V I TECHNOLOGIES INC
Form 10-K
March 01, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 27, 2003

or

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

Commission File No. 0-24241

V.I. TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**11-3238476**
(State or other jurisdiction	**(I.R.S. Employer**
of incorporation or organization)	**Identification No.)**
134 Coolidge Ave, Watertown, MA	**02472**

(Address of principal executive offices) **(Zip code)**

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

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

None

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

Common stock, $.01 par value

(Title of class)

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 x 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. x

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

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 28, 2003 as reported on the Nasdaq National Market, was approximately $25,774,000. 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.

53,107,559

(Number of shares of common stock outstanding as of February 20, 2004)

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant s Annual Report to Stockholders for the fiscal year ended December 27, 2003 are incorporated by reference into Part II of this Report. Portions of the Registrant s Definitive Proxy Statement for the 2004 Annual Meeting of Stockholders (the Definitive Proxy Statement), to be filed with the SEC within 120 days of December 27, 2003, 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 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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PART I

Item 1. BUSINESS

Overview

Based on the demonstrated effectiveness of our science as presented in industry publications and presentations, and on our competitive analysis, we believe that we are a leading developer of innovative biotechnology products designed to improve the safety of the world s blood supply. We have designed our proprietary INACTINE Pathogen Reduction System for red cells (the INACTINEsystem) to inactivate a wide range of viruses, bacteria, parasites and lymphocytes from red blood cells. The INACTINE system has also demonstrated in research studies high efficiency in removing prion proteins. Prion proteins in their pathogenic forms are the agents that cause Mad Cow Disease , or in humans, variant Creutzfeldt-Jakob Disease (vCJD), which is 100% fatal, and for which no diagnostic 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.

Our lead product candidate, the INACTINE system, is currently in a Phase III clinical trial for patients requiring acute transfusions. Until November 2003, we were also conducting a Phase III clinical trial with patients requiring chronic transfusions. On the advice of an independent data safety monitoring committee (DSMC), we stopped enrollment in the chronic trial and the continued testing of the INACTINE system for use in chronic patients is currently under review. We are currently evaluating possible corrective actions to address the issues observed in the trial. Possible corrective actions might require us to significantly change the INACTINE system so as to enable us to continue to test the system for use with chronic patients. If such significant changes were required, we may decide to pursue an indication for use of the existing process only in acute transfusions. A 2001 analysis by an outside consultant estimated that over 80% of the approximately 14 million annual red cell transfusions in the U.S. involved acute care patients. We believe that the relative usage of transfusion red cells in the major international markets we are targeting is similarly proportioned between acute and chronic patients. We also believe that pursuing an acute only indication would allow us bring the INACTINE system to market faster, taking advantage of substantial progress we have made in research, clinical, pathogen inactivation and toxicology studies. We might then choose to address the combined acute and chronic markets in a second generation INACTINE system. Should we decide to pursue this approach, we would require FDA concurrence. At present we are not aware of any other pathogen reduction systems for red blood cells in human clinical trials.

We are designing our INACTINE system to work with existing standard red blood cell collection bags and preservative solutions and to be easily implemented into the blood banking operation. Over 40 million red cell units are transfused annually in the North America, Europe and Japan making it one of the most frequently prescribed and important therapeutics in medicine. We believe that a pathogen reduction product for both acute and chronic patients could represent a $4 billion worldwide market opportunity with the acute indication representing in excess of $3 billion out of that total. We currently do not have any FDA approved products and we have not made any commercial sales of our products under development.

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 in Europe and Japan and six known pathogens in the U.S., with the implementation of Nucleic Acid Testing (NAT) for West Nile Virus in 2003. 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.

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

Market Opportunity

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 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 percent 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.

According to a 2000 University of Michigan study, only 15 percent of Americans today view the blood supply as safe, down from 48 percent in 1988. Blood safety concerns caused by transfusion-transmitted diseases such as AIDS and Hepatitis C have made a zero-defect blood supply the goal of regulators around the world, including the FDA. We believe these dynamics create significant demand for products that make blood safer.

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 percent 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. We believe that the INACTINE system will work successfully 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 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,

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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 thalasemia.

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 percent 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 five percent 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 five percent 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 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 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. 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 percent 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 percent of red blood cells in the United States are gamma irradiated, while 100 percent 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 percent 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 cytamegalovirus, 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, which we believe to be the fastest growing segment of blood use.

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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 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 (the INACTINE system) offers the following advantages over current approaches to blood safety:

Inactivates known pathogens. Our INACTINE system 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, INACTINE 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 effectiveness of the INACTINE system 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.

Potentially eliminate the need for gamma irradiation. Based on our preclinical testing, we believe our INACTINE system is at least as effective as gamma irradiation for the elimination of leukocytes that cause graft versus host disease without limiting the therapeutic properties of red blood cells.

Our Strategy

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

Be the first to market in the largest segment. We are focusing our INACTINE system on red blood cells, the largest segment of transfusion blood components in the United States, Europe and Japan. Our lead product candidate, the INACTINE system, is currently in a Phase III clinical trial for patients requiring acute transfusions. Until November 2003, we were also conducting a Phase III clinical trial with patients requiring chronic transfusions. On the advice of an independent data safety monitoring committee (DSMC), we stopped enrollment in the chronic trial and the continued testing of the INACTINE system for use in chronic patients is currently under review. We are evaluating possible corrective actions to address the issues observed in the trial. Possible corrective actions might require us to significantly change the INACTINE system so as to enable us to continue to test the system for use with chronic patients. If such significant changes were required, we may decide to pursue an indication for use of the existing process only in acute transfusions. A 2001 analysis by an outside consultant estimated that over 80% of the approximately 14 million annual red cell transfusions in the U.S. involved acute care patients. We believe that the relative

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usage of transfusion red cells in the major international markets we are targeting is similarly proportioned between acute and chronic patients. We also believe that pursuing an acute only indication would allow us bring the INACTINE system to market faster, taking advantage of substantial progress we have made in research, clinical, pathogen inactivation and toxicology studies. We might then choose to address the combined acute and chronic markets in a second generation INACTINE system. Should we decide to pursue this approach, we would require FDA concurrence. At present we are not aware of any other pathogen reduction systems for red blood cells in human clinical trials.

Expand our strategic alliances. 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. Our goal is to establish our INACTINE system as the industry standard for blood product safety.

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 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 the unit of red cells. The removal of INACTINE is accomplished via a highly automated cell wash device. Units treated with INACTINE 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 guanasine 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.

The following basic steps are involved in our INACTINE Pathogen Reduction System for red cells:

PEN110 is manually added to the unit of red cells in an asceptic fashion; however, an automated device is in advanced stages of development and the Company plans to introduce the device into the current Phase III study;

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.

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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

	Phase I	**Phase II**	**Phase III**
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 an acute 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	In process

Research Studies

Our research studies focused on determining the range of viruses and bacteria that our INACTINE system could inactivate, as well as the reduction of parasites and lymphocytes. In these studies, PEN110 demonstrated effectiveness against a broad spectrum of enveloped and non-enveloped viruses, and gram negative and gram positive bacteria, and parasites. In addition, our non-clinical studies focused on the effect of INACTINE on the therapeutic properties of red blood cells and blood storage time. *In vivo* testing of baboons with INACTINE treated red blood cells resulted in no detectable adverse effects on the cellular properties of the red blood cells and did not affect their 24-hour post-transfusion survival. We also demonstrated in our baboon studies that the levels of survival of red blood cells were equivalent to those of the untreated control group after one day and 28 days.

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 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 percent 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.

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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 involves cardiac surgical patients requiring acute transfusion support, and a second study involves patients requiring chronic transfusion support. Enrollment in the chronic study was stopped in November of 2003 on the recommendation of an independent data safety monitoring committee due to a concern regarding antibody responses observed in patients. No serious adverse reactions were observed. We are reviewing strategies to address these issues. The acute transfusion support study is ongoing. This study is expected to enroll 200 patients and is designed as a multi-center, double-blind, controlled and parallel-group study.

International Clinical and Regulatory Status

We intend to discuss our clinical and regulatory plans in Europe and Japan with the relevant regulatory agencies for their agreement. If agreed to by the relevant regulatory agencies, we intend to use our United States clinical data as a basis for submissions in Europe and Japan.

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 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 seeks 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.

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.

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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.

Pall remains a significant shareholder and, as of February 20, 2004, owned approximately 12% of our outstanding shares.

Haemonetics Corporation

In January 2000, we entered into a development and manufacturing agreement with Haemonetics. 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 our INACTINE system is commercialized, Haemonetics will provide contract manufacturing services for the cell wash equipment 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. This agreement will terminate after ten years unless extended by mutual agreement.

Amersham Pharmacia Biotech

In April 2000, we entered into a license and distribution agreement with Amersham Pharmacia Biotech to exclusively market and distribute our INACTINE technology to manufacturers of biopharmaceuticals and transgenic products and to plasma fractionators. Amersham Pharmacia Biotech is the life science business of Nycomed Amersham plc. We retained all rights for the marketing and distribution of our INACTINE technology with regard to blood components such as red blood cells, platelets and plasma. We will provide Amersham Pharmacia Biotech with technical support and training and conduct research and development projects as directed by Amersham Pharmacia Biotech during the duration of the agreement. Through December 27, 2003, we have received $1.9 million from Amersham Pharmacia Biotech under the agreement. We could also receive further payments of $1.0 million subject to product testing and FDA approval milestones. In addition, we will receive a percentage royalty based on net sales made by Amersham Pharmacia Biotech of products that incorporate our INACTINE system. The duration of the agreement is ten years. Either party may terminate the agreement due to a material breach that is not cured within 90 days. Amersham Pharmacia Biotech has the right to terminate the agreement after 30 days written notice to us after the initial evaluation phase. This termination right may not be exercised after April 2005.

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.

As of December 27, 2003, our INACTINE patent portfolio consisted of fourteen issued United States patents, twenty-two issued foreign patents and seventy 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

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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 fourteen 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. We are the only company with a pathogen reduction system for red cells currently in human clinical trials. Many companies and organizations, including our principal competitors, Cerus Corporation and Gambro, 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.

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. The alternative approaches to achieving safer blood component products include donor retesting, the use of blood

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substitutes, leukocyte filters and reduction systems, improved blood testing such as nucleic acid testing and gamma irradiation. All of these approaches are currently available, and each has gained some degree of market acceptance.

In the area of pathogen inactivation of blood and blood components, several companies are developing technologies which are, or in the future may be, the basis for products that will directly compete with our products. 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.

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.

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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 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.

On August 14, 2001, we completed the divestiture of our Plasma Operations located in Melville, New York to Precision Pharma Services, Inc. These operations were responsible for producing intermediate plasma fractions for Bayer and for viral inactivation of transfusion plasma for the Red Cross. The Plasma Operations accounted for all of our previously reported processing revenues. The total value of the transaction was approximately $34.0 million.

Our total costs over the last three fiscal years in our research and development activities were as follows: fiscal year 2003 $18.5 million, fiscal year 2002 $20.4 million and fiscal year 2001 $19.2 million.

