Gilead, development stage public companies, such as Incyte and Vertex, and private development stage companies, such as Pharmasset. Major competitors in the market for pathogen inactivation systems include Baxter Healthcare, Gambro BCT, and Cerus. If VITEX or its corporate partners commence commercial product sales, VITEX or its corporate partners will be competing against companies with greater marketing and manufacturing capabilities.

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VITEX's ability to compete successfully against currently existing and future alternatives to its product candidates and systems, and competitors who compete directly with it in the pathogen reduction industry will depend, in part, on its ability to:

- attract and retain skilled scientific and research personnel;
- develop technologically superior products;
- develop competitively priced products;
- obtain patent or other required regulatory approvals for the combined company's products;
- be early entrants to the market; and
- manufacture, market and sell its products, independently or through collaborations.

### **Third-party reimbursement policies may adversely affect the combined company's ability to commercialize and sell its products and services.**

The combined company's ability to successfully commercialize its products depends in part on the extent to which appropriate levels of reimbursement for its products and related treatments are obtained from government authorities, private health insurers, third party payers, and other organizations, such as managed care organizations, or MCOs. Any failure by doctors, hospitals and other users of the combined company's products or systems to obtain appropriate levels of reimbursement could adversely affect the combined company's ability to sell these products and systems.

Federal legislation, enacted in December 2003, has altered the way in which physician-administered drug programs covered by Medicare are reimbursed, generally leading to lower reimbursement levels. The new legislation has also added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, the United States Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations may increase pressures to lower prices. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. While the new law specifically prohibits the United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit de facto price controls on prescription drugs. In addition, the law triggers, for congressional consideration, cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. This legislation could adversely impact the combined company's ability to commercialize any of its products successfully.

Significant uncertainty exists about the reimbursement status of newly approved medical products and services. Reimbursement in the United States or foreign countries may not be available for any of the combined company's products, reimbursement granted may not be maintained, and limits on reimbursement available from third-party payers may reduce the demand for, or negatively affect the price of, the combined company's products. VITEX anticipates that it will need to work with a variety of organizations to lobby government agencies for improved reimbursement policies for its products. However, VITEX cannot guarantee that such lobbying efforts will take place or that they will ultimately be successful.

### **If the combined company is unable to protect its intellectual property, it may not be able to operate its business profitably.**

VITEX's success following the merger will depend on its ability to develop proprietary products and technologies, to obtain and maintain patents, to protect trade secrets, and to prevent others from infringing on its proprietary rights. VITEX has exclusive patents, licenses to patents or patent applications covering critical components of its technologies as well as certain jointly owned patents. VITEX also seeks to protect its proprietary technology and processes, in part, by confidentiality agreements with its employees and certain

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contractors. Patents, pending patent applications and licensed technologies may not afford adequate protection against competitors, and any pending patent applications now or hereafter filed by or licensed to VITEX may not result in patents being issued. In addition, certain of VITEX's technology relies on patented inventions developed using university resources. Universities may have certain rights, as defined by law or applicable agreements, in such patents, and may choose to exercise such rights. Under the terms of a license agreement between Panacos and the University of North Carolina, Panacos (VITEX following the merger) is an exclusive licensee to certain technology, including patents and patent applications, that relate to the company's product candidates, including PA-457. This license agreement imposes various commercialization, sublicensing, royalty and other obligations on us. If we fail to comply with these and other requirements, our license could convert from exclusive to non-exclusive or terminate entirely. Currently, Panacos (VITEX following the merger) is in compliance with the terms of the license agreement, and we do not have any reason to believe that the license may be terminated. VITEX cannot be certain that their confidentiality agreements will not be breached, that they will have adequate remedies for any breach, or that their trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that employees, consultants or contractors of the combined company use intellectual property owned by others, disputes may arise as to the rights related to or resulting from the know-how and inventions. In addition, the laws of certain non-United States countries do not protect intellectual property rights to the same extent as do the laws of the United States. Medical technology patents involve complex legal and factual questions and, therefore, VITEX cannot predict with certainty their enforceability.

The combined company is a party to various license agreements that give it exclusive rights to use specified technologies applicable to research, development and commercialization of its products, including PA-457. The agreements pursuant to which such technology is used permit the licensors to terminate agreements in the event that certain conditions are not met. If these conditions are not met and the agreements are terminated, the combined company's product development, research and commercialization efforts may be altered or delayed.

Patents or patent applications, if issued, may be challenged, invalidated or circumvented, or may not provide protection or competitive advantages against competitors with similar technology. Furthermore, competitors of the combined company may obtain patent protection or other intellectual property rights for technology similar to the combined company's that could limit its ability to use its technology or commercialize products that it may develop.

Litigation may be necessary to assert claims of infringement, to enforce patents issued to VITEX, to protect trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation or interference proceedings could result in substantial additional costs and diversion of management focus. If VITEX is ultimately unable to protect its technology, trade secrets or know-how, it may be unable to operate profitably. Although neither VITEX nor Panacos has been involved with any threats of litigation or negotiations regarding patent issues or other intellectual property, or other related court challenges or legal actions, it is possible that the combined company could be involved with such matters in the future.

**If the combined company is unable to operate its business without infringing upon intellectual property rights of others, it may not be able to operate its business profitably.**

The combined company's success depends on its ability to operate without infringing upon the proprietary rights of others. VITEX is aware that patents have been applied for and/or issued to third parties claiming technologies for decontamination of blood and blood products that may be similar to those needed by VITEX. VITEX endeavors to follow developments in these fields and it does not believe that its technologies and/or products infringe upon any proprietary rights of third parties. To the extent that planned or potential products turn out to be covered by patents or other intellectual property rights held by third parties, the combined company would need a license under such patents or other intellectual property rights to continue development and marketing of its products. Any required licenses may not be available on acceptable terms, if at all. If the combined company does not obtain such licenses, it may need to design around other parties' patents or it may not be able to proceed with the development, manufacture or sale of its products.

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Litigation may be necessary to defend against claims of infringement or to determine the scope and validity of the proprietary rights of others. Litigation or interference proceedings could result in substantial additional costs and diversion of management focus. If the combined company is ultimately unsuccessful in defending against claims of infringement, it may be unable to operate profitably.

### **If VITEX loses or is unable to hire and retain qualified personnel, it may not be able to develop its products and technology.**

VITEX is highly dependent on the members of its scientific and management staff. In particular, the combined company will depend on Dr. Samuel K. Ackerman, the Chairman of the Board and Chief Executive Officer. VITEX and Panacos do not have employment contracts with any key personnel. Although VITEX believes it has been successful in attracting and retaining its employees, it may not be able to attract and retain personnel on acceptable terms, if at all, given the competition for such personnel among other companies and research and academic institutions. If the combined company loses an executive officer or certain key members of its clinical or research and development staff or is unable to hire and retain qualified personnel, then its ability to develop and commercialize its products and technology may be hindered. VITEX has not purchased any key-man life insurance.

### **VITEX uses and generates hazardous materials in its research activities. Defending against any claims relating to the improper handling, storage, release or disposal of these materials could be time consuming and costly.**

VITEX is subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. It is possible that the combined company will be required in the future to incur significant costs to comply with environmental and health and safety regulations. The research and development activities to be undertaken by VITEX involve the use of hazardous materials, including chemicals that may cause cancer, volatile solvents, and biological materials, including materials infected with various viruses, including Human Immunodeficiency Virus, Human T-Cell Lyphotropic Virus, and Simian Immunodeficiency Virus. In addition, the operations of VITEX produce, and will continue to produce after the consummation of the merger, hazardous waste products. Although VITEX believes that its safety procedures for handling and disposing of such materials comply with the standard prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, VITEX could be held liable for any damages that result, and any such liability could exceed its insurance limits and its cash resources. VITEX has general liability insurance that covers its use of hazardous materials and chemicals. Neither VITEX nor Panacos has been notified that it has been the subject of any investigations relating to the generation of hazardous materials in the past.

### **The combined company may face exposure to product liability claims.**

VITEX may face exposure to product liability and other claims due to allegations that its products cause harm. These risks are inherent in the suspended Phase III clinical trials relating to the INACTINE™ system and the ongoing Phase II clinical trials relating to PA-457 and in the testing, and future manufacturing and marketing of the combined company's products. Although VITEX currently maintains product liability insurance, such insurance may not be adequate and the combined company may not be able to obtain adequate insurance coverage in the future at a reasonable cost, if at all. If the combined company is unable to obtain product liability insurance in the future at an acceptable cost or to otherwise protect against potential product liability claims, it could be inhibited in the commercialization of its products which could have a material adverse effect on its business. VITEX and Panacos currently have policies covering \$10 million of product liability for their respective clinical trials. Neither VITEX nor Panacos currently has sales of any products. The level of product liability insurance coverage and the associated cost of that insurance for the combined company will be determined following the merger. The coverage will be maintained and limits reviewed from time to time as the VITEX clinical programs progress to later stages of its clinical trials and as the length of the trials and the

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number of patients enrolled in the trials changes. VITEX intends to obtain a combined coverage policy that includes tail coverage in order to cover any claims that are made for any events that have occurred prior to the merger. Currently, each company's annual premium for product liability insurance is approximately \$110,000 – \$120,000.

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our earnings and cash flows are subject to fluctuations due to the effects of changes in interest rates on our investments of available cash balances in money market funds. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes.

**Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The consolidated financial statements and schedules required under Item 8 are set forth under Item 15 and are hereby incorporated by reference.

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**Item 9A. CONTROLS AND PROCEDURES**

(a) Evaluation of Disclosure Controls and Procedures. Our principal executive officer and acting principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, has concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that material information relating to us, including our consolidated subsidiary, was made known to him by others within those entities, particularly during the period in which this Annual Report on Form 10-K was being prepared.

(b) Changes in Internal Controls. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

Not applicable.

**PART III**

**Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Incorporated by reference from the portions of the Definitive Proxy Statement for our 2005 Annual Meeting of Stockholders entitled “Proposal 1 – Election of Directors”, “Additional Information”, “Section 16(a) Beneficial Ownership Reporting Compliance”, and “Code of Conduct and Ethics.”

**Item 11. EXECUTIVE COMPENSATION**

Incorporated by reference from the portions of the Definitive Proxy Statement for our 2005 Annual Meeting of Stockholders entitled “Executive Compensation” and “Additional Information – Compensation of Directors.”

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

Incorporated by reference from the portions of the Definitive Proxy Statement for our 2005 Annual Meeting of Stockholders entitled “Security Ownership by Management and Principal Stockholders” and “Equity Compensation Plan Information.”