Employees

As of December 27, 2003, we had thirty-two employees, of whom twenty-five were engaged in research and development and seven 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.

We make available on our website our annual report 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.

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Item 2. PROPERTIES

We currently lease 36,000 square feet of space in Watertown, Massachusetts to accommodate our research and development activities. This lease expires in 2010 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.

We also 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. At that time, the INACTINE system was in early development, was more labor intensive, and was expected to require a larger area for a given volume of red cells. Also, we believed that a separate site might be required for the Company s Biologics License Application. Since then, there has been significant progress in automating the system and reducing space requirements so that it currently can be implemented in community blood centers by the blood center staff. Further, we have concluded that the facility will not be required for our BLA. We have a smaller processing laboratory at our Watertown facility for clinical trial support and to display the INACTINE process. We have concluded that the second site is not required and are taking steps to sublease the space or terminate our obligations under the lease. This lease expires in 2008.

Item 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 27, 2003.

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PART II

Item 5. MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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, 2001 through December 27, 2003. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

	High	Low
Year Ended December 27, 2003 (fiscal 2003):		
First Quarter	$ 1.20	$ 0.55
Second Quarter	3.98	0.70
Third Quarter	3.32	1.86
Fourth Quarter	3.10	0.55
Year Ending December 28, 2002 (fiscal 2002):		
First Quarter	$ 7.35	$ 4.80
Second Quarter	6.00	2.39
Third Quarter	4.25	0.70
Fourth Quarter	1.50	0.40

The closing price of our common stock on February 20, 2004, as reported on the Nasdaq National Market was $1.48 per share. As of February 20, 2004, there were 126 holders of record 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.

On December 5, 2003, we entered into agreements to sell 4,446,665 shares of our common stock, at a price of $0.90 per share, to accredited investors in a transaction exempt from the registration requirements of the Securities Act pursuant to Rule 506 of Regulation D promulgated thereunder. The investors also received warrants to purchase 1,778,658 shares of our common stock at an exercise price of $1.32 per share, and options to purchase 1,111,658 shares of our common stock at an exercise price of $0.90 per share. The warrants are exercisable immediately and shall expire four years from the date of issuance. The purchase options are exercisable immediately, and shall expire five months following the effective date of the registration statement filed by us to cover the resale of the securities issued in the private placement. S.G. Cowen Securities Corporation acted as our placement agent in the transaction, and received a fee of $0.3 million and warrants to purchase 186,760 shares of common stock at an exercise price of $1.32 per share. SG Cowen Securities Corporation may also receive 33,349 shares of common stock upon the exercise by the other investors of their purchase options. In January 2004, these shares were registered under a Form S-3 Registration Statement.

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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 27, 2003. The selected financial data for each of the five years in the period ended December 27, 2003 have been derived from the consolidated financial statements of the Company, which consolidated financial statements have been audited by KPMG LLP, independent auditors.

	2003(1)	2002(2)	2001(2)	2000(3)	1999(4)
Statement of Operations Data:					
Revenues:					
Research funding (5)	$ 716	$ 4,225	$ 6,264	$ 4,030	$ 1,800
Processing revenues			20,628	35,445	42,423
ARC Incentive Program credit (charge)				1,235	(4,500)
Total revenues	716	4,225	26,892	40,710	39,723
Costs, expenses and charges:					
Research and development, gross	18,508	20,351	19,224	16,966	8,592
Selling, general and administrative	4,334	5,942	8,725	10,882	9,546
Cost of sales (5)			15,697	28,107	24,742
Plasma Operations divestiture (credit) charge		(1,628)	6,801		
Charges related to merger					
R&D restructuring					2,208
In-Process R&D					32,998
Charge related to product recall					2,583
Total costs and expenses	22,842	24,665	50,447	55,955	80,669
Loss from operations	(22,126)	(20,440)	(23,555)	(15,245)	(40,946)
Interest (expense) income, net	(227)	400	135	(138)	47
Settlement of insurance claim					3,500
Discount on customer advance, net				402	70
Total other income (expense)	(227)	400	135	264	3,617
Net loss	$ (22,353)	$ (20,040)	$ (23,420)	$ (14,981)	$ (37,329)
Basic and diluted net loss per share	$ (0.67)	$ (0.88)	$ (1.05)	$ (0.75)	$ (2.78)
Weighted average common shares used in computing basic and diluted net loss per share	33,360	22,752	22,316	19,860	13,405

	2003	2002	2001	2000	1999
Balance Sheet Data:					
Cash and cash equivalents, including restricted cash	$ 4,848	$ 7,249	$ 21,949	$ 7,768	$ 26,886
Short-term investments			3,332		
Working capital	6,810	5,486	23,363	4,464	19,784
Total assets	17,279	22,761	43,230	63,729	78,098
Long-term obligations, less current portion	2,181	954	4,491	4,791	7,701

Stockholders equity	12,245	12,858	32,788	45,157	55,385

Note: For presentation purposes, years ended December 27, 2003, December 28, 2002, December 29, 2001, December 30, 2000 and January 1, 2000 are presented as fiscal years 2003, 2002, 2001, 2000 and 1999, respectively.

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(1) 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 for a facility which we intend to either sublet or terminate the lease.
(2) 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.
(3) During 2000, we recorded a $1.2 million incentive sales credit reflecting unused sales incentives from the program which commenced in 1999.
(4) During 1999, we recorded a $4.5 million sales incentive charge. We negotiated a settlement with an insurance carrier related to a 1996 plasma loss under which we received a cash payment of $3.5 million. In connection with the merger with Pentose Pharmaceuticals in 1999, we recorded a $33.0 million write off of in-process research and development. Additionally, in anticipation of the merger, we recorded a research and development charge for $2.2 million for severance and related expenses. We recorded a one-time charge of $2.6 million for the voluntary recall of lots of PLAS+®SD.
(5) Research funding includes collaborator reimbursement amounts received from related parties in the amounts of $3.6 million, $5.8 million, $4.0 million and $1.8 million in 2002, 2001, 2000 and 1999, respectively. Cost of sales includes royalties and materials used in the production of PLAS+®SD which were paid or owed to related parties in the amounts of $0.9 million, $0.4 million and $0.8 million in 2001, 2000 and 1999, 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 products designed to improve the safety of the world s blood supply. Our INACTINE Pathogen Reduction System for red cells (the INACTINEsystem) is designed to inactivate a wide range of viruses, bacteria, parasites and lymphocytes from red blood cells and to remove prion proteins. Prion proteins in their pathogenic forms are the agents that cause Mad Cow Disease , or in humans, variant Creutzfeldt-Jakob Disease (vCJD), which is 100% fatal, and for which no diagnostic 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 therapeutics in medicine. A pathogen reduction product for both acute and chronic patients could represent a $4 billion market opportunity with acute indications representing in excess of $3 billion out of that total. We currently do not have any FDA approved products and we have not made any commercial sales of our products under development.

Our lead product candidate, the INACTINE system, is currently in a Phase III clinical trial for patients requiring acute transfusions. Until November 2003, we were also conducting a Phase III clinical trial with patients requiring chronic transfusions. On the advice of an independent data safety monitoring committee (DSMC), we stopped enrollment in the chronic trial and the continued testing of the INACTINE system for use in chronic patients is currently under review. We are evaluating possible corrective actions to address the issues observed in the trial. Possible corrective actions might require us to significantly change the INACTINE system so as to enable us to continue to test the system for use with chronic patients. If such significant changes were required, we may decide to pursue an indication for use of the existing process only in acute transfusions. A 2001 analysis by an outside consultant estimated that over 80% of the approximately 14 million annual red cell transfusions in the U.S. involved acute care patients. We believe that the relative usage of transfusion red cells in the major international markets we are targeting is similarly proportioned between acute and chronic patients. We also believe that pursuing an acute only indication would allow us bring the INACTINE system to market faster, taking advantage of substantial progress we have made in research, clinical, pathogen inactivation and toxicology studies. We might then choose to address the combined acute and chronic markets in a second

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generation INACTINE system. Should we decide to pursue this approach, we would require FDA concurrence. At present we are not aware of any other pathogen reduction systems for red blood cells in human clinical trials.

The Phase III clinical trial in patients requiring acute transfusions is our most significant current activity. We fund our operations primarily through sale of common stock, partner collaborations, research and development grants, short-term debt and capital lease financing. Our burn rate is approximately $1 million per month and may increase modestly during 2004. Cash reserves of about $15.5 million as of February 16, 2004 should be sufficient to fund operations during 2004 and into the first quarter of 2005.

Recent Developments

Fundraising In February 2004, we completed a private placement transaction with the sale to investors of 11,110,477 shares of our common stock plus warrants and options for total gross proceeds to us of $10.9 million.

Settlement of Plasma Operations Receivables In January 2004, we settled our outstanding receivables from Precision Pharma Services, Inc. in the amount of $5.5 million at December 27, 2003 in exchange for $1.7 million in cash plus the return to us of 4.4 million shares of our common stock held by Precision, with a value of approximately $4.9 million based on the market closing price of the Nasdaq National Market on the date prior to settlement.

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 (SAB) No. 101 (SAB 101), *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 of property and equipment and intangible assets, 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. We amortize acquired intangible assets using the straight-line method over their economic lives, which range from 5 to 15 years. Determining the

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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 accurate 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*. 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.

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.

As discussed in Note 10 to the consolidated financial statements, during 2002 we 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. At that time, the INACTINE system was in early development, was more labor intensive, and was expected to require a larger area for a given volume of red cells. Also, it was believed that a separate site might be required for our FDA Biologics License Application. Since then, there has been significant progress in automating the system and reducing space requirements so that it currently can be implemented in community blood centers by blood center staff. Further, we concluded that the facility will not be required for our BLA. We have a smaller processing laboratory at the Watertown facility for clinical trial support and to display the INACTINE process. We have therefore concluded that the second site is not required and are taking steps to sublease the space or otherwise restructure our obligations under the lease. The site has not been placed in service and, accordingly, most build-out costs were not amortized. Due to this decision and reflecting our lease obligations, we recorded a non-cash charge of $1.4 million within research and development costs in fiscal year 2003 to write off our capitalized build-out costs and to provide for estimated lease and associated carrying costs until the facility is sublet or the lease is terminated.

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*. 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. We adopted SFAS No. 142 during the first quarter of 2002 without a material impact on our financial position or results of operations.

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During the fourth quarter of 2003, we halted a Phase III clinical trial which we were conducting in a chronic population due to safety concerns of an independent Data Safety Monitoring Committee. While there were no serious adverse events associated with the trial, we are evaluating our alternatives to deal with the issues which were observed. This development triggered an impairment review of goodwill and long-lived assets under SFAS No. 142 and SFAS No. 144, respectively. The results of our reviews indicated that an impairment charge was not required.

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 described in Note 4 to the consolidated financial statements, we had outstanding receivables from Precision Pharma Services, Inc. totaling $5.5 million at December 27, 2003. Precision provides contract plasma fractionation services. Its largest customer, who is under contract with Precision until the end of 2004, recently announced that it is offering its plasma business for sale. This created uncertainty about Precision s business and ability to make payments of the amounts due to the Company. Subsequent to year-end, this uncertainty was resolved when we fully realized the outstanding receivables through a settlement in which we received $1.7 million in cash proceeds and the return of 4.4 million shares of our common stock with a value of approximately $4.9 million based on the market closing price of the Nasdaq National Market on the date prior to settlement.

Results of Operations

Fiscal Year 2003 as Compared to Fiscal Year 2002

Net Revenues- Research Funding

Fiscal Year 2003	Fiscal Year 2002	Increase/(Decrease)	%
$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 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 year 2003 and 2002, respectively.

Research and Development

Fiscal Year 2003	Fiscal Year 2002	Increase/(Decrease)	%
$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

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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 is currently 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 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. 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. 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 the laboratory.

In the fourth quarter of 2003, following the 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. These actions lowered our spending rate in December 2003 into the range of approximately $1.0 million per month from the previous $2.0 per month, primarily related to research and development. We expect fiscal 2004 research and development costs to be initially in the range of $1.0 million per month and to increase modestly as the Phase III acute trial continues.

Cumulatively, we have invested $146.7 million in research and development on pathogen inactivation technologies for blood products since our inception in 1995, including the cost of in-process research and development resulting from our 1999 merger with Pentose Pharmaceuticals, Inc.

Our Phase III clinical trial program for the INACTINE system began in January 2003. The Phase III acute trial is ongoing. We are evaluating our alternatives to deal with the issues identified in the Phase III chronic trial. We are evaluating possible corrective actions to address the issues observed in the trial. Possible corrective actions might require us to significantly change the INACTINE system so as to enable us to continue to test the system for use with chronic patients. If such significant changes were required, we may decide to pursue an indication for use of the existing process only in acute transfusions. We believe that pursuing an acute only indication would allow us to bring the INACTINE system to market faster, taking advantage of substantial progress we have made in research, clinical, pathogen inactivation and toxicology studies. We might then choose to address the combined acute and chronic markets in a second generation INACTINE system. Should we decide to pursue this approach, we would require FDA concurrence. At this point we are unable to assess what additional studies, if any, would be required by FDA or the time or cost in completing the studies. Our work is designed to lead to the preparation and filing of a Biologics License Application (BLA) for submission to the FDA which initiates the final step of FDA review, prior to a decision by the FDA whether to grant approval to market the system in the U.S. The time involved in this stage of the FDA review is not within our control, and we cannot reasonably estimate this time period. After we reach consensus with the FDA on the U.S. clinical and regulatory requirements for licensure, we will be developing and implementing a strategy to achieve marketing approval of the INACTINE system in the European Community and Japan. We have not yet developed estimates of the timing and related cost for these markets.

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

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either unpredictable or outside our control, including the enrollment rates and results of the Phase III clinical trial, the extent of further studies which could be required for filing a BLA 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. These factors are also described in the section entitled Risk Factors in this report. Accordingly, we are unable to estimate, with any degree of precision, either the total future costs that will be required to continue and complete the commercialization of the INACTINE system, or the period in which we can expect material net cash inflows from the system.

General and Administrative Expenses

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

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

Plasma Operations Impairment

Fiscal Year 2003	Fiscal Year 2002	Increase/(Decrease)	%
$	$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

Fiscal Year 2003	Fiscal Year 2002	Increase/(Decrease)	%
$0.2 million expense	$0.4 million income	$(0.6 million)	(150)%

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.

Fiscal Year 2002 as Compared to Fiscal Year 2001

Net Revenues-Research Funding

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$4.2 million	$6.3 million	$(2.1 million)	(33)%

Research funding decreased as a result of our August 2002 modification of the Pall collaboration. Under terms of that modification, we assumed responsibility from Pall for funding of the INACTINE red cell program. Prior to August 2002, research funding was principally from Pall Corporation.

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Processing revenue for 2001 was related to the Plasma Operations which we divested in August 2001; accordingly, we had no processing revenue in 2002.

Research and Development

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$20.4 million	$19.2 million	$1.2 million	6%

The increase from 2001 includes a non-recurring $1.0 million royalty prepayment in 2002 in connection with engineering services for the INACTINE system as well as component development costs and outside studies of the safety profile of the INACTINE system.

Selling, General and Administrative Expenses

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$5.9 million	$8.7 million	$(2.8 million)	(32)%

The decrease reflects lower administrative staffing levels required for our operations subsequent to the divestiture of the Plasma Operations in August 2001.

Cost of Sales

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$	$15.7 million	$(15.7 million)	(100)%

Cost of sales in fiscal year 2001 contains costs incurred by the Plasma Operations prior to the divestiture of those operations on August 14, 2001. Accordingly, there were no cost of sales in 2002.

Plasma Operations Impairment

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$1.6 million credit	$6.8 million charge	$(8.4 million)	(124)%

We recorded a net asset impairment charge during fiscal 2001 due to the divestiture of our Plasma Operations in August of that year. In 2002, we recorded credits 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 Income, Net

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$0.4 million income	$0.1 million income	$0.3 million	300%

The difference from fiscal 2001 to 2002 was due primarily to lower average term debt obligations during 2002.

Provision for Income Taxes

For fiscal years 2002 and 2001, we have recorded no income tax expense or benefit. At December 28, 2002 and December 29, 2001, we established a full valuation allowance against our net deferred tax asset positions of $47.2 million and $38.0 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.

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Liquidity and Capital Resources

We finance our operations primarily through sales of our common stock, research and development grants, short-term debt and capital lease financing.

At December 27, 2003, we had working capital of $6.8 million, including cash of $4.3 million, in comparison with working capital of $5.5 million, including cash of $6.7 million at the prior year end. Subsequent to fiscal year end, we settled term receivables related to the 2001 sale of our plasma operations for cash of $1.7 million and for the return of 4.4 million shares of our common stock. Also, in February 2004, we completed a private placement of our common stock for gross proceeds of $10.9 million.

As previously discussed, we restructured our operations in November 2003 to reduce our cash spending from $2 million per month into the range of $1 million per month. We expect our monthly spending rate to continue in that approximate range in early 2004 and to increase modestly as we continue our clinical trials in 2004. The rate of enrollment in our clinical trial program will be the most significant factor in 2004 spending. A combination of our opening cash balances and fundraising through February 2004 has resulted in available cash balances of approximately $15.5 million as of February 16, 2004. These cash balances are invested with the primary objectives of safety of principal and liquidity. We believe that these resources will be sufficient to fully meet our cash needs during 2004 and into the first quarter of 2005.

Our cash activity during 2003 was comprised of the following (in millions):

Net proceeds from equity transactions	$ 21.7
Collection of receivables	0.9
Cash used in operating activities	(21.2)
Net repayment under revolving credit facility	(2.5)
Repayment on advances and capital lease obligations	(1.2)
Additions to property and equipment	(0.1)
Decrease in cash position	$ (2.4)

Our 2003 equity transactions included the issuance of common stock in connection with a $14.0 million rights offering, a $4.0 million equity milestone investment by Pall Corporation and a private placement of $4.0 million in December 2003. In fiscal 2002, we generated cash primarily from the receipt of partner research funding, drawdowns under a Pall Corporation revolving credit facility, and collection of outstanding receivables.

The following table represents our outstanding contractual obligations at December 27, 2003, in thousands:

	Total	Less than 1 Year	Years 1-3	Years 4-5	More than 5 Years
Operating Leases	$ 7,008	$ 1,114	$ 3,606	$ 2,266	$ 22

Repayment of Advances	2,440	1,061	1,379		
Total	9,448	$ 2,175	$ 4,985	$ 2,266	$ 22

New Accounting Pronouncements

In January 2003, the FASB issued Interpretation (FIN) No. 46, Consolidation of Variable Interest Entities (FIN 46) and, in December 2003, issued a revision to that interpretation (FIN 46R). FIN 46R replaces FIN 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity (VIE) is defines as (a) an ownership, contractual or monetary interest in an entity where the ability to influence financial decisions is not proportional to the investment interest, or (b) an entity lacking the invested capital sufficient to fund future activities without the support of a third party. FIN 46R establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary, including those to which the usual condition for consolidation does not apply. At December 27, 2003, the Company had no financial instruments falling within the scope of FIN 46R.

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In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. This Statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. SFAS No. 149 is effective for contracts entered into or modified and for hedging relationships designated after June 30, 2003. At December 27, 2003, the Company had no financial instruments falling within the scope of SFAS No. 149.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. At December 27, 2003, the Company had no financial instruments falling within the scope of SFAS No. 150.

Pro Forma Results of Operations

The following unaudited pro forma statements of operations are based on our historical consolidated financial statements after giving effect to the divestiture of our Plasma Operations as if the sale had occurred on the first day of fiscal year 2001. In deriving these unaudited pro forma statements, we eliminated revenues, cost of sales, research and development expenses, sales and marketing costs, divestiture adjustments and interest expense associated with the Plasma Operations from the historical financial statements. These unaudited pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the results of operations that actually would have been reported had the divestiture occurred on the first fiscal day of 2001, or of our future results of operations.

Pro Forma Condensed Consolidated Statements of Operations

For the fiscal years ended December 27, 2003, December 28, 2002 and December 29, 2001

(unaudited) (in thousands, except for per share data)

	December 27, 2003	December 28, 2002	December 29, 2001
Revenues research funding	$ 716	$ 4,225	$ 6,264
Cost and expenses:			
Research and development costs	18,508	20,351	19,128
General and administrative expenses	4,334	5,942	8,416
Total operating costs and expenses	22,842	26,293	27,544
Loss from operations	(22,126)	(22,068)	(21,280)
Interest income (expense), net	(227)	400	470
Net loss	$ (22,353)	$ (21,668)	$ (20,810)

Basic and diluted net loss per share	$ (0.67)	$ (0.95)	$ (0.93)
Weighted average common shares used in computing basic and diluted net loss per share	33,360	22,752	22,325

Fiscal 2003 as Compared to Pro Forma Fiscal 2002

Net Revenues Research Funding

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

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The decrease in research funding is primarily a result of our August 2002 modification of the Pall collaboration, under terms of which we assumed responsibility from Pall for funding of the INACTINE red cell program. Prior to August 2002, research funding 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 year 2003 and 2002, respectively.

Research and Development

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

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 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. 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. 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 the laboratory.

In the fourth quarter of 2003, following the 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. These actions lowered our spending rate in December 2003 into the range of approximately $1.0 million per month from the previous $2.0 million per month, primarily related to research and development. We expect fiscal 2004 research and development costs to be initially in this range of $1.0 million per month and to increase modestly as the Phase III acute trial continues.

General and Administrative Expenses

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

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

Interest (Expense) Income, Net

Fiscal Year 2003	Fiscal Year 2002	Increase/(Decrease)	%
$0.2 million expense	$0.4 million income	$(0.6 million)	(150)%

We recorded net interest expense of $0.2 million in fiscal year 2003 versus net interest income of $0.4 million in fiscal year 2002, a decrease of $0.6 million. 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.