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Incorporated by reference from the portion of the Definitive Proxy Statement for our 2005 Annual Meeting of Stockholders entitled “Certain Relationships and Related Transactions.”

**Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Incorporated by reference from the portion of the Definitive Proxy Statement for our 2005 Annual Meeting of Stockholders entitled “Independent Registered Public Accounting Firm.”

**Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

*(a) Consolidated Financial Statements*

<a href="#">Report of Independent Registered Public Accounting Firm</a>	Page 59
<a href="#">Consolidated Balance Sheets as of December 31, 2004 and December 27, 2003</a>	Page 60
<a href="#">Consolidated Statements of Operations for the years ended December 31, 2004, December 27, 2003 and December 28, 2002</a>	Page 61
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 31, 2004, December 27, 2003 and December 28, 2002</a>	Page 62
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2004, December 27, 2003 and December 28, 2002</a>	Page 63
<a href="#">Notes to Consolidated Financial Statements</a>	Page 64

Other information and consolidated financial statement schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto.

*(b) Exhibits*

The following exhibits are required to be filed with this Report by Item 15 and are incorporated by reference to the source cited in the Exhibit Index below or are filed herewith.

<b>Exhibit Number</b>	<b>Description</b>
2.1	Agreement and Plan of Merger dated as of June 2, 2004 among the Company, Panacos and certain stockholders of Panacos. Filed as Annex A to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference. Note: As permitted by Item 601(b)(2) of Regulation S-K, schedules and exhibits to this agreement have not been filed herewith. The Registrant will furnish supplementally a copy of any omitted schedule to the Commission upon request.
2.2	Amendment No. 1 to Agreement and Plan of Merger dated as of November 5, 2004 among the Company, Panacos and certain stockholders of Panacos. Filed as Annex B to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.
2.3	Amendment No. 2 to Agreement and Plan of Merger dated as of November 28, 2004 among the Company, Panacos and certain stockholders of Panacos. Filed as Annex C to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.
2.4	Amendment No. 3 to Agreement and Plan of Merger dated as of December 8, 2004 among the Company, Panacos and certain stockholders of Panacos. Filed as Annex D to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.
2.5	Amendment No. 4 to Agreement and Plan of Merger dated as of February 14, 2005 among the Company, Panacos and certain stockholders of Panacos. Filed as Annex E to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.

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<u>Exhibit Number</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of the Company. Filed as Exhibit 3.8 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
3.2	Certificate of Amendment of Restated Certificate of Incorporation, dated July 28, 2003. Filed as Exhibit 4.5 to the Registrant's Registration Statement on Form S-8 (Registration Statement No. 333-108733) and incorporated herein by reference.
3.3	Amended and Restated By-laws of the Company. Filed as Exhibit 3.10 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
4.1	Specimen of Common Stock Certificate. Filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
4.2	Form of Warrant dated December 5, 2003 issued to investors. Filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-3, as amended (Registration Statement No. 333-111186) and incorporated herein by reference.
4.3	Form of Warrant dated February 11, 2004 issued to investors (exercisable at \$1.75 per share). Filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-3, as amended (Registration Statement No. 333-113182) and incorporated herein by reference.
4.4	Form of Warrant dated February 11, 2004 issued to investors (exercisable at \$1.32 per share). Filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-3, as amended (Registration Statement No. 333-113182) and incorporated herein by reference.
4.5	Form of Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of December 9, 2004, by and between the Company and the Purchasers named therein. Filed as Annex G to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.
10.1*	1998 Equity Incentive Plan. Filed as Exhibit 99 to the Registrant's Registration Statement on Form S-8 (Registration Statement No. 333-108733) and incorporated herein by reference.
10.2*	1998 Director Stock Option Plan. Filed as Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (Registration Statement No. 333-75484) and incorporated herein by reference.
10.3*	1999 Supplemental Equity Compensation Plan. Filed as Annex G to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4 (No. 333-87443) and incorporated herein by reference.
10.4*	Amended and Restated 1998 Employee Stock Purchase Plan. Filed as Exhibit 99 to the Registrant's Registration Statement on Form S-8 (Registration Statement No. 333-108734) and incorporated herein by reference.
10.5*	Supplemental Equity Compensation Plan. Filed as Annex H to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.
10.6	Registration Rights Agreement between the Company and the Investors named therein, dated February 19, 1998. Filed as Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
10.7+	Stock Purchase Agreement between Pall Corporation and the Company, dated February 19, 1998. Filed as Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.

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<u>Exhibit Number</u>	<u>Description</u>
10.8+	Joint Development, Marketing and Distribution Agreement between the Company and Pall Corporation, dated February 19, 1998. Filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
10.9	Amendment No. 1 to the Joint Development, Marketing and Distribution Agreement between Pall Corporation and the Company, dated July 19, 1999. Filed as Exhibit 4.4 to the Registrant's 1999 Quarterly Report on Form 10-Q filed August 11, 1999 and incorporated herein by reference.
10.10++	Marketing Rights, Development, Royalty, Revolving Credit and Security Agreement between Pall Corporation and V.I. Technologies, Inc. dated August 6, 2002. Filed as Exhibit 10.42 to the Registrant's 2002 Quarterly Report on Form 10-Q filed August 13, 2002 and incorporated herein by reference.
10.11++	Amendment No. 1 dated August 6, 2002 to Stock Purchase Agreement dated February 19, 1998 by and between V.I. Technologies, Inc. and Pall Corporation. Filed as Exhibit 10.43 to the Registrant's Quarterly Report on Form 10-Q filed August 13, 2002 and incorporated herein by reference.
10.12	Letter Agreement with Pall Corporation dated December 10, 2002. Filed as Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed March 26, 2003 and incorporated herein by reference.
10.13	Letter Agreement with Pall Corporation dated January 17, 2003. Filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed March 26, 2003 and incorporated herein by reference.
10.14*	Letter Agreement between the Company and John R. Barr, dated November 10, 1997. Filed as Exhibit 10.27 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
10.15*	Form of Indemnification Agreement. Filed as Exhibit 10.33 to the Registrant's Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
10.16	Indenture of lease made and entered into as of August 4, 1999 by and between V.I. Technologies, Inc. ("Tenant") and Coolidge Partners, LLC ("Landlord"). Filed as Exhibit 10.1 to the Registrant's 2000 Quarterly Report on Form 10-Q filed May 4, 2000 and incorporated herein by reference.
10.17++	Development and Supply Agreement between V.I. Technologies, Inc. and Haemonetics Corporation dated January 25, 2000. Filed as Exhibit 10.41 to the Registrant's Quarterly Report on Form 10-Q filed November 13, 2001 and incorporated herein by reference.
10.18++	Asset Purchase Agreement, dated August 13, 2001, by and among V.I. Technologies, Inc. and Precision Pharma Services, Inc. Filed as Exhibit 2.1 to the Registrant's Form 8-K filed August 28, 2001 and incorporated herein by reference.
10.19++	Agreement with the American National Red Cross dated April 9, 2003. Filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed May 7, 2003 and incorporated herein by reference.
10.20	Agreement and Mutual Release between the Company and Precision Pharma Services, Inc. dated January 12, 2004. Filed as Exhibit 10.24 to the Registrant's Annual Report on Form 10-K filed March 1, 2004 and incorporated herein by reference.
10.21	Securities Purchase Agreement, dated as of December 9, 2004, by and between the Company and the Purchasers named therein. Filed as Annex G to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.
10.22	Registration Rights Agreement, dated as of December 9, 2004, by and between the Company and the Purchasers named therein. Filed as Annex G to the Joint Proxy Statement – Prospectus contained in the Registration Statement on Form S-4, as amended (Registration Statement No. 333-121416) and incorporated herein by reference.

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<u>Exhibit Number</u>	<u>Description</u>
14.1	VI. Technologies, Inc. Code of Business Conduct and Ethics. Filed as Exhibit 14.1 to the Registrant's Annual Report on Form 10-K filed March 26, 2003 and incorporated herein by reference.
21.1	List of Subsidiaries of the Registrant. Filed herewith.
23.1	Consent of KPMG LLP. Filed herewith.
31	Certification of Chief Executive Officer and Acting Chief Financial Officer under Section 302. Filed herewith.
32	Section 906 certification of periodic financial report by Chief Executive Officer and Acting Chief Financial Officer. Filed herewith.
*	Management contracts and compensatory plans or arrangements.
+	Certain confidential material contained in the document was omitted and filed separately with SEC pursuant to Rule 406 under the Securities Act of 1933, as amended.
++	Certain confidential material contained in the document was omitted and filed separately with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Certification of Chief Executive Officer

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**V.I. TECHNOLOGIES, INC.**

By: /s/ John R. Barr

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John R. Barr  
President and Chief Executive Officer  
March 2, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John R. Barr</u> John R. Barr	President, Chief Executive Officer and Director (Principal Executive Officer) and Acting Principal Financial Officer	March 2, 2005
<u>/s/ Samuel K. Ackerman, M.D.</u> Samuel K. Ackerman, M.D.	Chairman of the Board of Directors	March 2, 2005
<u>/s/ Richard A. Charpie</u> Richard A. Charpie	Director	March 2, 2005
<u>/s/ Jeremy Hayward-Surry</u> Jeremy Hayward-Surry	Director	March 2, 2005
<u>/s/ Irwin Lerner</u> Irwin Lerner	Director	March 2, 2005
<u>/s/ Joseph M. Limber</u> Joseph M. Limber	Director	March 2, 2005
<u>/s/ Doros Platika, M.D.</u> Doros Platika, M.D.	Director	March 2, 2005
<u>/s/ David Tendler</u> David Tendler	Director	March 2, 2005

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
V.I. Technologies, Inc.:

We have audited the accompanying consolidated balance sheets of V.I. Technologies, Inc. as of December 31, 2004 and December 27, 2003 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of V.I. Technologies, Inc. as of December 31, 2004 and December 31, 2003 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant recurring losses from operations, and its current cash balances as of December 31, 2004 are not sufficient to support its operations over the next year. Accordingly, this raises substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Boston, Massachusetts  
February 25, 2005