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Pro Forma Fiscal 2002 as Compared to Pro Forma Fiscal 2001

Net Revenues

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$4.2 million	$6.3 million	$(2.1 million)	(33)%

Research funding decreased as a result of our August 2002 modification of the Pall collaboration. Under terms of that modification, we assumed responsibility from Pall for funding of the INACTINE red cell program. Prior to August 2002, research funding was principally from Pall Corporation.

Research and Development

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$20.4 million	$19.1 million	$1.3 million	7%

The increase from 2001 includes a non-recurring $1.0 million royalty prepayment in 2002 in connection with engineering services for the INACTINE system as well as component development costs and outside studies of the safety profile of the INACTINE system.

General and Administrative Expenses

Fiscal Year 2002	Fiscal Year 2001	Increase/(Decrease)	%
$5.9 million	$8.4 million	$(2.5 million)	(30)%

The decrease reflects lower administrative staffing levels required for our operations subsequent to the divestiture of the Plasma Operations in August 2001 as well as a credit of approximately $0.3 million in the fourth quarter of fiscal 2002 for adjustment of compensation-related accrued expenses.

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. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition, results of operations, or cash flows could be materially adversely affected. These risks should be read in

conjunction with the other information set forth in this report.

Risks Related to Our Business

We have historically incurred operating losses and these losses will continue.

We have historically incurred substantial operating losses due to our research and development activities in blood safety and we expect these losses to continue for the foreseeable future. As of December 27, 2003, we had an accumulated deficit of approximately $151.2 million. Our fiscal year 2003 losses were $22.4 million. During the next several years, we expect to continue our INACTINE development efforts and other research activities. The INACTINE red blood cell Phase III clinical trial program is being conducted in the U.S. and clinical studies will likely occur in other geographic markets. Product commercialization activities will be at a higher level and our expenditures for research and development may increase after 2004. We will actively seek new financing from time to time and will seek marketing partners to provide financial support to our INACTINE red blood cell program. However, at this time we are not able to assess the probability of success in our fundraising efforts or the terms under which we may secure financial support. It is likely that we will continue to incur operating losses for the foreseeable future.

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We will need additional capital in the future, but our access to such capital is uncertain.

Our current resources are insufficient to fund all of our commercialization efforts. As of February 16, 2004, we had cash on hand of approximately $15.5 million. At present, we are consuming approximately $1.0 million in cash per month and expect this spending rate to increase modestly as we continue our clinical trial program in 2004. We believe that our present cash resources will be adequate to meet our requirements during 2004 and into the first quarter of 2005. Our capital needs beyond fiscal 2004 will depend on many factors, including our research and development activities, the scope of our clinical trial program, the timing of regulatory approval for our products under development and the successful commercialization of our products. Our needs may also depend on the magnitude and scope of these activities, the progress and the level of success in our 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 additional collaboration and licensing arrangements and the cost of manufacturing scale-up and development of marketing activities, if undertaken by us. We do not have committed external sources of funding, and we may not be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, we may be required to:

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

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

Our success depends on new products and systems which we are developing, but may be unable to commercialize due to numerous factors, including regulatory requirements on both us and our customers.

The success of our business depends on the successful development and commercialization of pathogen reduction products and systems, including products based on the INACTINE system. Successful commercialization of our products and systems under development depends, in significant part, on our ability to:

- complete their development in a timely fashion;
- demonstrate their safety in clinical trials;
- obtain and maintain patents or other proprietary protections;

obtain required regulatory approvals;

implement efficient, commercial-scale manufacturing processes;

sell into relevant markets before competitors;

obtain approval for reimbursement under health care systems; and

establish and maintain sales, marketing, distribution and development collaborations.

Our pathogen inactivated blood products are under development and have 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

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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 2003 and 2002, we spent approximately $18.5 million and $20.4 million on research and development, respectively.

We must provide the FDA and foreign regulatory authorities with pre-clinical and clinical data that demonstrate our products are safe and effective before they can be approved for commercial sale. Our lead product candidate, the INACTINE system, is currently in a Phase III clinical trial for patients requiring acute transfusions. Until November 2003, we were also conducting a Phase III clinical trial with patients requiring chronic transfusions. On the advice of an independent data safety monitoring committee (DSMC), we stopped enrollment in the chronic trial and the continued testing of the INACTINE system for use in chronic patients is currently under review. We are evaluating possible corrective actions to address the issues observed in the trial. Possible corrective actions might require us to significantly change the INACTINE system so as to enable us to continue to test the system for use with chronic patients. If such significant changes were required, we may decide to pursue an indication for use of the existing process only in acute transfusions. Should we decide to pursue this approach, we would require FDA concurrence. We are unable to assess what additional studies the FDA may require, if any, under this approach. The acute study currently continues to enroll patients. At this time we cannot ensure that the acute trial will complete enrollment in a timely manner or predict whether unanticipated events or circumstances, including antibody responses to INACTINE treated red cells observed in the chronic study, could prevent completion of the trial.

The results from pre-clinical studies and early clinical trials conducted by us will not ensure that results obtained in our Phase III clinical trials 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. Our completion of clinical trials may also be delayed by slower than anticipated patient enrollment, negative or inconclusive clinical results or other adverse events occurring during the clinical trials. Therefore, we cannot ensure that clinical trials will demonstrate sufficient safety and efficacy to obtain required marketing approvals on a timely basis, if at all.

Delays in our clinical testing or approval from government authorities will increase our product development costs and may impair our ability to commercialize our products and allow competitors to bring products to market before we do. Our 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 we have 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 our 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 our business. Later discovery of problems with our product 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 our 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

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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 us and our products and systems, there are regulatory requirements applicable to our prospective customers, 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 our pathogen reduction systems. FDA delays in approving these supplements may deter some blood centers from using our 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 our products.

If we fail to establish and maintain relationships with strategic collaborators and distributors, we may be unable to market our products.

We intend to enlist strategic collaborators for sales, marketing and distribution support and for financial support in the development of our INACTINE Pathogen Reduction System for red cells. We will seek distribution partners for the commercialization of our INACTINE system for red cells. If we fail to develop new strategic partnerships or to maintain existing alliances, the failure will delay or possibly inhibit the commercialization of our products.

For example, in order to effectively market our products outside the United States, we 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 we cannot guarantee that the negotiations with new collaborators will yield positive results. Even if we find 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 us.

Our technologies are new and unproven. We will need to gain market acceptance to generate revenue.

We believe that market acceptance of our products and systems will depend on our ability to provide acceptable evidence of their safety, efficacy and cost-effectiveness. Implementation of our systems will involve new investment by our customers, which we believe will result in significant improvements in safety and cost savings in health care. We believe that market acceptance of our products and systems will also depend upon the extent to which physicians, patients and health care payers perceive that the benefits of using our products and systems justify the additional costs and processing requirements. Our products and systems may not gain any significant degree of market acceptance among blood centers, physicians, patients and health care payers, even if clinical trials demonstrate safety and efficacy and necessary regulatory approvals and health care reimbursement approvals are obtained. If our products and systems fail to achieve market acceptance, we may never become profitable.

A small number of customers will determine market acceptance of our products.

A defined number of blood collection services will dominate any market for the INACTINE Pathogen Reduction System for red cells. 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, each of which

distributes approximately 6 percent of the nation s supply of blood and blood components. In Western 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 our products to any of these large customers could significantly diminish potential product revenue.

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We rely on a limited number of suppliers to manufacture our inactivation compound and other components of our INACTINE Pathogen Reduction System for red cells.

Our INACTINE system uses a small molecule compound known as PEN110 to inactivate pathogens. We have a contract with one manufacturer for PEN110 and will seek to qualify additional manufacturers to produce this compound to meet our anticipated commercialization requirements. If any of these additional manufacturers, which have not yet been identified, or our existing manufacturer cannot produce and deliver this compound in the required quantities, to the required standards, or in a timely manner we may face delays in the commercialization of the INACTINE system before we are 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, cell debris and other impurities. We worked with an engineering firm to develop the automated delivery system which is now being qualified for use in our clinical trials. This system and related system disposables could be manufactured by several suppliers and we have not yet entered commercial supply agreements.

We are currently using a cell washing system manufactured by Haemonetics, which we exclusively license from Haemonetics pursuant to a development and manufacturing agreement. When and if our 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, we would be required to identify other third-party manufacturers.

We 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 us to seek new approvals from governmental regulatory authorities, which could result in delays in product delivery. We may not be able to receive any such required regulatory approvals.

If we do not successfully distinguish and commercialize our technology, we may be unable to compete successfully or to generate revenue significant to sustain our operations.

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

Many of our competitors or potential competitors, including our principal competitors Cerus Corporation and Gambro, have substantially greater financial and other resources than we have and may also have greater experience in conducting pre-clinical studies, clinical trials and other regulatory approval procedures as well as in marketing their products. If we or our corporate partners commence commercial product sales, we or our corporate partners will be competing against companies with greater marketing and manufacturing capabilities. Our competitors may obtain patent protection, receive FDA approval or commercialize products before we do.

Our ability to compete successfully against currently existing and future alternatives to our pathogen reduction technology and competitors who compete directly with us in the pathogen reduction industry will depend, in part, on our ability to:

attract and retain skilled scientific and research personnel;

develop technologically superior products;

develop competitively priced products;

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obtain patent or other required regulatory approvals for our products;

be early entrants to the market; and

manufacture, market and sell our products, independently or through collaborations.

Third-party reimbursement policies may adversely affect our ability to commercialize and sell our products and services.

Our ability to successfully commercialize our products depends in part on the extent to which appropriate levels of reimbursement for our 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 our products or systems to obtain appropriate levels of reimbursement could adversely affect our ability to sell these products and systems.

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 our 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, our products. We anticipate that we will need to work with a variety of organizations to lobby government agencies for improved reimbursement policies for our products. However, we cannot guarantee that such lobbying efforts will take place or that they will ultimately be successful.

If we are unable to protect our intellectual property, we may not be able to operate our business profitably.

Our success depends on our ability to develop proprietary products and technologies, to obtain and maintain patents, to protect trade secrets, and to prevent others from infringing on our proprietary rights. We have exclusive patents, licenses to patents and patent applications covering critical components of our technologies. We also seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees and certain contractors. Our 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 us may not result in patents being issued. We cannot be certain that our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors 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, we cannot predict with certainty their enforceability.

Our 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, our competitors may obtain patent protection or other intellectual property rights for technology similar to ours that could limit our ability to use our technology or commercialize products that we may develop.

Litigation may be necessary to assert claims of infringement, to enforce patents issued to us, 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 we are ultimately unable to protect our technology, trade secrets or know-how, we may be unable to

operate profitably.

If we are unable to operate our business without infringing upon intellectual property rights of others, we may not be able to operate our business profitably.