V. I. TECHNOLOGIES, INC.  
Consolidated Balance Sheets

	December 31, 2004	December 27, 2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,961,744	\$ 4,258,322
Restricted cash	250,000	169,238
Other receivables, net	151,105	4,176,496
Prepaid expenses and other current assets	798,903	637,946
	<u>4,161,752</u>	<u>9,242,002</u>
Property and equipment, net	2,957,954	3,496,466
Intangible asset, net	—	2,719,926
Goodwill	397,549	397,549
Restricted cash	420,750	420,750
Other assets, net	—	1,379,489
	<u>7,938,005</u>	<u>17,656,182</u>
<b>Total assets</b>	<b>\$ 7,938,005</b>	<b>\$ 17,656,182</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,748,264	\$ 915,370
Accrued expenses	1,345,812	723,381
Financed insurance costs	114,556	—
Current portion of deferred revenue	—	152,628
Current portion of advances	1,172,472	1,061,336
Current portion of lease incentive liability	32,337	32,337
	<u>4,413,441</u>	<u>2,885,052</u>
Total current liabilities	4,413,441	2,885,052
Long-term portion of advances	207,017	1,379,489
Long-term portion of lease incentive liability	312,595	344,933
Deferred rent expense	644,972	—
Deferred revenue	—	801,297
	<u>5,578,025</u>	<u>5,410,771</u>
<b>Total liabilities</b>	<b>5,578,025</b>	<b>5,410,771</b>
Stockholders' equity:		
Preferred stock, par value \$.01 per share; authorized 1,000,000 shares; no shares issued and outstanding	—	—
Common stock, par value \$.01 per share; authorized 75,000,000 shares; issued 58,837,494 shares and outstanding 54,455,141 shares at December 31, 2004 and issued and outstanding 45,929,875 at December 31, 2003	588,375	459,299
Additional paid-in-capital	174,899,241	163,433,235
Deferred compensation	(36,671)	(460,581)
Treasury stock, 4,382,353 shares, at cost	(3,742,591)	—
Accumulated deficit	(169,348,374)	(151,186,542)
	<u>2,359,980</u>	<u>12,245,411</u>
<b>Total stockholders' equity</b>	<b>2,359,980</b>	<b>12,245,411</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 7,938,005</b>	<b>\$ 17,656,182</b>

The accompanying notes are an integral part of the consolidated financial statements.

**V.I. TECHNOLOGIES, INC.**  
**Consolidated Statements of Operations**

	Year ended December 31, 2004	Year ended December 27, 2003	Year ended December 28, 2002
<b>Revenues:</b>			
Research funding	\$ 1,682,021	\$ 715,766	\$ 4,224,889
<b>Costs and expenses:</b>			
Research and development costs	13,289,080	18,507,614	20,350,784
General and administrative expenses	6,456,182	4,334,557	5,942,142
Plasma Operations divestiture credit	—	—	(1,627,950)
<b>Total operating costs and expenses</b>	<b>19,745,262</b>	<b>22,842,171</b>	<b>24,664,976</b>
Loss from operations	(18,063,241)	(22,126,405)	(20,440,087)
Interest income (expense), net	(98,591)	(226,580)	400,252
<b>Net loss</b>	<b>\$ (18,161,832)</b>	<b>\$ (22,352,985)</b>	<b>\$ (20,039,835)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.35)</b>	<b>\$ (0.67)</b>	<b>\$ (0.88)</b>
Weighted average shares used in calculation of basic and diluted net loss per share	52,489,145	33,359,934	22,752,222

The accompanying notes are an integral part of the consolidated financial statements.

**V.I. TECHNOLOGIES, INC.**  
**Consolidated Statements of Stockholders' Equity**  
**Years ended December 31, 2004, December 27, 2003 and December 28, 2002**

	Common Stock		Additional Paid-In Capital	Deferred Compensation	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
<b>Balance at December 29, 2001</b>	<b>22,730,316</b>	<b>\$227,303</b>	<b>\$141,354,765</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$(108,793,722)</b>	<b>\$ 32,788,346</b>
Issuance of common stock under stock option and purchase plans	41,505	415	109,727	—	—	—	110,142
Net loss	—	—	—	—	—	(20,039,835)	(20,039,835)
<b>Balance at December 28, 2002</b>	<b>22,771,821</b>	<b>227,718</b>	<b>141,464,492</b>	<b>—</b>	<b>—</b>	<b>(128,833,557)</b>	<b>12,858,653</b>
Issuance of common stock under stock option and purchase plans	176,030	1,760	115,867	—	—	—	117,627
Issuance of shares of restricted common stock under a stock option plan	544,316	5,443	468,112	(460,581)	—	—	12,974
Issuance of shares of common stock to Pall Corp. under an equity investment commitment, net	3,921,569	39,216	3,882,628	—	—	—	3,921,844
Issuance of shares of common stock under a rights offering, net	14,069,474	140,695	13,929,767	—	—	—	14,070,462
Issuance of shares of common stock under a private placement, net	4,446,665	44,467	3,572,369	—	—	—	3,616,836
Net loss	—	—	—	—	—	(22,352,985)	(22,352,985)
<b>Balance at December 27, 2003</b>	<b>45,929,875</b>	<b>459,299</b>	<b>163,433,235</b>	<b>(460,581)</b>	<b>—</b>	<b>(151,186,542)</b>	<b>12,245,411</b>
Issuance of common stock under stock option and purchase plans	9,776	98	7,888	—	—	—	7,986
Amortization of deferred compensation expense of shares of restricted common stock issued under a stock option plan	(7,624)	(76)	40,512	423,910	—	—	464,346
Issuance of shares of common stock under a private placement, net	12,905,467	129,054	11,417,606	—	—	—	11,546,660
Repurchase of 4,382,353 shares of treasury stock, at cost	—	—	—	—	(3,742,591)	—	(3,742,591)
Net loss	—	—	—	—	—	(18,161,832)	(18,161,832)
<b>Balance at December 31, 2004</b>	<b>58,837,494</b>	<b>\$588,375</b>	<b>\$174,899,241</b>	<b>\$ (36,671)</b>	<b>\$(3,742,591)</b>	<b>\$(169,348,374)</b>	<b>\$ 2,359,980</b>

The accompanying notes are an integral part of the consolidated financial statements.

**V. I. TECHNOLOGIES, INC.**  
**Consolidated Statements of Cash Flows**

	December 31, 2004	December 27, 2003	December 28, 2002
<b>Cash flows from operating activities:</b>			
Net loss	\$ (18,161,832)	\$ (22,352,985)	\$ (20,039,835)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization	973,524	1,093,479	1,108,054
Net discount (accretion) of interest	—	162,030	(142,500)
Plasma Operations divestiture credit	—	—	(1,627,950)
Reserve for disposal of long-lived assets and facility costs	—	1,364,943	—
Compensation expense on restricted common stock	464,346	12,974	—
Impairment charge on intangible asset	2,493,263	—	—
Charge on cumulative effect of correction in lease accounting	644,972	—	—
Receipt of tenant allowance	—	—	297,198
<b>Changes in operating accounts:</b>			
Other receivables, net	(4,550)	(95,775)	1,149,840
Prepaid expenses and other current assets	176,774	55,738	85,485
Accounts payable	832,894	(659,361)	37,927
Accrued expenses	622,431	(607,634)	(1,294,779)
Deferred revenue	(953,925)	(152,628)	(152,628)
Lease incentive liability	(32,337)	(32,337)	(32,337)
<b>Net cash used in operating activities</b>	<b>(12,944,440)</b>	<b>(21,211,556)</b>	<b>(20,611,525)</b>
<b>Cash flows from investing activities:</b>			
Additions to property and equipment	(208,350)	(91,092)	(1,776,075)
Proceeds from Plasma Operations divestiture	1,666,839	924,588	2,000,000
Proceeds of short-term investments	—	—	3,332,385
Restricted cash due to legal proceedings	(250,000)	—	—
<b>Net cash provided by investing activities</b>	<b>1,208,489</b>	<b>833,496</b>	<b>3,556,310</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock	12,567,472	22,470,493	110,142
Costs associated with equity financing	(1,012,826)	(743,724)	—
Deferred costs of anticipated financing	(168,493)	—	—
Repayment of revolving credit facility	—	(5,000,000)	(2,500,000)
Proceeds from revolving credit facility	—	2,500,000	5,000,000
Repayment of advances	(1,061,336)	(1,091,428)	—
Proceeds from financed insurance costs	146,716	—	—
Repayment of financed insurance costs	(32,160)	—	—
Principal repayment of capital lease obligations	—	(157,640)	(255,434)
<b>Net cash provided by financing activities</b>	<b>10,439,373</b>	<b>17,977,701</b>	<b>2,354,708</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(1,296,578)</b>	<b>(2,400,359)</b>	<b>(14,700,507)</b>
Cash and cash equivalents, beginning of year	4,258,322	6,658,681	21,359,188
<b>Cash and cash equivalents, end of year</b>	<b>\$ 2,961,744</b>	<b>\$ 4,258,322</b>	<b>\$ 6,658,681</b>
<i>Supplemental disclosure of non-cash financing and investing cash flow information:</i>			
Settlement of Plasma Operations receivable (see Note 4)	\$ 3,742,591	\$ —	\$ —

The accompanying notes are an integral part of the consolidated financial statements.

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2004, December 27, 2003 and December 28, 2002**

**1. Organization and Business Overview**

V.I. Technologies, Inc. ("VITEX" or the "Company") is a development stage biotechnology company developing novel anti-infective products. The INACTINE™ Pathogen Reduction System for red cells, or the "INACTINE™ system, is designed to inactivate a wide range of viruses, bacteria, parasites and lymphocytes from red blood cells and to remove soluble prion proteins. Prion proteins in their pathogenic forms are the agents that cause "Mad Cow Disease", or in humans, variant Creutzfeldt-Jakob Disease, or vCJD, which is 100% fatal, and for which no diagnostic test or therapy currently exists. The technology works by binding to the RNA or DNA of the pathogen. Once bound, the compound forms an irreversible bond to the pathogenic nucleic acid, preventing replication and thereby "killing" the pathogens.

The Company faces certain risks and uncertainties similar to other biotechnology companies including its ability to obtain additional funding; its future profitability; protection of patents and property rights; uncertainties regarding the development of the Company's technologies; the success of its clinical trials; competition and technological change; governmental regulations including the need for product approvals; and attracting and retaining key officers and employees.

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates the realization of its assets and the satisfaction of its liabilities in the normal course of business. As shown in these consolidated financial statements, the Company has incurred recurring losses from operations and, as of December 31, 2004, has an accumulated deficit of \$169.3 million. The Company's available unrestricted cash balances on February 28, 2005 were approximately \$1.0 million. Management believes that VITEX's present cash resources will be adequate to meet its requirements only through the first quarter of 2005. Accordingly, this raises substantial doubt about the Company's ability to continue as a going concern.

At present, after its recent restructuring in December 2004, VITEX has been consuming approximately \$1.0 million in cash per month. The Company expects to close on a \$20 million proposed financing concurrent with the Panacos Pharmaceuticals, Inc. ("Panacos") proposed merger (see Note 18). Following the proposed merger, the combined company expects to have a monthly burn rate that averages approximately \$2.6 million per month during 2005. VITEX believes that these resources will be sufficient to meet the cash needs of the combined company into the fourth quarter of 2005. The Company expects its rights offering, which is expected to close by April 2005 (see Note 20), to increase that cash horizon. However, there is no guarantee that the Company will be able to successfully complete this transaction.

In the event that the merger with Panacos does not materialize or in the event that fund raising efforts, including the rights offering, are not successful in raising the minimum proceeds needed to continue operations through 2005 post-merger, the Company intends to delay or reduce expenditures so as to continue its operations on a very limited scale and within its available resources.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiary, V.I. Technologies Ltd., an entity incorporated for regulatory purposes in the United Kingdom. All intercompany balances and transactions have been eliminated in consolidation.

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2004, December 27, 2003 and December 28, 2002**

*Operating Segment*

The Company operates in a single reportable segment: blood products. These products are used in the health care industry and are regulated in the United States by the U.S. Food and Drug Administration.

*Fiscal Year End*

In 2004, the Company changed its fiscal year end to December 31, calendar year end. Previously, the Company prepared its financial statements on the basis of a 52-week fiscal year ending on the Saturday closest to the end of the calendar year. Therefore, the Company year end for fiscal year 2004 changed from January 1, 2005 to December 31, 2004. In these notes to the accompanying financial statements, the years ended December 27, 2003 and December 28, 2002 are referred to as fiscal years 2003 and 2002, respectively. There were no material transactions between the Company's accounts for December 27, 2003 through December 31, 2003 and for December 28, 2002 through December 31, 2002.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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. Significant estimates made by the Company include the useful lives of fixed assets, recoverability of long-lived assets, estimate of accrued legal contingencies, and the collectibility of other receivables.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with maturities under three months at the time of purchase to be cash equivalents.

*Restricted Cash*

Long-term restricted cash of \$0.4 million at December 31, 2004 and 2003 is comprised of a certificate of deposit for a letter of credit on the Company's leased facility. Short-term restricted cash at December 31, 2004 is comprised of \$0.25 million of a security attachment related to litigation. Short-term restricted cash of \$0.2 million at December 31, 2003 is comprised of a certificate of deposit for a letter of credit on a previously leased facility. During 2004, this \$0.2 million letter of credit was drawn upon by the landlord of the previously leased facility (see Note 12).

*Property and Equipment*

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the respective assets. These range from five to fifteen years for leasehold improvements, and three to five years for all other tangible assets.

*Long-lived Assets*

The Company reviews its long-lived assets for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. If the sum of the expected cash flows, undiscounted and without interest, is less than the carrying amount of the asset, an impairment loss is recognized as the amount by which the carrying amount of the asset exceeds its fair value.

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2004, December 27, 2003 and December 28, 2002**

*Goodwill*

Goodwill was acquired in the merger with Pentose Pharmaceuticals, Inc. (“Pentose”) in 1999 and has not been amortized after fiscal 2001 in accordance with SFAS No. 142, “*Goodwill and Other Intangible Assets*” (“SFAS No. 142”). Accumulated goodwill amortization amounted to \$0.14 million at December 31, 2004 and December 27, 2003. The Company designated the fourth quarter for its annual review of impairment. There was no impairment indicated by the tests in fiscal 2004, 2003 or 2002.

*Revenue Recognition*

The Company recognizes revenues under research collaborations, including grants received from the government and minimum royalty payments as the research costs eligible for reimbursement under the collaboration agreements are incurred. Non-refundable up-front and milestone payments related to license and distribution agreements are deferred and amortized over the period in which the licensee has distribution rights. The Company continually reviews these estimates for any events which could result in a change in the deferral period. Amounts received in advance of the incurrence of reimbursable research expenses are deferred and recognized when the related expenses have been incurred.

*Research and Development*

All research and development costs are charged to operations as incurred.

*Income Taxes*

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the amounts of existing assets and liabilities carried on the consolidated financial statements and their respective tax bases and the benefits arising from the realization of operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

*Net Loss Per Share*

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding. The weighted average number of shares of unvested restricted common stock is excluded from basic weighted average common shares outstanding. Diluted net loss per share is the same as basic net loss per share since the inclusion of potential common stock equivalents (restricted stock, stock options and warrants) in the computation would be anti-dilutive. The dilutive effect of common stock equivalents for the fiscal years 2004, 2003, and 2002, had they been included in the computation, would have been approximately 41,000, 171,000 and 152,000, respectively.

*Fair Values of Financial Instruments*

The fair values of the Company’s financial instruments approximate the carrying value due to the short maturity or variable interest rate applicable to such instruments.

*Stock-based Compensation*

At December 31, 2004, the Company has four stock-based employee compensation plans, which are described more fully in Note 8.

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2004, December 27, 2003 and December 28, 2002**

The Company accounts for those plans in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25") and complies with the disclosure provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), and SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure". No stock-based employee compensation cost is reflected in net loss for stock options granted, as all options granted had an exercise price equal to the market value of the underlying common stock on the date of the grants. Equity instruments issued to non-employees are accounted for in accordance with the provisions of SFAS No. 123 and EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services".

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock based compensation.

	2004	2003	2002
<b>Net loss:</b>			
As reported	\$ (18,161,832)	\$ (22,352,985)	\$ (20,039,835)
Add: Stock-based compensation expense determined under the fair-value method	(2,083,732)	(3,393,680)	(2,273,221)
Deduct: Stock-based compensation expense included in reported net loss	464,346	12,974	—
<b>Pro forma</b>	<b>\$ (19,781,218)</b>	<b>\$ (25,733,691)</b>	<b>\$ (22,313,056)</b>
<b>Basic and diluted net loss per share:</b>			
As reported	\$ (0.35)	\$ (0.67)	\$ (0.88)
Pro forma	\$ (0.38)	\$ (0.77)	\$ (0.98)

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option valuation model with the following assumptions:

	2004		2003		2002	
	Stock Options	ESPP	Stock Options	ESPP	Stock Options	ESPP
Volatility	90%	95%	120%	99%–262%	94%	69%–166%
Expected dividend yield	0%	0%	0%	0%	0%	0%
Risk-free interest rate	3.1%	1.7%	3.0%	0.9%–1.2%	3.1%	1.6%–1.9%
Expected life in years	4	0.25	5	0.25	5	0.25

The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

In December 2003, the Company granted 544,316 shares of restricted common stock to employees excluding the executive officers. The total value of the grant was \$0.5 million and the stock vested quarterly during 2004. In May 2004, Company granted 50,000 restricted shares of the Company's common stock to an employee. The total value of the grant was \$0.05 million. The shares vest annually over a two year period. Compensation expense is being recognized ratably over the two-year vesting period. Compensation expense of \$0.46 million and \$0.013 million was recorded in fiscal year 2004 and 2003, respectively.

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2004, December 27, 2003 and December 28, 2002**

*Comprehensive Income (Loss)*

The Company adopted SFAS No. 130, "Reporting Comprehensive Income", which requires that all components of comprehensive income (loss) be reported in the consolidated financial statements in the period in which they are recognized. For all periods reported, the Company's comprehensive loss is equal to its net loss reported in the accompanying consolidated statements of operations.

*Reclassifications*

Certain prior year balances have been reclassified to conform to current year presentation. These reclassifications had no effect on the Company's reported net loss or financial position.

*New Accounting Pronouncements*

In December 2004, the FASB issued FASB Statement No. 123 (revised 2004), "Shared-Based Payment" ("Statement 123(R)"). Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, "Accounting for Stock Issued to Employees", which was permitted under Statement 123, as originally issued. The revised Statement requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements. All public companies must use either the modified prospective or the modified retrospective transition method. The Company has not yet evaluated the impact of adoption of this pronouncement which must be adopted in the third quarter of our fiscal year 2005. See above for information related to the pro forma effects on our reported net loss and net loss per share of applying the fair value recognition provisions of the previous SFAS 123 to stock-based compensation.

Also in December 2004, as part of its short-term international convergence project with the International Accounting Standards Board, the FASB issued Statement 153 to address the accounting for nonmonetary exchanges of productive assets. Statement 153 amends APB No. 29, "Accounting for Nonmonetary Exchanges", which established a narrow exception for nonmonetary exchanges of similar productive assets from fair value measurement. This Statement eliminates that exception and replaces it with an exception for exchanges that do not have commercial substance. Under Statement 153, nonmonetary exchanges are required to be accounted for at fair value, recognizing any gains or losses, if their fair value is determinable within reasonable limits and the transaction has commercial substance. The Statement specifies that a nonmonetary exchange has commercial substance if future cash flows of the entity are expected to change significantly as a result of the exchange. The Company plans to adopt this Statement in fiscal 2005 and adoption is not expected to impact on its financial position or results of operations.

**3. Intangible Asset**

The intangible asset consisted of core technology of \$3.7 million acquired in the Pentose merger in 1999 and was being amortized on a straight-line basis over fifteen years. Accumulated amortization amounted to \$1.0 million at December 27, 2003. Amortization expense for intangible asset amounted to \$0.2 million for each of fiscal years 2004, 2003 and 2002.

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As described in Note 11, in November 2004 the Company temporarily suspended enrollment in its Phase III surgical, or acute, study for its lead product candidate, the INACTINE™ red cell system. This development triggered an impairment review of long-lived assets and goodwill under the provisions of SFAS No. 144 and SFAS No. 142, respectively. Based on the results of the review of long-lived assets, the Company wrote off the core technology. The intangible asset had a remaining net book value of \$2.5 million. The charge was booked in the fourth quarter of 2004 to research and development costs. Based on the results of the review for goodwill, no impairment charge was indicated as the Company's market capitalization exceeded the book value of its net assets.

#### 4. Plasma Operations Receivables

In 2001, the Company divested its plasma operations to Precision Pharma Services, Inc, a private company owned by its management and Ampersand Ventures ("Ampersand"), a VITEX shareholder. The Company recorded a charge of \$6.8 million on the divestiture in fiscal 2001 and a credit of \$1.6 million in fiscal 2002 including \$1.2 million related to a favorable settlement of a Plasma Operations tax dispute with the U.S. Bureau of Alcohol, Tobacco and Firearms as well as the settlement of certain other liabilities below recorded amounts.