Our success depends on our ability to operate without infringing upon the proprietary rights of others. We are aware that patents have been applied for and/or issued to third parties claiming technologies for decontamination

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of blood and blood products that may be similar to those needed by us. We endeavor to follow developments in these fields and we do not believe that our 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, we would need a license under such patents or other intellectual property rights to continue development and marketing of our products. Any required licenses may not be available on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties patents or we may not be able to proceed with the development, manufacture or sale of our products.

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 we are ultimately unsuccessful in defending against claims of infringement, we may be unable to operate profitably.

If we lose or are unable to hire and retain qualified personnel, we may not be able to develop our products and technology.

We are highly dependent on the members of our scientific and management staff but have no formal employment agreements with our employees. Although we believe we have been successful in attracting and retaining our employees, we 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 we lose an executive officer or certain key members of our clinical or research and development staff or are unable to hire and retain qualified personnel, then our ability to develop and commercialize our products and technology may be hindered. We have not purchased any key-man life insurance. To date, no executive officer or key employee has notified us of any plans to terminate employment with us.

We use and generate hazardous materials in our research activities. Defending against any claims relating to the improper handling, storage, release or disposal of these materials could be time consuming and costly.

We are 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. There can be no assurance that we will not be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development activities, including development of the INACTINE Pathogen Reduction System for red cells, involve the controlled use of hazardous materials, including certain hazardous chemicals, viruses and radioactive materials. Although we believe that our 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, we could be held liable for any damages that result, and any such liability could exceed our insurance limits and our cash resources.

We may face exposure to product liability claims.

We may face exposure to product liability and other claims due to allegations that our products cause harm. These risks are inherent in our Phase III clinical trials which are currently underway and in the testing, and future manufacturing and marketing of human blood products, including our INACTINE system. Although we currently maintain product liability insurance, such insurance may not be adequate and we may not be able to obtain adequate insurance coverage in the future at a reasonable cost, if at all. If we are unable to obtain product liability insurance in the future at an acceptable cost or to otherwise protect against potential product liability claims, we could be inhibited in the commercialization of our products which could have a material adverse effect on our business.

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Risks Related to Our Stock

Our stock price is volatile and you may not be able to resell your shares at or above the price you paid for them.

We first publicly issued common stock on June 11, 1998 at $12.00 per share in our initial public offering. Between June 11, 1998 and February 20, 2004 the closing sale price has ranged from a high of $17.62 per share to a low of $0.45 per share. The market price of our common stock could continue to fluctuate substantially due to a variety of factors, including:

- quarterly fluctuations in results of operations;
- the announcement of new products or services by us or competitors;
- changes in or failure to meet earnings estimates by securities analysts;
- sales of common stock by existing stockholders or the perception that these sales may occur;
- adverse judgments or settlements obligating us to pay damages;
- negative publicity;
- loss of key personnel;
- developments concerning proprietary rights, including patents and litigation matters; and
- clinical trial or regulatory developments in both the United States and foreign countries.

In addition, overall stock market volatility has often significantly affected the market prices of securities for reasons unrelated to a company s operating performance. In the past, securities class action litigation has been commenced against companies that have experienced periods of volatility in the price of their stock. Securities litigation initiated against us could cause us to incur substantial costs and could lead to the diversion of management s attention and resources, which could have a material adverse effect on our revenue and earnings.

The sale of a substantial number of shares of our common stock could cause the market price of our common stock to decline and may impair our ability to raise capital through additional offerings.

On February 11, 2004, we completed a private placement financing in which we sold investors 11,110,477 shares of our common stock, warrants to purchase an aggregate of 4,444,183 shares of our common stock, and purchase options to purchase 2,777,615 shares of our common stock. In addition, we issued warrants to purchase an aggregate of 466,639 shares of our common stock to the placement agent in the transaction. We will issue warrants to purchase up to 83,328 shares of our common stock to the placement agent when investors exercise their purchase options. We agreed to register for resale the common stock issued or issuable upon exercise of the warrants and purchase options that were issued in the financing.

All of those shares of common stock and the shares issuable upon exercise of the warrants and purchase options will be freely saleable once a Registration Statement covering the resale of such shares becomes effective. We expect such a Registration Statement will become effective during the first quarter of 2004. These shares represent approximately 35% of the total number of our shares of common stock that are currently issued and outstanding. Sales of these shares in the public market, or the perception that future sales of these shares could occur, could have the effect of lowering the market price of our common stock below current levels and make it more difficult for us and our shareholders to sell our equity securities in the future.

Our executive officers, directors and holders of more than 5% of our common stock collectively beneficially own approximately 33% of the outstanding common stock as of February 20, 2004. In addition, approximately 2,171,000 shares of common stock issuable upon exercise of vested stock options could become available for immediate resale if such options were exercised.

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Sale or the availability for sale, of shares of common stock by stockholders could cause the market price of our common stock to decline and could impair our ability to raise capital through an offering of additional equity securities.

Our executive officers and directors own sufficient shares of our common stock to significantly affect the results of any stockholder vote.

Our executive officers and directors, including those directors representing Ampersand Ventures, beneficially own approximately 22% of our common stock as of February 20, 2004. As a result, these executive officers and directors as a group might have the ability to significantly influence the outcome of matters requiring a stockholder vote.

Anti-takeover provisions may frustrate attempts to replace our current management and discourage investors from buying our common stock.

Certain provisions of our restated certificate of incorporation and restated by-laws in effect as of February 20, 2004, as well as the Delaware General Corporation Law, reduce the power of stockholders generally, even those with a majority of the voting power in our Company, to remove incumbent directors and to fill vacancies on the Board of Directors without the support of the incumbent directors.

In addition, our restated certificate of incorporation and restated by-laws provide that stockholder action may not be effected without a duly called meeting. Our restated certificate of incorporation and restated by-laws also do not permit our stockholders to call special meetings of stockholders. This effectively limits the ability of our stockholders to conduct any form of consent solicitation.

Provisions of the DGCL, our restated certificate of incorporation and restated by-laws could discourage a third party from attempting to acquire, or make it more difficult for a third party to acquire, control of our Company without approval of our Board of Directors, even if such acquisition were beneficial to other stockholders. Moreover, the provisions of the DGCL and our restated certificate of incorporation and restated by-laws relating to the removal of directors and the filling of vacancies on the Board of Directors preclude a third party from removing incumbent directors without cause and simultaneously gaining control of the Board of Directors by filling, with its own nominees, the vacancies created by removal. Such provisions could also limit the price that certain investors might be willing to pay in the future for shares of the common stock. Such provisions also allow the Board of Directors to authorize the issuance of preferred stock with rights superior to those of the common stock.

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 herein incorporated by reference.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING

AND FINANCIAL DISCLOSURE

None.

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Item 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. Our principal executive officer and 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, have 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 them 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.

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PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Incorporated by reference from the portions of the Definitive Proxy Statement 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 entitled Executive Compensation and Additional Information Compensation of Directors .

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Incorporated by reference from the portions of the Definitive Proxy Statement 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 entitled Certain Relationships and Related Transactions .

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Incorporated by reference from the portion of the Definitive Proxy Statement entitled Independent Public Accountants.

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) Consolidated Financial Statements

Report of Independent Auditors	Page 46
Consolidated Balance Sheets as of December 27, 2003 and December 28, 2002	Page 47
Consolidated Statements of Operations for the years ended December 27, 2003, December 28, 2002 and December 29, 2001	Page 48
Consolidated Statements of Stockholders Equity for the years ended December 27, 2003, December 28, 2002 and December 29, 2001	Page 49
Consolidated Statements of Cash Flows for the years ended December 27, 2003, December 28, 2002 and December 29, 2001	Page 50
Notes to Consolidated Financial Statements	Page 51

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) Reports on Form 8-K

Current Report on Form 8-K, filed November 19, 2003, announcing our financial results for the third quarter ended September 27, 2003 as well as our receipt of a recommendation from an independent Data Safety Monitoring Committee to halt enrollment in our Phase III chronic trial of the INACTINE Pathogen Reduction System for red blood cells (File No. 000-24241);

Current Report on Form 8-K, filed November 25, 2003, announcing our restructuring of operations leading to a significant reduction in ongoing operating expenses (File No. 000-24241); and

Current Report on Form 8-K, filed December 9, 2003, announcing that we had entered into definitive agreements for a $3.4 million private placement (File No. 000-24241).

(c) 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.

Exhibit Number	Description
2.1	Agreement and Plan of Merger dated as of July 28, 1999 among the Company, Pentose and certain stockholders of Pentose. Filed as Exhibit 2 to the Registration Statement on Form S-4 (No. 333-87443) and incorporated herein by reference.
2.2	Amendment dated as of November 8, 1999 to Agreement and Plan of Merger dated as of July 28, 1999 among VITEX, Pentose and certain stockholders of Pentose. Filed as Exhibit 2.1 to the Registration Statement on Form S-4, as amended (No. 333-87443) and incorporated herein by reference.
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.

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Exhibit Number	Description
3.2	Certificate of Amendment of Restated Certificate of Incorporation, dated November 12, 1999. Filed as Exhibit 3.2 to the Registrant s 2000 Annual Report on Form 10-K and incorporated herein by reference.
3.3	Certificate of Amendment of Restated Certificate of Incorporation, dated May 30, 2001. Filed as Exhibit 3.3 to the Registrant s Registration Statement on Form S-3 dated March 22, 2001, as amended on June 4, 2001 (Registration Statement No. 333-57418) and incorporated herein by reference.
3.4	Certificate of Amendment of Restated Certificate of Incorporation, dated March 10, 2003. Filed as Exhibit 3.4 to the Registrant s 2002 Annual Report on Form 10-K and incorporated herein by reference.
3.5	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.
3.6	Amended and Restated By-laws of the Company; Filed as Exhibit 3.3 to the Registrant s Registration Statement on Form S-3 dated March 22, 2001, as amended on June 4, 2001 (Registration Statement No. 333-57418) 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	Stock Warrant between the Company and Bear, Stearns & Co. Inc., dated April 29, 1997. Filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
4.3	Warrant to Purchase Common Stock between the Company and the Trustees of Columbia University in the City of New York, dated June 21, 1996. Filed as Exhibit 4.3 to the Registrant s Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
4.4	Contingent Stock Subscription Warrant between the Company and CB Capital Investors, Inc., dated April 29, 1997. Filed as Exhibit 4.4 to the Registrant s Registration Statement on Form S-1, as amended (Registration Statement No. 333-46933) and incorporated herein by reference.
4.5	Form of Warrant, dated December 5, 2003 issued to investors in a private placement. Filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-3 dated December 15, 2003, as amended (Registration Statement No. 333-111186) and incorporated herein by reference.
4.6	Form of Warrant. Filed as Annex C to the Registrant s Definitive Proxy Statement filed January 26, 2004 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 Stock Option Plan. Filed as Annex C 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	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.