The total purchase price included a non-interest bearing \$3.0 million holdback originally scheduled for payment in August 2003. This was rescheduled to December 2004 in connection with a \$6.0 million investment by Precision in the Company's rights offering of common stock in June 2003 (see Note 7). The rescheduling resulted in a \$0.3 million charge to interest expense in fiscal year 2003 on remeasurement of the debt to its net present value. In addition, Precision was required to fund a continuing obligation of the Company that was being amortized over a three year period ending February 2006. The outstanding balance at December 27, 2003 was \$2.7 million.

In January 2004, the Company and Precision settled the obligations by Precision paying VITEX \$1.7 million in cash and returning 4.4 million shares of VITEX common stock with a value of \$4.9 million based on the market closing price of the Nasdaq National Market on the date prior to settlement. The Company recorded the full realization of the Precision obligation and a treasury stock transaction in the amount of \$3.7 million for the return of its 4.4 million shares of common stock.

#### 5. Property and Equipment

Property and equipment consist of the following components:

	December 31, 2004	December 27, 2003
Leasehold improvements	\$ 3,125,649	\$ 3,125,649
Laboratory equipment	2,348,289	2,348,289
Office furniture and equipment	868,316	874,306
Construction in progress	289,204	80,854
	<u>\$ 6,631,458</u>	<u>\$ 6,429,098</u>
Accumulated depreciation and amortization	(3,673,504)	(2,932,632)
	<u>\$ 2,957,954</u>	<u>\$ 3,496,466</u>

There are no outstanding capital leases at December 31, 2004 or December 31, 2003. Amortization expense for equipment under a capital lease amounted to \$0.1 million for fiscal years 2003 and 2002.

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During 2003, the Company wrote off construction in progress of \$1.1 million for a facility which it did not intend to place in service (see Note 12).

#### 6. Accrued Expenses

Accrued expenses consist of the following components:

	December 31, 2004	December 27, 2003
Accrued employee compensation	\$ 351,453	\$ 231,280
Accrued contingency costs (see Note 12)	764,270	—
Accrued facility costs	—	246,199
Other	230,089	245,902
	<u>\$ 1,345,812</u>	<u>\$ 723,381</u>

#### 7. Stockholders' Equity

##### *Common Stock*

On June 5, 2003, the Company concurrently closed a shareholder rights offering in the amount of \$14.4 million and a Pall equity milestone investment under its collaboration agreement (see Note 13) in the amount of \$4.0 million, realizing total gross proceeds from the two transactions of \$18.4 million. VITEX issued a total of 14.1 million and 3.9 million shares of common stock for the rights offering and the Pall equity milestone investment, respectively. The price was \$1.02 per share for each of the transactions. Transaction costs for the rights offering and Pall milestone were approximately \$0.3 million and \$0.1 million, respectively.

On December 5, 2003, the Company sold 4,446,665 shares of the Company's common stock to outside investors at a negotiated price of \$0.90 per share for a total of \$4.0 million gross proceeds. In addition to the common stock, the investors also received four-year warrants to purchase 1,965,418 shares of common stock at \$1.32 per share and five-month purchase options to purchase 1,111,658 shares of common stock at \$0.90 per share. Total transaction costs were approximately \$0.4 million. In addition, the placement agent received warrants to purchase up to an additional 220,109 shares of common stock at \$1.32 per share. During 2004, all purchase options were exercised for gross proceeds of \$1.0 million and related transaction costs of \$0.07 million.

On December 19, 2003, the Company granted 544,316 restricted shares of the Company's common stock to employees excluding its executive officers. The Company recorded deferred compensation of \$0.5 million. The shares vested quarterly during 2004 and the compensation expense was recognized over the one-year vesting period.

On February 10, 2004, the Company sold 7,332,219 shares and 3,778,258 shares of the Company's common stock to outside investors at a negotiated price of \$0.90 and \$1.15 per share, respectively, for a total of \$10.9 million gross proceeds. In addition to the common stock, the investors received four-year warrants to purchase 2,932,884 shares and 1,511,299 shares of common stock at \$1.32 per share and \$1.75 per share, respectively, and five-month purchase options to purchase 1,833,052 shares and 944,563 shares of common stock at \$0.90 per share and \$1.15 per share, respectively. Total transaction costs were approximately \$0.9 million. In addition, the placement agent received warrants to purchase up to an additional 328,453 shares and 158,687 shares of common stock at \$1.32 per share and \$1.75 per share, respectively. During 2004, approximately 0.68 million of the \$0.90 per share purchase options were exercised for gross proceeds of \$0.6 million and related transaction costs of \$0.04 million.

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On May 11, 2004, the Company granted 50,000 restricted shares of the Company's common stock to an employee. The Company recorded deferred compensation of \$0.05 million. The shares vest annually over a two year period. Compensation expense is being recognized ratably over the two-year vesting period.

In September 2004, VITEX received a notice from the Nasdaq Stock Market, Inc. ("Nasdaq") that the bid price of its common stock had closed below \$1.00 per share for the previous 30 consecutive trading days and that, in accordance with Nasdaq rules, VITEX would be provided 180 calendar days to regain compliance with the minimum bid price requirement under the rules for continued listing. VITEX had until February 28, 2005 to regain compliance with the minimum bid price requirement. In addition, in November 2004, VITEX received a notice from the Nasdaq that its stockholders' equity as of September 25, 2004 had fallen below the Nasdaq requirement for continued listing of \$10.0 million. VITEX's stockholders' equity as of December 31, 2004 was \$2.4 million. Nasdaq noted that it is reviewing VITEX's eligibility for continued listing on Nasdaq and, to facilitate this review, requested that VITEX provide Nasdaq with its plan to achieve and sustain compliance with all listing requirements. VITEX submitted its plan to regain compliance on November 19, 2004. As a condition to the closing of the financing with Great Point Partners, LLC (see Note 18), VITEX agreed, to effect a reverse stock split. VITEX anticipates that the reverse split will result in the per share price of VITEX common stock exceeding \$1.00 per share immediately following the split, but there can be no assurance that the price will close above \$1.00 per share for the time required to be in compliance with the Nasdaq stock price requirement. On December 9, 2004, Nasdaq notified VITEX that, on the basis of the plan submitted on November 19, 2004, it was granting VITEX an extension of time until February 17, 2005 to regain compliance with the stockholders' equity requirement for continued listing, and until February 28, 2004 to regain compliance with the stock price requirement. On February 18, 2005, VITEX received from Nasdaq a notice of extension of the deadline for reaching compliance with the minimum stockholders' equity requirement until March 15, 2005. VITEX believes that the proposed merger and financing transactions contemplated in this document will be sufficient to meet that requirement. VITEX has requested an extension of the deadline until March 31, 2005 to achieve compliance with the minimum bid price requirement from Nasdaq in order to allow the Company to complete the proposed merger and financing contemplated, although there can be no assurance that Nasdaq will grant the Company's request.

*Warrants*

At December 31, 2004 the Company had 5,260,104 warrants outstanding with an exercise price of \$1.32 and 1,669,986 warrants outstanding with an exercise price of \$1.75. The warrants expire between December 2007 and January 2008.

*Preferred Stock*

Preferred stock may be issued from time to time in one or more series, with such designations, rights, and preferences as shall be determined by the Board of Directors. No preferred stock was outstanding as of December 31, 2004 or December 27, 2003.

**8. Stock Plans**

*Employee Stock Purchase Plan*

Under the 1998 Employee Stock Purchase Plan (the "1998 Purchase Plan"), employees may purchase shares of common stock at a discount from fair market value. The 1998 Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code. Rights to

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purchase common stock under the 1998 Purchase Plan are granted at the discretion of the Compensation Committee of the Board of Directors, which determines the frequency and duration of individual offerings under the 1998 Purchase Plan and the dates when stock may be purchased. Eligible employees participate voluntarily and may withdraw from any offering at any time before stock is purchased. Participation terminates automatically upon termination of employment. The purchase price per share of common stock to the purchaser under the 1998 Purchase Plan is 85 percent of the lesser of the Company's common stock average fair market value at the beginning of the offering period or on the applicable exercise date and may be paid through payroll deductions, periodic lump sum payments or both. The 1998 Purchase Plan terminates in February 2008. The 1998 Purchase Plan was twice amended to increase the shares of common stock reserved from 89,445 to 400,000. There are 222,910 shares available for future purchase as of December 31, 2004. During the fiscal years ended December 31, 2004, December 27, 2003 and December 28, 2002, 3,405 shares, 65,396 shares and 29,600 shares of common stock were issued, respectively.

*Director Stock Option Plan*

All of the directors who are not employees of the Company (the "Eligible Directors") are currently eligible to participate in the Director Stock Option Plan (the "1998 Director Plan"). Each non-employee who is initially elected to the Company's Board of Directors shall, upon his initial election by the Company's stockholders, automatically be entitled to an option to purchase 15,000 shares of common stock. In addition, each Eligible Director will be entitled to receive an annual option to purchase 2,000 shares of common stock.

The initial election grant of 15,000 options vests over a four-year period with 25 percent of the grant vesting after six months, and 25 percent vesting at the end of the second, third and fourth year thereafter, provided that the option-holder is still a director of the Company at the opening of business on such date. The annual grant of 2,000 options vests one year from date of grant. The 1998 Director Plan has a term of ten years. The exercise price for the options is equal to the last sale price for the common stock on the business day immediately preceding the date of grant. The exercise price may be paid in cash or shares. There are 250,000 shares of common stock reserved for issuance under the 1998 Director Plan, of which 97,000 options are available for future grants at December 31, 2004.

*Equity Incentive Plans*

The 1998 Equity Incentive Plan (the "1998 Equity Plan") was twice amended to increase the shares of common stock reserved from 3,000,000 shares to 4,750,000. As of December 31, 2004, 602,925 options are available for future grants. The 1998 Equity Plan permits the granting of both incentive stock options and nonstatutory stock options as well as restricted stock. The option price of the shares for incentive stock options cannot be less than the fair market value of such stock on the business day immediately preceding the date of grant. Options are exercisable over a period determined by the Board of Directors, but not longer than ten years after the grant date. The vesting period is 25 percent on each of the first, second, third, and fourth anniversary of the grant date. All stock options issued to date have been granted at the fair market value of the stock on the respective grant dates. On December 19, 2003, the Company issued 544,316 restricted shares of the Company's common stock under the 1998 Equity Plan. The vesting period is 25 percent on the first, second, third and fourth quarterly anniversary of the grant date. On May 11, 2004, the Company issued 50,000 restricted shares of the Company's common stock under the 1998 Equity Plan. The vesting period is 50 percent on the first and second annual anniversary of the grant date.

In connection with the Pentose merger in 1999, the Company adopted the 1999 Supplemental Stock Option Plan (the "1999 Plan") authorizing the granting of both incentive and nonstatutory stock options on 1,000,000 shares

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of common stock reserved under the plan of which 292,878 options are available for future grants as of December 31, 2004. The vesting period is 25 percent on each of the first, second, third, and fourth anniversary of the grant date. The option price of the shares for incentive stock options cannot be less than the fair market value of such stock on the business day immediately preceding the date of grant or 110 percent of the fair market value per share if the optionee owns more than 10 percent of the total combined voting power of the Company.

*Supplemental Equity Compensation Plan*

The VITEX Board of Directors has adopted, subject to stockholder approval and approval of the merger with Panacos, the Supplemental Equity Compensation Plan (the "New Plan"). Up to 73,695,948 shares of common stock (subject to adjustment in the event of stock splits and other similar events) may be issued pursuant to awards granted under the New Plan. The adoption of the New Plan is being submitted for shareholder approval to ensure qualification of the New Plan under Nasdaq National Market, incentive stock option and Internal Revenue Rules.

The New Plan was adopted by the VITEX Board in the form that was previously approved by the Panacos Board of Directors. Following the merger, and the grant of options to purchase VITEX common stock to former Panacos optionholders, VITEX will be able to make grants under the New Plan using the remaining shares that were unallocated to Panacos optionholders at the time of the merger. The New Plan permits the grant of incentive and non-statutory stock options and stock rights. Although the Compensation Committee of the VITEX Board of Directors administers the New Plan and has discretion in granting awards, the exercise price of any incentive stock option, or ISO, may not be less than 100% of the fair market value of VITEX's common stock on the date of the grant for grants to employees that own less than 10% of VITEX's capital stock, and not less than 110% of the fair market value of VITEX's common stock on the date of the grants to employees that own more than 10% of VITEX's common stock. In the case of nonstatutory stock options, the exercise price cannot be less than the par value of VITEX's common stock.

Information as to options for shares of common stock granted for fiscal years 2004, 2003 and 2002 is as follows:

	2004		2003		2002	
	Options	Weighted-average exercise price	Options	Weighted-average exercise price	Options	Weighted-average exercise price
Outstanding, beginning of year	4,007,204	\$ 4.85	2,606,287	\$ 6.51	2,397,483	\$ 6.95
Granted	98,800	1.05	1,809,365	2.11	547,937	4.83
Exercised	(6,371)	0.82	(115,296)	0.56	(11,905)	5.10
Forfeited	(801,693)	4.07	(293,152)	4.39	(327,228)	6.92
Outstanding, end of year	3,297,940	4.94	4,007,204	4.85	2,606,287	6.51
Exercisable, end of year	2,473,630	5.60	2,171,210	6.14	1,475,078	7.12
Weighted average fair value of options granted during the year		\$ 0.70		\$ 1.88		\$ 1.75

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The following table summarizes the information on stock options outstanding at December 31, 2004:

Range of exercise prices	Options Outstanding			Options Exercisable	
	Number outstanding	Weighted-average remaining contractual life	Weighted average exercise price	Number exercisable	Weighted-average exercise price
\$0.00–2.07	147,941	7.2	\$ 0.83	74,391	\$ 0.73
\$2.08–2.78	1,348,084	6.3	2.15	788,361	2.11
\$2.79–5.79	415,886	4.2	4.79	286,886	4.47
\$5.80–6.79	246,824	4.7	6.51	212,440	6.48
\$6.80–7.74	271,360	3.8	7.28	243,707	7.33
\$7.75–9.24	607,845	2.9	8.27	607,845	8.27
\$9.25–10.88	160,000	5.2	9.31	160,000	9.31
\$10.89–11.63	100,000	0.3	11.63	100,000	11.63
	<b>3,297,940</b>			<b>2,473,630</b>	

**9. Income Taxes**

The Company's deferred tax assets and liabilities were as follows:

	December 31, 2004	December 27, 2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 58,553,037	\$ 52,512,802
Research and development tax credits	3,228,616	3,070,898
Other, net	876,144	1,088,568
Total deferred tax assets	62,657,797	56,672,268
Valuation allowance	(62,287,995)	(55,143,554)
Net deferred tax assets	369,802	1,528,714
Deferred tax liability:		
Depreciation and amortization	(369,802)	(1,528,714)
	<b>\$ —</b>	<b>\$ —</b>

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31, 2004	Year ended December 27, 2003	Year ended December 28, 2002
Tax at federal statutory rate	(34.0)%	(34.0)%	(34.0)%
Change in valuation allowance	33.5%	35.7%	38.6%
Research and development credits	(0.9)%	(2.3)%	(2.6)%
Merger costs	2.2%	— %	— %
Other	(0.8)%	0.6%	(2.0)%
Provision for taxes	<b>— %</b>	<b>— %</b>	<b>— %</b>

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At December 31, 2004 and December 27, 2003, a valuation allowance has been applied to offset the respective deferred tax assets in recognition of the uncertainty that such tax benefits will be realized. The valuation allowance increased by \$7.1 million, \$8.0 million, and \$9.1 million in fiscal years 2004, 2003 and 2002, respectively.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment. In order to fully realize the deferred tax asset, the Company will need to generate future taxable income of approximately \$146.4 million. At December 31, 2004, the Company has available net operating loss carryforwards for federal and state income tax reporting purposes of approximately \$146.4 million, and has available research and development credit carryforwards for federal income tax reporting purposes of approximately \$3.2 million, which are available to offset future taxable income, if any. Federal carryforwards will expire beginning in 2010. State net operating loss carryforwards have begun to expire. Deferred tax assets and related valuation allowance of \$0.6 million related to the net operating loss carryforward results from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in-capital rather than a reduction of income tax expense.

The Company experienced a change in ownership during July 1998, which resulted in approximately \$22.8 million of the Federal net operating loss being subject to an annual limitation of approximately \$7.4 million. In addition, the net operating loss carryforwards of \$146.4 million includes \$11.5 million from the acquisition of Pentose in 1999, which is subject to an annual limitation of \$2.1 million.

The Company's ability to utilize all its net operating loss carryforwards may be limited if there is a change in ownership, as defined by Section 382 of the Internal Revenue Code, in connection with the proposed merger with Panacos in 2005 (see Note 18).

#### **10. Revenue**

Prior to the modification of the Pall Corporation ("Pall") collaboration in August 2002, research funding revenue was primarily from Pall, a shareholder. Pall's reimbursement of costs of the Company's red blood cell program, net of program costs incurred by Pall, totaled \$3.6 million in fiscal year 2002. Also included within research funding is amortized revenue related to non-refundable up-front and milestone payments of Amersham Pharmacia Biotech ("Amersham") which had been amortized over the life of the related agreement. These amounts totaled \$0.15 million for each of fiscal years 2003 and 2002. In 2004, the contract with Amersham was terminated and the Company recognized the full balance of deferred revenue of approximately \$1.0 million into research funding (see Note 13). In addition, the Company recorded minimum royalty payments from Amersham of \$0.1 million, and \$0.2 million in fiscal years 2003 and 2002, respectively. Research funding also includes grants received from the National Institutes of Health ("NIH") in the amount of \$0.7 million, \$0.5 million and \$0.3 million in fiscal years 2004, 2003 and 2002, respectively. The following table is a summary of revenues:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Pall	\$ —	\$ —	\$ 3,578,313
NIH	728,096	463,138	298,750
Amersham	953,925	252,628	347,826
	<u>          </u>	<u>          </u>	<u>          </u>
Total	<u>\$ 1,682,021</u>	<u>\$ 715,766</u>	<u>\$ 4,224,889</u>

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**11. Phase III Clinical Trials and Restructuring of Operations**

In 2003, the Company initiated Phase III clinical trials for its INACTINE™ red cell system in both an acute and a chronic population. In November 2003, VITEX's Phase III chronic study of INACTINE™ red cells was placed on clinical hold by the FDA due to the availability of insufficient safety information and was subsequently halted by VITEX following a review of an independent data safety monitoring committee, or DSMC. As a result of this development, the Company restructured its operations in late November 2003 to reduce spending and to concentrate its efforts on the acute trial. The Company reduced staffing by over 50% by eliminating over 40 positions and curtailing non-essential activities. There were no charges in 2003 associated with this restructuring. Also, the Company performed a review of its long-lived assets and goodwill to assess possible impairment as a result of the November 2003 recommendation. The review indicated that an impairment charge was not required.

In November 2004, VITEX suspended enrollment in its Phase III surgical, or acute, study for its lead product candidate, the INACTINE™ red cell system, following identification of an immune response to INACTINE-treated red cells in one patient in the study during ongoing immunologic testing of subjects enrolled in the trial. As a result of this development, the Company restructured its operations in December 2004 to allow VITEX to conserve cash until the completion of the proposed merger with Panacos (see Note 18). The Company reduced staffing by over 40% and incurred a severance charge of \$0.1 million recorded to research and development in the fourth quarter of 2004. Each of the employees eligible for severance received severance pay equal to his or her one-month salary. All payments were made by December 31, 2004. Also, the Company performed a review of its long-lived assets and goodwill in accordance SFAS No. 144 and SFAS No. 142, respectively, to assess possible impairment as a result of the halt of the enrollment in the surgical Phase III trial. The review indicated that an impairment charge was required for its intangible asset. Accordingly, the Company incurred a charge of \$2.5 million in the fourth quarter of 2004 to write-off certain core technology acquired in its 1999 acquisition of Pentose (see Note 3).

This suspension in enrollment means that both the Phase III trial of INACTINE for acute indications and the Phase III trial of INACTINE for chronic indications have been halted, in the case of the chronic trial, following a clinical hold by the FDA. Although no clinical consequences of the immune response are apparent based on review of available data, additional patients will not be enrolled in the acute trial pending full evaluation. VITEX has notified the FDA that it has suspended enrollment in the study and that it intends to continue discussions with FDA regarding the conditions, if any, under which the trial might be continued while VITEX is completing its review of all relevant data. VITEX intends to conduct these discussions as part of an ongoing dialogue with the FDA regarding conditions for licensure of the INACTINE™ system.