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Exhibit Number	Description
10.6+	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.
10.7+	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.
10.8	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.
10.9++	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.
10.10++	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.
10.11	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.
10.12	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.
10.13*	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.
10.14*	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.
10.15	Indenture of lease made and entered into as of August 4, 1999 by and between Pentose Pharmaceuticals, 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.
10.16++	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.
10.17++	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	Securities Purchase Agreement, dated December 5, 2003, between the Registrant and the Purchasers set forth on the signature pages thereto. Filed as Exhibit 10.1 to the Registrant s Registration Statement on Form S-3 dated December 15, 2003, as amended (Registration Statement No. 333-111186) and incorporated herein by reference.

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Exhibit Number	Description
10.21	Registration Rights Agreement, dated December 5, 2003. Filed as Exhibit 10.2 to the Registrant s Registration Statement on Form S-3 dated December 15, 2003, as amended (Registration Statement No. 333-111186) and incorporated herein by reference.
10.22	Form of Securities Purchase Agreement. Filed as Annex B to the Registrant s Definitive Proxy Statement filed January 26, 2004 and incorporated herein by reference.
10.23	Form of Registration Rights Agreement. Filed as Annex A to the Registrant s Definitive Proxy Statement filed January 26, 2004 and incorporated herein by reference.
10.24	Agreement and Mutual Release between the Company and Precision Pharma Services, Inc. dated January 12, 2004. Filed herewith.
14.1	V.I. 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.
23.1	Consent of KPMG LLP. Filed herewith.
31.1	Certification of Chief Executive Officer. Filed herewith.
31.2	Certification of Chief Financial Officer. Filed herewith.
32	Section 906 certification of periodic financial report by Chief Executive Officer and 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

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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

John R. Barr

President and Chief Executive Officer

February 27, 2004

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.

Signatures	Title	Date
/s/ John R. Barr John R. Barr	President, Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2004
/s/ Samuel K. Ackerman, M.D. Samuel K. Ackerman, M.D.	Chairman of the Board of Directors	February 27, 2004
/s/ Thomas T. Higgins Thomas T. Higgins	Executive Vice President, Operations, (Principal Financial Officer and Principal Accounting Officer)	February 27, 2004
/s/ Richard A. Charpie Richard A. Charpie	Director	February 27, 2004
/s/ Jeremy Hayward-Surry Jeremy Hayward-Surry	Director	February 27, 2004
/s/ Irwin Lerner Irwin Lerner	Director	February 27, 2004
/s/ Joseph M. Limber	Director	February 27, 2004

Joseph M. Limber		
/s/ Doros Platika, M.D.	Director	February 27, 2004
Doros Platika, M.D.		
/s/ David Tendler	Director	February 27, 2004
David Tendler		

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REPORT OF INDEPENDENT AUDITORS

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 27, 2003 and December 28, 2002 and the related consolidated statements of operations, stockholders equity and cash flows for each of the years in the three-year period ended December 27, 2003. 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 auditing standards generally accepted in the United States of America. 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 27, 2003 and December 28, 2002 and the results of its operations and its cash flows for each of the years in the three-year period ended December 27, 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Boston, Massachusetts

February 19, 2004

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V. I. TECHNOLOGIES, INC.

Consolidated Balance Sheets

	December 27, 2003	December 28, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,258,322	$ 6,658,681
Restricted cash	589,988	589,988
Other receivables, net	4,176,496	6,493,122
Prepaid expenses and other current assets	637,946	693,684
Total current assets	9,662,752	14,435,475
Property and equipment, net	3,119,196	4,960,725
Intangible assets, net	2,719,926	2,967,191
Goodwill	397,549	397,549
Other assets, net	1,379,489	
Total assets	$ 17,278,912	$ 22,760,940
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Revolving credit facility	$	$ 2,500,000
Accounts payable	915,370	1,574,731
Accrued expenses	723,381	1,084,816
Current portion of deferred revenue	152,628	152,628
Current portion of advances	1,061,336	3,478,547
Capital lease obligations		157,640
Total current liabilities	2,852,715	8,948,362
Advances	1,379,489	
Deferred revenue	801,297	953,925
Total liabilities	5,033,501	9,902,287
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 and outstanding 45,929,875 at December 27, 2003 and 22,771,821 at December 28, 2002	459,299	227,718
Additional paid-in-capital	163,433,235	141,464,492
Deferred compensation	(460,581)	
Accumulated deficit	(151,186,542)	(128,833,557)
Total stockholders equity	12,245,411	12,858,653
Total liabilities and stockholders equity	$ 17,278,912	$ 22,760,940

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

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V.I. TECHNOLOGIES, INC.

Consolidated Statements of Operations

	Year ended December 27, 2003	Year ended December 28, 2002	Year ended December 29, 2001
Revenues:			
Research funding	$ 715,766	$ 4,224,889	$ 6,264,233
Processing revenue			20,628,258
Net revenues	715,766	4,224,889	26,892,491
Costs and expenses:			
Research and development costs	18,507,614	20,350,784	19,224,249
Selling, general and administrative expenses	4,334,557	5,942,142	8,725,129
Cost of sales			15,696,850
Plasma Operations divestiture (credit) charge		(1,627,950)	6,800,835
Total operating costs and expenses	22,842,171	24,664,976	50,447,063
Loss from operations	(22,126,405)	(20,440,087)	(23,554,572)
Interest income (expense), net	(226,580)	400,252	134,607
Net loss	$ (22,352,985)	$ (20,039,835)	$ (23,419,965)
Basic and Diluted net loss per share	$ (0.67)	$ (0.88)	$ (1.05)
Weighted average shares used in calculation of basic and diluted net loss per share	33,359,934	22,752,222	22,316,424

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

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V.I. TECHNOLOGIES, INC.

Consolidated Statements of Stockholders Equity

Years ended December 27, 2003, December 28, 2002 and December 29, 2001

	Common Stock		Additional Paid-In	Deferred	Accumulated	Total Stockholders
	Shares	Amount	Capital	Compensation	Deficit	Equity
Balance at December 30, 2000	20,780,839	$ 207,808	$ 130,323,222	$	$ (85,373,757)	$ 45,157,273
Issuance of common stock under stock option and purchase plans	282,810	2,828	1,048,210			1,051,038
Issuance of shares of common stock under a private placement	1,666,667	16,667	9,983,333			10,000,000
Net loss					(23,419,965)	(23,419,965)
Balance at December 29, 2001	22,730,316	227,303	141,354,765		(108,793,722)	32,788,346
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)
Balance at December 28, 2002	22,771,821	227,718	141,464,492		(128,833,557)	12,858,653
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)
Balance at December 27, 2003	45,929,875	$ 459,299	$ 163,433,235	$ (460,581)	$ (151,186,542)	$ 12,245,411

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

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V. I. TECHNOLOGIES, INC.

Consolidated Statements of Cash Flows

	December 27, 2003	December 28, 2002	December 29, 2001
Cash flows from operating activities:			
Net loss	$ (22,352,985)	$ (20,039,835)	$ (23,419,965)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,061,142	1,075,717	3,379,630
Net discount (accretion) of interest	162,030	(142,500)	107,419
Plasma Operations divestiture (credit) charge		(1,627,950)	6,800,835
Reserve for disposal of long-lived assets and facility costs	1,364,943		
Compensation expense on restricted common stock	12,974		
Changes in operating accounts:			
Other receivables, net	(95,775)	1,149,840	952,457
Prepaid expenses and other current assets	55,738	85,485	196,358
Accounts payable	(659,361)	37,927	(796,450)
Accrued expenses	(607,634)	(1,294,779)	(2,526,416)
Deferred revenue	(152,628)	(152,628)	(145,069)
Due to related parties, net			(120,288)
Trade receivables			2,703,972
Inventory			(32,671)
Net cash used in operating activities	(21,211,556)	(20,908,723)	(12,900,188)
Cash flows from investing activities:			
Additions to property and equipment	(91,092)	(1,478,877)	(1,725,411)
Proceeds from Plasma Operations divestiture	924,588	2,000,000	25,000,000
Proceeds (purchases) of short-term investments		3,332,385	(3,332,385)
Restricted cash to support letter of credit			(589,988)
Net cash provided by investing activities	833,496	3,853,508	19,352,216
Cash flows from financing activities:			
Net proceeds from issuance of common stock	21,726,769	110,142	11,051,038
Principal repayment of long-term debt			(2,687,500)
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	(1,091,428)		
Principal repayment of capital lease obligations	(157,640)	(255,434)	(1,224,076)
Net cash provided by financing activities	17,977,701	2,354,708	7,139,462
Net (decrease)/increase in cash and cash equivalents	(2,400,359)	(14,700,507)	13,591,490
Cash and cash equivalents, beginning of period	6,658,681	21,359,188	7,767,698
Cash and cash equivalents, end of period	$ 4,258,322	$ 6,658,681	$ 21,359,188

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

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 27, 2003, December 28, 2002 and December 29, 2001

1. Organization and Business Overview

V.I. Technologies, Inc. (Vitex or the Company), a biotechnology company headquartered in Watertown, Massachusetts, is developing products designed to improve the safety of the world s blood supply. The Company s INACTINE Pathogen Reduction System for red cells (the INACTINE System) is designed to inactivate a wide range of viruses, bacteria, parasites and lymphocytes from red blood cells and has also demonstrated in non-clinical trials high efficiency in removing prion proteins. 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 s lead product candidate, the INACTINE System, is in a Phase III clinical trial.

Efforts are underway to demonstrate the system s success in three areas necessary for commercial viability: broad pathogen kill, a wide safety margin for the patient, and minimal interference with the function of the red cell.

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 27, 2003, has an accumulated deficit of $151.2 million. In fiscal year 2003, the Company s net cash flows used in operating activities was approximately $21.2 million which the Company financed primarily though sales of common stock totaling $21.7 million during the year. In November 2003, the Company restructured its operations and reduced spending (see Note 11). To finance its spending in 2004, the Company sold common stock for gross proceeds of $4.0 million in December 2003, settled outstanding receivables for Precision Pharma Services, Inc (Precision) collecting cash proceeds of $1.7 million in January 2004 and sold common stock for gross proceeds of $10.9 million in January 2004. Further, certain shareholders of the Company exercised stock options totaling $0.35 million subsequent to year end 2003. Management believes that a combination of its cash on hand at the beginning of fiscal 2004 plus completed fundraising through February 16, 2004 will be sufficient to support the Company s operations through fiscal 2004.

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.

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.

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

Fiscal Year End

The Company prepares its financial statements on the basis of a 52-week fiscal year ending on the Saturday closest to the end of the calendar year. In these notes to the accompanying financial statements, the years ended December 27, 2003, December 28, 2002 and December 29, 2001 are referred to as fiscal years 2003, 2002 and 2001, respectively..

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 and intangible assets, recoverability of long-lived assets 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

Restricted cash at December 27, 2003 and December 28, 2002 is comprised of $0.6 million of certificates of deposit for letters of credit on the Company s leased facilities.

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.

Intangible Assets

Intangible assets principally consist of core technology acquired in the Pentose Pharmaceutical, Inc. (Pentose) merger in 1999. Core technology is being amortized on a straight-line basis over fifteen years. Periodically, the Company reviews the recoverability of its intangible assets. The measurement of possible impairment is based primarily on the ability to recover the balance of the intangible assets from expected future operating cash flows on an undiscounted basis. Accumulated amortization relating to intangible assets amounted to $1.0 million and $0.7 million, at December 27, 2003 and December 28, 2002, respectively. Amortization expense for intangible assets amounted to $0.2 million for fiscal years 2003, 2002 and 2001.

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

Goodwill

Goodwill was acquired in the Pentose merger in 1999 and, as discussed in Note 3, was not amortized after fiscal 2001. Accumulated goodwill amortization amounted to $0.14 million at December 27, 2003 and December 28, 2002. Amortization expense for goodwill amounted to $0.1 million for fiscal year 2001.

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.

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 $3.57 million and $5.8 million in fiscal years 2002 and 2001, respectively. Also included within research funding is amortized revenue related to non-refundable up-front and milestone payments of Amersham Pharmacia Biotech (Amersham) which are amortized over the life of the related agreement. These amounts totaled $0.15 million for each of fiscal years 2003, 2002 and 2001 (see Note 12). In addition, the Company recorded minimum royalty payments from Amersham of $0.1 million, $0.2 million and $0.05 million in fiscal years 2003, 2002 and 2001, respectively. Research funding also includes grants received from the National Institutes of Health in the amount of $0.46 million, $0.3 million and $0.3 million in fiscal years 2003, 2002 and 2001, respectively.

Revenue earned by the Company s Plasma Operations was recognized in the period in which the processing services were rendered and upon satisfaction of certain quality control requirements. It was not subject to repayment or future performance obligations. Processing revenue was derived from providing services to Bayer Corporation and to the American National Red Cross. Bayer and the Red Cross contributed 89 percent and 11 percent, respectively, of total processing revenue in fiscal 2001 prior to the Plasma Operations divestiture described in Note 4.

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.

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

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. 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 2003, 2002 and 2001, had they been included in the computation, would have been approximately 171,000, 152,000, and 211,000, 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 27, 2003, the Company has four stock-based employee compensation plans, which are described more fully in Note 8.

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.

	2003	2002	2001
Net loss:			
As reported	$ (22,352,985)	$ (20,039,835)	$ (23,419,965)
Add: Stock-based compensation expense	3,380,706	2,273,221	1,160,977
Pro forma	$ (25,733,691)	$ (22,313,056)	$ (24,580,942)
Basic and diluted net loss per share:			
As reported	$ (0.67)	$ (0.88)	$ (1.05)
Pro forma	$ (0.77)	$ (0.98)	$ (1.10)

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:

	2003		2002		2001	
	Stock Options	ESPP	Stock Options	ESPP	Stock Options	ESPP
Volatility	120%	99% 262%	94%	69% 166%	70%	57%-92%
Expected dividend yield	0%	0%	0%	0%	0%	0%
Risk-free interest rate	3.0%	0.9% 1.2%	3.1%	1.6% 1.9%	4.6	1.8%-4.3%
Expected life in years	5	0.25	5	0.25	5	0.25

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

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 vests quarterly during 2004. Compensation expense of $0.013 million was recorded in fiscal year 2003.

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. Specifically, intellectual property costs were reclassified from research and development costs to selling, general and administrative expenses in the amount of $1.2 million for fiscal year 2002 and $1.0 million for fiscal year 2001. Intellectual property costs in fiscal year 2003 totaled $0.5 million.

New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46) and, in December 2003, issued a revision to that interpretation (FIN 46R). FIN 46R replaces FIN 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity (VIE) is defined as (a) an ownership, contractual or monetary interest in an entity where the ability to influence financial decisions is not proportional to the investment interest, or (b) an entity lacking the invested capital sufficient to fund future activities without the support of a third party. FIN 46R establishes standards for determining under what circumstances

VIEs should be consolidated with their primary beneficiary, including those to which the usual condition for consolidation does not apply. At December 27, 2003, the Company had no financial instruments falling within the scope of FIN 46R.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. This Statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities . SFAS No. 149 is effective for contracts entered into or modified and for hedging relationships designated after June 30, 2003. At December 27, 2003, the Company had no financial instruments falling within the scope of SFAS No. 149.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. At December 27, 2003, the Company had no financial instruments falling within the scope of SFAS No. 150.

3. Goodwill and Other Intangible Assets

The Company adopted SFAS No. 142 *Goodwill and Other Intangible Assets* on the first day of fiscal 2002. The Company s intangible assets on that date consisted of goodwill (workforce) of $0.4 million and core technology of $3.2 million. The Company designated the fourth quarter for its annual review of impairment. There was no impairment indicated by the tests in fiscal 2003 or 2002.

In accordance with SFAS No. 142, goodwill is no longer amortized. Previously, goodwill was amortized over five years and amortization expense was $0.1 million in fiscal 2001. Had the Company accounted for goodwill under SFAS No. 142 on the first day of fiscal 2001, its net loss for that year would have been reduced by $0.1 million and net loss per share would have been unchanged.

Core technology is amortized over its estimated useful life of fifteen years. At December 27, 2003, core technology was recorded at gross carrying value of $3.7 million less accumulated amortization of $1.0 million. Amortization expense on core technology was $0.2 million in fiscal years 2003, 2002 and 2001. In each of the next five years, amortization expense is estimated to be approximately $0.2 million per annum.

4. Plasma Operations Receivables

In August 2001, the Company divested its plasma operations to Precision for approximately $34.0 million. Precision is 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 (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. This holdback is recorded in other receivables in the balance sheet at December 27, 2003 at its current net present value of $2.8 million.

In addition, Precision was required to fund a $3.5 million continuing obligation of the Company. This obligation is being amortized over a three year period ending in February 2006. The outstanding balance at December 27, 2003 was $2.7 million. Both obligations were subordinated to senior debt obligations to Precision s principal bank.

The Company reported in its 2003 third quarter report on Form 10-Q that it was in preliminary discussions with Precision to settle the obligations. At that time, Vitex reported that Precision s largest customer intended to exit the plasma business thereby creating uncertainty about Precision s ability to make payments against amounts due to the Company. 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

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

on the market closing price of the Nasdaq National Market on the date prior to settlement. In January 2004, 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 4.4 million shares of its common stock.

The Company s unaudited pro forma results for fiscal year 2001 assuming the divestiture occurred on the first day of fiscal year 2001 are as follows:

	2001
Net revenues	$ 6,264,233
Net loss	$ (20,810,430)
Basic and diluted loss per share	$ (0.93)

These unaudited pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the results of operations that actually would have resulted had the divestiture occurred on the first day of fiscal 2001 or the future results of operations.

5. Property and Equipment

Property and equipment consist of the following components:

	2003	2002
Leasehold improvements	$ 2,640,588	$ 2,640,588
Laboratory equipment	2,348,289	2,226,834
Office furniture and equipment	874,306	882,329
Construction in progress	80,854	1,241,104
	5,944,037	6,990,855
Accumulated depreciation and amortization	(2,824,841)	(2,030,130)
	$ 3,119,196	$ 4,960,725

There are no outstanding capital leases at December 27, 2003. The cost of laboratory equipment held under capital leases and the related accumulated depreciation amounted to $0.6 million and $0.3 million at December 28, 2002, respectively. Amortization expense for equipment under a capital lease amounted to $0.1 million, $0.1 million and $0.4 million, respectively, for fiscal years 2003, 2002 and 2001, respectively.

During 2003, the Company wrote off construction in progress of $1.1 million for a facility which it does not intend to place in service (see Note 10).

6. Accrued Expenses

Accrued expenses consist of the following components:

	2003	2002
Accrued operating taxes	$	$ 75,000
Accrued employee compensation	231,280	624,470
Accrued facility costs (see Note 10)	246,199	
Other	245,902	385,346
	$ 723,381	$ 1,084,816

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

7. Stockholders Equity

Common Stock

On March 2, 2001, the Company sold 1,666,667 shares of the Company s common stock to an outside investor at the market price of $6.00 per share for a total of $10.0 million gross proceeds.

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 12) 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 July 25, 2003, the Company s shareholders voted to increase the number of authorized shares of common stock from 60 million to 75 million.

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 warrants to purchase 1,965,418 shares of common stock at $1.32 per share and purchase options to purchase 1,111,658 shares of common stock at $0.90 per share. Total transaction costs were approximately $0.4 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 vest quarterly during 2004. Compensation expense will be recognized over the one-year vesting period.

See Note 17 for common stock transactions subsequent to year end.

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 27, 2003 or December 28, 2002.

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 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

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

deductions, periodic lump sum payments or both. The 1998 Purchase Plan terminates in February 2008. The 1998 Purchase Plan was amended in June 2002 to increase the shares of common stock reserved from 89,445 to 200,000 and in July 2003 to increase the shares of common stock reserved from 200,000 to 400,000. There are 226,315 shares available for future purchase as of December 27, 2003. During the fiscal years ended December 27, 2003, December 28, 2002 and December 29, 2001, 65,396 shares, 29,600 shares and 19,037 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 67,000 options are available for future grants at December 27, 2003.

Equity Incentive Plans

As of December 29, 2001, the Company had 3,000,000 shares of common stock reserved for issuance under the 1998 Equity Incentive Plan (the 1998 Equity Plan). The 1998 Equity Plan was amended in June 2002 to increase the shares of common stock reserved to 4,000,000. The 1998 Equity Plan was amended in July 2003 to increase the shares of common stock reserved to 4,750,000. As of December 27, 2003, 68,800 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.

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 of common stock reserved under the plan of which 146,486 options are available for future grants as of December 27, 2003. 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.

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Information as to options for shares of common stock granted for fiscal years 2003, 2002 and 2001 is as follows:

	2003		2002		2001	
	Options	Weighted-average exercise price	Options	Weighted-average exercise price	Options	Weighted-average exercise price
Outstanding, beginning of year	2,606,287	$ 6.51	2,397,483	$ 6.95	2,632,558	$ 6.79
Granted	1,809,365	2.11	547,937	4.83	542,629	6.90
Exercised	(115,296)	0.56	(11,905)	5.10	(263,773)	3.63
Forfeited	(293,152)	4.39	(327,228)	6.92	(513,931)	7.41
Outstanding, end of year	4,007,204	4.85	2,606,287	6.51	2,397,483	6.95
Exercisable, end of year	2,171,210	6.14	1,475,078	7.12	1,181,768	7.13
Weighted average fair value of options granted during the year		$ 1.88		$ 1.75		$ 4.26

The following table summarizes the information on stock options outstanding at December 27, 2003:

	Options Outstanding			Options Exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life	Weighted average exercise price	Number exercisable	Weighted-average exercise price
$0.03	11,092	2.4	$ 0.03	11,092	$ 0.03

$0.5 0.75	48,920	6.7	0.66	8,235	0.62
$0.76 1.12	53,250	7.7	0.88	12,500	0.85
$1.13 1.68	12,000	9.0	1.35	12,000	1.35
$1.69 2.52	1,664,396	9.5	2.14	464,141	2.08
$2.53 3.78	82,180	1.8	2.89	77,305	2.85
$3.79 5.67	557,718	6.9	5.23	259,218	4.90
$5.68 $8.50	1,302,381	5.4	7.53	1,089,846	7.68
$8.51 12.75	274,731	5.3	10.24	236,337	10.40
$12.76 $17.59	536	0.1	4.85	536	17.58
	4,007,204			2,171,210	

Investor Options and Warrants

The Company issued 4,446,665 shares of its common stock in December 2003 for gross proceeds of $4.0 million. Investors in that transaction received a purchaser option to acquire an additional 25% of these shares (or 1,111,658 shares) at the transaction price of $0.90 per share during the five-month period following registration of the initial shares. This option period ends in June 2004. Between 2003 fiscal year end and February 16, 2004, options on 388,884 shares have been exercised for total gross proceeds of $0.35 million. Investors also received four-year warrants to purchase 1,965,418 shares of common stock at $1.32 per share. The value of these options and warrants at December 27, 2003 was $0.2 million and $0.6 million, respectively.