Prior to the suspension of the surgical trial, the FDA had expressed concerns regarding the licensing of the current INACTINE™ system for an acute indication in light of the presence of antibodies observed in the chronic trial, and has requested justification from VITEX for pursuit of an acute-only indication in the context of these findings. The FDA has also indicated that a control system with respect to an acute-only indication would be required to ensure that patients who have previously received red cells treated by the current INACTINE™ system do not receive INACTINE™ red cells in subsequent hospitalizations. VITEX has met with the FDA and presented proposals on supplemental clinical trials. However, the FDA has indicated that it will require the review of additional data, including the results of the Phase III trial for INACTINE™ in acute indications, before fully responding to VITEX's proposals for additional clinical trials. The occurrence of an immune response in the acute trial and the decision to suspend enrollment in it will require VITEX to formulate and present to FDA a regulatory plan for approval of INACTINE that takes into account all findings to date, which is likely to significantly delay determination of any acceptable regulatory pathway. The FDA has indicated that any such regulatory plan for the acute-only indication must address the development of a control system, as described

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above. In addition, VITEX believes that modifications to the current INACTINE process that are designed to reduce the likelihood of an immunologic response to treated red cells will also be required. At this time, VITEX cannot determine the length of time required for it to develop such a regulatory plan, nor can VITEX estimate the length of time required for the FDA to approve such a plan, or whether such a plan will be approved at all. Enrollment in the acute trial will continue to be suspended until such time as a regulatory plan is approved by the FDA and implemented by VITEX, if ever. VITEX has begun preclinical testing on the modifications to the current INACTINE™ process that are designed to reduce the likelihood of an immunologic response to treated red cells. However, this work is early and preliminary and no assurance can be given that VITEX will be able to develop a control system that will be technically feasible, approved by the FDA, and economically viable, or that the modifications to the current INACTINE™ process will succeed in reducing the likelihood of an immunologic response. Prior to the suspension of enrollment in the acute study, the FDA also directed VITEX to implement additional patient safety monitoring procedures in the Phase III acute trial. VITEX implemented these procedures and, until accrual into the trial was suspended, was periodically updating the FDA on the trial data. While VITEX believes that the steps taken addressed the FDA recommendations prior to suspending enrollment in the acute trial, further steps could be required by the FDA. VITEX also received from the FDA a written request for further information relating to an August 2004 amendment to its IND. The amendment included responses to questions raised by the FDA relating to procedures for patient safety monitoring used in the Phase III chronic study, which had been placed on clinical hold by the FDA due to the availability of insufficient safety information, and subsequently halted by VITEX following a DSMC review. VITEX has responded to the FDA's request and is awaiting further communications from the agency on this matter.

With the Phase III trial for INACTINE™ in chronic indications halted by VITEX, following the clinical hold by the FDA and the subsequent review by the DSMC, and enrollment suspended in the Phase III trial for INACTINE in acute indications, the Company's ongoing development plan for INACTINE™ for chronic, acute or other indications is highly uncertain. VITEX cannot ensure that the acute trial will resume or complete enrollment in a timely manner. The exact nature, timing and estimated costs of the efforts necessary to bring to market the product resulting from VITEX's pathogen inactivation research and development projects involve a number of key variables which are either unpredictable or outside VITEX's control, including whether the likelihood of an immune response to INACTINE™ treated red cells can be adequately reduced, whether, and under what circumstances, the FDA will agree with a plan by VITEX to proceed with clinical trials, the enrollment rates and results of the Phase III clinical trial, should it be continued, the extent of further studies which could be required for filing a Biologics License Application with the FDA, the length of the FDA and foreign regulatory approval processes, the success of VITEX's fundraising efforts, its ability to establish and maintain relationships with marketing partners and strategic collaborators, and the timing of commencement of commercialization of its product. Inability to satisfy one or more of these conditions, or to do so in a commercially acceptable manner, may render continued development of the INACTINE™ system infeasible.

**12. Legal Proceedings**

*Red Cell Processing Laboratory*

During fiscal year 2002, the Company invested \$1.1 million in build-out costs for a 16,500 sq. ft. laboratory near Boston, Massachusetts intended for use as a processing site for INACTINE™-treated red blood cells. In 2003, the Company concluded that the second site was not required. In fiscal year 2003, the Company recorded a non-cash charge of \$1.4 million within research and development costs to write-off its capitalized build-out costs and to provide for estimated lease and associated carrying costs until the facility was sublet or the lease was terminated. The facility lease ran to 2008 and total remaining payments under the lease were approximately \$1.0 million. The Company anticipated subleasing the facility under terms similar to its primary lease obligations or reaching a

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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satisfactory lease termination agreement with the landlord. In February 2004, the lease on that facility was terminated by the landlord who retained a twelve-month security deposit posted by the Company in the amount of \$0.17 million, which was charged against a reserve established in fiscal year 2003. In the fourth quarter of 2004, the landlord filed a complaint against VITEX seeking damages of not less than \$531,905, plus attorneys' fees, representing a claim for damages relating to re-rental of the facility at a lower rental rate plus associated costs. While the Company has received limited explanations concerning the landlord's calculation of damages, certain calculations remain unexplained and the Company has not received supporting documentation for any of the calculations, many of which it disputes. However, based on the evidence provided, namely the landlord's affidavits, the trial court issued an order preventing the Company from using up to \$300,000 of our assets except in the ordinary course of business, and further has allowed an attachment of \$250,000 of the Company's funds as security for a potential future judgment in the landlord's favor. VITEX is vigorously defending against this claim. At December 31, 2004, the Company believes it has sufficient reserves to cover its litigation of this issue.

*Former Employee Suit*

In February 2005, VITEX was served with a complaint filed in the United States District Court for the Eastern District of New York by a former employee of the Melville plant which was divested to Precision in August 2001 (see Note 4). The complaint alleges that VITEX underpaid overtime pay to this employee while he was employed by the Company in our Melville plant. VITEX currently intends to file a motion to dismiss the claim and, based on a review of the employee's payroll records, believes that any overtime pay due to this employee will be less than \$1,000.

Also in February 2005, VITEX was served with a complaint filed in New York State Court by a former employee of the Melville plant. Precision is also party to the suit. The suit is a class action in which the lead plaintiff, representing the class, claims VITEX underpaid overtime to employees of the processing plant. Based on the Company's understanding of the statute of limitations, the period in question for VITEX will be from approximately February 1999 to August 2001, when it divested the plant to Precision. The Complaint alleges an amount in excess of \$125,000 in unpaid overtime plus the costs of the action and reasonable attorney's fees due from the two defendants. At December 31, 2004, the Company believes it has sufficient reserves to cover its litigation of this issue.

**13. Collaborations**

*Pall Corporation.* In 1998, the Company and Pall Corporation ("Pall") entered into a series of agreements (the "original Pall Agreements") providing for, among other things, a collaboration on the development and marketing of systems employing the Company's pathogen reduction technologies for red blood cell and platelet concentrates. Pall is a leading manufacturer and supplier of filtration products, including those relating to the collection, preservation, processing, manipulation, storage and treatment of blood and blood components. Under those original Pall Agreements, Pall received exclusive worldwide distribution rights to all the Company's systems incorporating pathogen reduction technology for red blood cells and platelets. The parties also equally shared research, development, clinical and regulatory responsibilities and agreed to equally share profits from operations.

In August 2002, the Company and Pall modified their collaboration (the "modified collaboration") on the INACTINE™ Pathogen Reduction System for red cells to permit the addition of new distribution partners. VITEX acquired worldwide distribution rights previously held by Pall and assumed responsibility for funding the program. Pall acquired a royalty interest in each INACTINE™ treatment of red cells. Pall also provided the

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Company a one year \$5.0 million revolving credit facility and committed to an additional \$4.0 million equity investment which occurred in 2003, related to the initial use of the INACTINE™ system in the Phase III trials.

Under the original Pall Agreements and the modified collaboration, Pall provided the Company reimbursement for red cell program expenses of approximately \$3.6 million during fiscal years 2002 and \$17.4 million from the commencement of the collaboration through August 2002. Pall also made equity investments in the Company totaling \$20.0 million at market price, including \$4.0 million in 2003. The Company fully utilized the \$5.0 million revolving credit facility and repaid the outstanding balance upon maturity in 2003. On December 31, 2004, Pall owned 11.3% percent of the Company's outstanding shares. To date, we have purchased \$1.6 million from Pall principally for filters used in the INACTINE™ system with approximately \$19,000, \$65,000 and \$49,000 in fiscal years 2004, 2003 and 2002, respectively.

*Amersham Pharmacia Biotech.* In 2000, the Company entered into a ten-year worldwide license and distribution agreement with Amersham, the life science business of Nycomed Amersham plc., to exclusively market and distribute the Company's INACTINE™ technology to manufacturers of biopharmaceuticals and transgenic products and to plasma fractionators. VITEX retained the rights for the marketing and distribution of the technology in all other areas including blood components such as red cells, platelets and plasma.

Under the terms of the agreement, the Company received non-refundable up-front payments and milestone payments totaling \$1.5 million in fiscal 2000. In addition, the Company received a percentage royalty based on net sales made by Amersham of products which incorporated the INACTINE™ system. The Company provided Amersham with technical support, training and conducts research and development projects as directed by Amersham under the agreement. In accordance with SAB 104, the up-front payments and milestone payments were to be recognized from the date of receipt of the payments through the end of the term of the agreement, approximately ten years. The Company recorded research funding revenue of \$0.1 million and \$0.2 million for fiscal years 2003 and 2002, respectively, from royalty payments due under the terms of the agreement. In addition, for each of fiscal years 2003 and 2002, the Company recognized revenue of \$0.2 million from the amortization of non-refundable up-front and milestone payments, which is recorded within research funding on the consolidated statements of operations.

In November of 2004, VITEX provided notice of termination to Amersham Pharmacia Biotech and the agreement was terminated in December of 2004. There are no payments due under by either party as a result of the termination and no future obligations. The primary reasons for sending the notice of termination was the decision by VITEX to conserve resources in the INACTINE™ program and focus on the development of potential modifications to the INACTINE™ system for red blood cells to reduce the likelihood of an immune response that was observed in the Phase III program for INACTINE™ pathogen inactivation program for red blood cells.

In 2004, prior to the termination of the agreement, VITEX recorded research funding revenue of approximately \$0.1 from the amortization of non-refundable up-front and milestone payments. Upon termination of the agreement, in the fourth quarter of 2004, the Company recognized the full amount of the remaining deferred revenue of approximately \$0.8 million. Other than the full recognition of deferred revenue, the cancellation of the agreement had no material effect on the 2004 financial results.