At December 27, 2003, the Company also had 15,812 outstanding warrants to purchase common stock with exercise prices ranging from $2.80 to $6.14. These warrants expire at various dates between March 2004 and March 2006.

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

9. Income Taxes

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

	2003	2002
Deferred tax assets:		
Research and development tax credits	$ 3,070,898	$ 2,563,502
Net operating loss carryforwards	52,512,802	45,744,201
Other, net	1,088,568	708,885
Total deferred tax assets	56,672,268	49,016,588
Valuation allowance	(55,143,554)	(47,172,511)
Net deferred tax assets	1,528,714	1,844,077
Deferred tax liabilities	(1,528,714)	(1,844,077)
	$	$

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

	2003	2002
Tax at federal statutory rate	(34.0)%	(34.0)%
State tax, net of federal benefit	%	%
Change in valuation allowance	35.7%	38.6%
Research and development credits	(2.3)%	(2.6)%
Other	0.6%	(2.0)%
Provision for taxes	%	%

At December 27, 2003 and December 28, 2002 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 $8.0 million in fiscal year 2003 and $9.1 million in fiscal year 2002.

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 $131.3 million. At December 27, 2003, the Company has available net operating loss carry-forwards for federal and state income tax reporting purposes of approximately $131.3 million, and has available research and development credit carry-forwards for federal income tax reporting purposes of approximately $3.1 million, which are available to offset future taxable income, if any. Federal carry-forwards will expire beginning in 2010. State carry-forwards will expire beginning in 2004. 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 $131.3 million includes $11.5 million from the acquisition of Pentose in 1999 which is subject to an annual limitation of $2.1 million.

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10. 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.

At that time, the INACTINE system was in early development, was more labor intensive, and was expected to require a larger area for a given volume of red cells. Also, it was believed that a separate site might be required for the Company s FDA Biologics License Application (BLA). Since then, there has been significant progress in automating the system and reducing space requirements so that it currently can be implemented in community blood centers by the blood center staff. Further, the Company has concluded that the facility will not be required for its BLA. The Company has a smaller processing laboratory at the Watertown facility for clinical trial support and to display the INACTINE process. It has concluded that the second site is not required and is taking steps to sublease the space. The site has not been placed in service and, accordingly, most build-out costs were not amortized. Due to this decision and reflecting its lease obligations, the Company recorded a non-cash charge of $1.4 million within research and development costs in fiscal year 2003 to write-off its capitalized build-out costs and to provide for estimated lease and associated carrying costs until the facility is sublet or the lease is terminated. The facility lease runs to 2008. Total remaining payments under the lease are approximately $1.0 million. The Company anticipates subleasing the facility under terms similar to its primary lease obligations or reaching a satisfactory lease termination agreement with the landlord.

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. The chronic study was divided into two parts: Part A and Part B. Upon completion of Part A, an interim safety analysis including review by an independent Data Safety Monitoring Committee (DSMC) required by the FDA was performed. On November 17, 2003 the DSMC issued its recommendation that the trial not proceed into Part B, and that the data be reviewed by the Company. This recommendation reflected a concern by the DSMC with antibody responses to INACTINE treated red cells and associated clinical assessments in trial participants. There were no serious adverse events associated with the study treatment. The Company has halted the chronic trial, reviewed patient trial data and evaluated the recommendation of the DSMC, and is assessing its alternatives to address the needs of the chronic population. The acute study is continuing to enroll patients.

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. These actions lowered the Company s spending rate to the range of approximately $1.0 million per month from the previous $2.0 million per month. Also, the Company performed a review of its long-lived assets and goodwill to assess possible impairment. The review was performed in accordance with the guidelines of SFAS No. 142, *Goodwill and Other Intangible Assets* and SFAS No.144, *Accounting for the Impairment or Disposal of Long-Lived Assets* . The review indicated that an impairment reserve was not required.

12. 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

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

leading manufacturer and supplier of filtration products, including those relating to the collection, preservation, processing, manipulation, storage and treatment of blood and blood products. 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 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 Company a one year $5.0 million revolving credit facility and committed to an additional $4.0 million equity investment.

Under the original Pall Agreements and the modified collaboration, Pall provided the Company reimbursement for red cell program expenses of approximately $3.6 million and $5.8 million during fiscal years 2002 and 2001 and 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 27, 2003, Pall owned 13.4% percent of the Company s outstanding shares.

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. Under the agreement Amersham will exclusively market and distribute the Company s INACTINE Pathogen Reduction System for red cells to manufacturers of biopharmaceuticals and transgenic products and to plasma fractionators. Vitex retains 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 and could also receive further payments of $1.0 million subject to certain product testing and FDA approval milestones. In addition, the Company will receive a percentage royalty based on net sales made by Amersham of products which incorporate the INACTINE system. The Company provides Amersham with technical support, training and conducts research and development projects as directed by Amersham during the ten-year term of the agreement. In accordance with SAB 101, the payments will be recognized from the date of receipt of the payments through the end of the term of the agreement or approximately ten years. For each of fiscal years 2003, 2002 and 2001, 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. The balance of $1.0 million is reflected as deferred revenue in the consolidated balance sheet as of December 27, 2003. In addition, the Company recorded research funding revenue of $0.1 million, $0.2 million and $0.05 million for fiscal years 2003, 2002 and 2001, respectively, from royalty payments due under the terms of the agreement.

Plasma Operations Agreements

Prior to the divestiture of its Plasma Operations (see Note 4), the Company maintained commercial relationships with two principal customers: Bayer Corporation (Bayer) and the American National Red Cross (the Red Cross). The Company processed Bayer plasma into intermediate plasma derivatives and returned these products for further manufacturing within Bayer s production facilities. Commercial terms were documented in the 1995 Agreement for Custom Processing (the Processing Agreement) which, with amendments extended to 2003. This Processing Agreement was assigned to Precision in the Plasma Operations divestiture.

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V.I. TECHNOLOGIES, INC.

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The Company also processed plasma for the Red Cross into virally inactivated transfusion plasma which was marketed by the Red Cross under the brand, PLAS+®SD. Commercial terms were documented in the 1997 Supply, Manufacturing, and Distribution Agreement (the Agreement). Prior to the divestiture of the Plasma Operations, the Company exercised its rights to terminate the Agreement in June 2001.

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 of approximately 8.0 percent. In March 2003, the Company and Red Cross restructured the obligation to bear interest at 10.0 percent 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. Precision reimbursed the Company for these payments. At December 27, 2003, the balance sheet reflects an outstanding balance of $2.4 million due the Red Cross.

13. Other Related Party Transactions

License Agreements

The Company was spun-off from the New York Blood Center, Inc. (NYBC) in 1995. Under terms of the spin-off, NYBC transferred to the Company various net assets including the Plasma Operations plant, related operating and product licenses and certain other tangible and intangible assets. The Company also became the licensee of a portfolio of patents and patent applications held by the NYBC, including those related to the use of the SD viral inactivation technology. In exchange for these net assets, the NYBC received all of the issued and outstanding common stock of the Company. In 2001 the Company terminated the last active license from NYBC and made required royalty payments of $0.7 million.

Other Services

The Company purchased $0.2 million of production related materials and supplies from Pall Corporation in fiscal year 2001.

The Company has an arrangement for scientific consulting services with its Chairman under terms of which it paid fees of $0.1 million in each of fiscal years 2003, 2002 and 2001. In 2001, the Company purchased $0.1 million in processing services from a company in which the Chairman was an officer and investor and Ampersand is an investor.

14. Supplemental Disclosure of Cash Flow Information

Information on cash paid for interest and non-cash investing and financing activities are as follows:

	2003	2002	2001
Cash paid during the year for interest	$ 358,000	$ 65,000	$ 276,000
Capital lease obligations incurred for purchase of equipment			259,000

15. 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 $0.1 million in each of fiscal years 2003, 2002, and 2001.

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V.I. TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 27, 2003, December 28, 2002 and December 29, 2001

16. Commitments and Contingencies

Lease and Other Commitments

Future minimum lease payments under non-cancelable operating leases at December 27, 2003 are as follows:

2004	$ 1,113,826
2005	1,123,945
2006	1,232,949
2007	1,249,460
2008	1,241,033
Thereafter	1,047,200

The Company leases its office facilities under non-cancelable operating leases that expire at various dates through 2009. Rent expense was approximately $1.3 million, $1.2 million and $1.0 million for fiscal years 2003, 2002, and 2001, respectively.

17. Subsequent Events

Fundraising

On February 10, 2004, the Company sold 11.1 million shares of its common stock for total gross proceeds of $10.9 million. Investors received a purchaser option to buy an additional 25% of these shares (2.8 million shares) within the five-month period post registration and also received four-year warrants to purchase an additional 4.4 million shares. The placement agent received warrants to purchase up to an additional 0.5 million shares.

Divestiture Receivables

As described in Note 4, in January 2004, the Company settled $5.5 million in outstanding receivables from Precision in exchange for receiving $1.7 million in cash plus the return of 4.4 million Vitex shares, with a value of $4.9 million based on the market closing price of the Nasdaq National Market on the date prior to settlement.

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

	December 27, 2003	September 27, 2003	June 28, 2003	March 29, 2003
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)

	December 28, 2002	September 28, 2002	June 29, 2002	March 30, 2002
Net revenues research funding	$ 204	$ 182	$ 1,878	$ 1,961
Plasma Operations Divestiture credit	1,297	331		
Net loss	(4,641)	(5,957)	(5,492)	(3,950)
Loss per share basic and diluted	$ (0.20)	$ (0.26)	$ (0.24)	$ (0.17)

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EXHIBIT INDEX

10.24	Agreement and Mutual Release between the Company and Precision Pharma Services, Inc. dated January 12, 2004.
23.1	Consent of KPMG LLP.
31.1	Certification of Chief Executive Officer.
31.2	Certification of Chief Financial Officer.
32	Section 906 certification of periodic financial report by Chief Executive Officer and Chief Financial Officer.