*Plasma Operations Agreements*

Prior to the divestiture of its Plasma Operations (see Note 4), the Company maintained commercial relationships the American National Red Cross ("the Red Cross"). The Red Cross had made a total of \$3.5 million in non-interest bearing, unsecured advances which the Company recorded at net present value using an interest rate

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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of approximately 8.0%. In March 2003, the Company and Red Cross restructured the obligation to bear interest at 10.0% per year and to amortize in equal monthly installments of principal and interest of approximately \$0.1 million over three years to February 2006. The Company made an initial principal repayment of \$0.35 million plus monthly payments of principal and interest in fiscal 2003 in the aggregate amount of \$1.1 million. Prior to the settlement in January 2004 with Precision (see Note 4), Precision reimbursed the Company for these payments. At December 31, 2004, the balance sheet reflects an outstanding balance of \$1.4 million due the Red Cross. Total payments to be made in 2005 and 2006 are \$1.3 million and \$0.2 million, respectively.

#### 14. Other Related Party Transactions

The Company has an arrangement for scientific consulting services with its Chairman under terms of which it paid fees of \$0.17 million in fiscal 2004 and \$0.1 million in each of fiscal years 2003 and 2002.

#### 15. Supplemental Disclosure of Cash Flow Information

Information on cash paid for interest during the year is as follows:

	Year ended		
	December 31, 2004	December 27, 2003	December 28, 2002
Cash paid during the year for interest	\$ 197,000	\$ 358,000	\$ 65,000

#### 16. Profit Sharing 401(k) Plans

The Company offers 401(k) savings benefits to substantially all employees. Eligible employees may elect to contribute a portion of their wages to the 401(k) plan, subject to certain limitations. The Company provides a discretionary match to employee contributions. Total Company contributions were \$0.03 million for the fiscal year 2004 and \$0.1 million in each of fiscal years 2003 and 2002.

#### 17. Commitments and Contingencies

##### *Lease and Other Commitments*

Future minimum lease payments under non-cancelable operating leases at December 31, 2004 are as follows:

2005	\$ 942,191
2006	1,047,200
2007	1,047,200
2008	1,047,208
2009	1,025,383
Thereafter	21,817

The Company leases its office facilities under non-cancelable operating leases that expire at various dates through 2010. The Company has two five-year options to renew the operating leases.

In 2004, the Company recorded a one-time, non-cash charge of \$0.6 million reflecting a cumulative impact of a correction of leased property accounting related to rent acceleration and rent holidays for the past five years. The amount was not material to the Company's reported results in any one year. Rent expense was approximately \$1.7 million, \$1.3 million and \$1.2 million for fiscal years 2004, 2003, and 2002, respectively. Rent expense for fiscal 2004 includes the above one-time charge.

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In addition, the Company has recorded certain reclassification amounts to prior years financial statements to gross-up the impact of the receipt of tenant allowances in connection with its facility leases of \$0.3 million and \$0.5 million in 2002 and 2000, respectively. The Company had previously reported these amounts on a net basis against the recorded leasehold improvements. On the December 27, 2003 consolidated balance sheet, the Company increased property and equipment and the corresponding lease incentive liability by \$0.4 million. In the December 28, 2002 statement of cash flows, the Company reflected the receipt of tenant allowances of \$0.3 million as a separate component of operating activities and an a corresponding increase to additions to property and equipment.

**18. Proposed Merger with Panacos Pharmaceuticals and Fundraising**

In June 2004, VITEX signed a definitive merger agreement with Panacos Pharmaceuticals (“Panacos”). The terms of the proposed merger were subsequently amended in November 2004, December 2004 and February 2005. The Boards of Directors of VITEX and Panacos each approved the transaction.

Panacos Pharmaceuticals is a development stage company involved in the discovery and development of the next generation of small molecule, antiviral drugs for the treatment of Human Immunodeficiency Virus (HIV) infection and other major virus diseases. Panacos is focusing exclusively on diseases with large markets, where there is a clear unmet need for more effective therapies. A major commercial advantage of the HIV market is the rapid clinical development and approval process for new drugs. The total time from initiation of clinical trials to market may be as little as four years, shorter than for many other disease indications. Panacos completed its pre-clinical program for its lead candidate to treat HIV, PA-457, at the end of 2003 and filed an IND with the FDA in December 2003. Panacos entered Phase I clinical testing of PA-457 in March 2004. It has completed the Phase I programs and begun the Phase II program. PA-457 is the first in a new class of drugs called maturation inhibitors discovered by Panacos scientists. The FDA has granted fast track status to PA-457, available for drugs designed to treat a serious or life threatening condition with an unmet medical need. The proposed merger will expand the Company into anti-infective therapeutics and added additional pre-clinical and clinical drug candidates to VITEX’s product portfolio.

Concurrent with the closing of the proposed merger with Panacos expected to close in mid-March 2005, VITEX will receive \$20 million in gross proceeds from a private placement transaction. Under the terms of the transaction, Great Point Partners, LLC and affiliated investors will purchase \$15.0 million in VITEX common stock and warrants to purchase common stock, and Ampersand Ventures (“Ampersand”), A.M. Pappas & Associates, LLC and certain other investors will purchase \$5.0 million in VITEX common stock and warrants to purchase common stock. Ampersand is an existing investor in VITEX and Panacos, and A.M. Pappas is an existing investor in Panacos. The completion of the proposed merger and a reverse stock split are conditions to the closing of the financing. VITEX will issue approximately 227,500,000 shares of its stock in this transaction, based on a per share price of \$0.20 per share. VITEX will issue approximately 102,375,000 warrants to purchase shares of VITEX stock which are exercisable for a five-year period from the date of issuance at a price of \$0.24 per share.

In the event that the closing of the financing does not occur for any reason within 120 days of December 9, 2004, with certain exceptions, including if the closing of the financing does not occur by reason of the termination of the merger agreement or the non-consummation of the merger, VITEX will have to pay to the purchasers affiliated with Great Point Partners, LLC a fee equal to \$1,670,000 in the aggregate and will reimburse all unreimbursed expenses of Great Point Partners, LLC related to the Securities Purchase Agreement and transactions.

**V.I. TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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Prior to the amendment in the fourth quarter of fiscal 2004 to the proposed merger with Panacos, VITEX was considered the accounting acquirer in the merger and as such, under accounting rules, merger-related costs were recorded within deferred costs on the consolidated balance sheet until the close of the proposed merger. As of the third quarter of 2004, VITEX had recorded approximately \$1.0 million in such deferred costs. Due to the terms of the amendment in the fourth quarter of 2004, Panacos is now considered to be the accounting acquirer, and therefore VITEX expensed costs previously deferred. As of December 31, 2004, VITEX has incurred approximately \$1.2 million in merger-related costs which are recorded in general and administrative costs on the consolidated statement of operations.

**19. Quarterly Financial Data (Unaudited, in thousands, except per share data)**

	<u>December 31,</u> <u>2004</u>	<u>September 25,</u> <u>2004</u>	<u>June 26,</u> <u>2004</u>	<u>March 27,</u> <u>2004</u>
Net revenues-research funding	\$ 1,232	\$ 140	\$ 181	\$ 129
Net loss	(7,175)	(3,624)	(3,633)	(3,730)
Loss per share—basic and diluted	(0.13)	(0.07)	(0.07)	(0.08)

	<u>December 27,</u> <u>2003</u>	<u>September 27,</u> <u>2003</u>	<u>June 28,</u> <u>2003</u>	<u>March 29,</u> <u>2003</u>
Net revenues-research funding	\$ 403	\$ 105	\$ 104	\$ 104
Net loss	(2,734)	(6,686)	(6,569)	(6,364)
Loss per share—basic and diluted	(0.07)	(0.16)	(0.23)	(0.28)

**20. Subsequent Events- Rights Offering (Unaudited)**

The Company plans to file a registration statement with the Securities and Exchange Commission (the “SEC”) in March 2005 for a proposed offering of its common stock with a maximum value of approximately \$5.5 million through the distribution of subscription rights to its shareholders. Under the terms of the rights offering, which VITEX plans to commence in March 2005, the Company’s shareholders will receive a certain number of subscription rights for each share of VITEX common stock owned at the record date of March 4, 2005, thereby entitling them to purchase shares of its common stock representing a total of a maximum of 27.5 million shares, prior to the anticipated reverse split. VITEX’s largest shareholder, Ampersand Ventures, held 9.3 million shares of VITEX common stock as of February 28, 2005, prior to the anticipated reverse split. Ampersand agreed not to participate in the rights offering as a condition to their participation in the \$20 million private placement. The exercise price will be \$0.20 per share, the same as the price paid by Great Point Partners and affiliates in the \$20 million private placement which will close concurrently with the proposed Panacos merger in mid-March 2005. There is no guarantee that the Company will be able to successfully complete any of these transactions.

**EXHIBIT INDEX**

21.1	List of Subsidiaries of the Registrant
23.1	Consent of KPMG LLP
31	Certification of Chief Executive Officer and Acting Chief Financial Officer under Section 302
32	Section 906 certification of periodic financial report by Chief Executive Officer and Acting Chief Financial Officer

**LIST OF SUBSIDIARIES OF THE REGISTRANT**

V.I. Technologies Ltd., an entity incorporated for regulatory purposes in the United Kingdom.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors  
V.I. Technologies, Inc.:

We consent to the incorporation by reference in the registration statements on Form S-8 (Nos. 333-104049, 333-104050, 333-108733 and 333-108734) and on Form S-3 (Nos. 333-113182, 333-111186 and 333-57418) of V.I. Technologies, Inc. of our report dated February 25, 2005 relating to the consolidated balance sheets of V.I. Technologies, Inc. as of December 31, 2004 and December 27, 2003 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004, which report appears in the December 31, 2004 annual report on Form 10-K of V.I. Technologies, Inc.

Our report dated February 25, 2005 with respect to the consolidated balance sheets of the Company as of December 31, 2004 and December 27, 2003, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004 contains an explanatory paragraph that states that the Company has incurred significant recurring losses from operations and its current cash balances as of December 31, 2004 are not sufficient to support its operations over the next year. These factors, among others, discussed in Note 1 to the consolidated financial statements raise substantial doubt about the Company's ability to continue as a going concern.

/s/ KPMG LLP

Boston, Massachusetts  
March 2, 2005

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND  
ACTING CHIEF FINANCIAL OFFICER UNDER SECTION 302**

I, John R. Barr, certify that:

1. I have reviewed this annual report on Form 10-K of V.I. Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - b) paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2005

/s/ John R. Barr

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John R. Barr  
Chief Executive Officer and acting Chief Financial Officer

**V. I. Technologies, Inc.**  
**Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**  
**(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of V.I. Technologies, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2004 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 2, 2005

/s/ John R. Barr

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John R. Barr  
Chief Executive Officer and acting Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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