

VIACELL INC  
Form 10-K  
March 31, 2006

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2005**

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

**For the transition period from            to**

**Commission file number: 0-51110**

**ViaCell, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

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

**04-3244816**

*(I.R.S. Employer  
Identification No.)*

**245 First Street,**

**Cambridge, Massachusetts**

*(Address of principal executive offices)*

**02142**

*(Zip code)*

**(Registrant's telephone number, including area code)**

**(617) 914-3400**

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

**None**

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

**Common Stock, \$0.01 par value**

*(Title of class)*

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Edgar Filing: VIACELL INC - Form 10-K

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

The aggregate market value of the Registrant's Common Stock held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter was \$301,894,783.

As of March 29, 2006, the Registrant had 38,602,549 shares of Common Stock, \$0.01 par value, issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive Proxy Statement for our 2006 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

---

**Table of Contents**

**ViaCell, Inc.**  
**Annual Report on Form 10-K**  
**For the Fiscal Year Ended December 31, 2005**  
**NOTE ABOUT REFERENCES TO VIACELL**

Throughout this report, the words we, our, us and ViaCell refer to ViaCell, Inc. and its subsidiaries.

**NOTE ABOUT TRADEMARKS**

ViaCell® and ViaCord® are registered trademarks of ViaCell, Inc. ViaCyte<sup>sm</sup> is a service mark of ViaCell, Inc.

**NOTE ABOUT FORWARD-LOOKING STATEMENTS**

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to the potential and anticipated results of our development programs, and our views as to the possible outcome of pending litigation and actions related to our intellectual property portfolio. We have based these forward-looking statements on our current expectations about such future events. While we believe these expectations are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those discussed in this report under the heading Risk Factors That May Affect Results beginning at page 19. Given these risks and uncertainties, you are cautioned not to place substantial weight on forward-looking statements. The forward-looking statements included in this report are made only as of the date of this report. We do not undertake any obligation to update or revise any of these statements.

## TABLE OF CONTENTS

|  | Page No |
|--|---------|
| <b><u>PART I</u></b>   |         |
| <b><u>ITEM 1</u></b>   | 4       |
| DESCRIPTION OF BUSINESS  |         |
| <b><u>ITEM 1A</u></b>  | 19      |
| RISK FACTORS THAT MAY AFFECT RESULTS   |         |
| <b><u>ITEM 1B</u></b>  | 33      |
| UNRESOLVED STAFF COMMENTS  |         |
| <b><u>ITEM 2</u></b>   | 33      |
| DESCRIPTION OF PROPERTY  |         |
| <b><u>ITEM 3</u></b>   | 34      |
| LEGAL PROCEEDINGS  |         |
| <b><u>ITEM 4</u></b>   | 35      |
| SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS  |         |
| <b><u>PART II</u></b>  |         |
| <b><u>ITEM 5</u></b>   | 36      |
| MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS                       |         |
| <b><u>ITEM 6</u></b>   | 38      |
| SELECTED CONSOLIDATED FINANCIAL DATA   |         |
| <b><u>ITEM 7</u></b>   | 39      |
| MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS          |         |
| <b><u>ITEM 7A</u></b>  | 56      |
| QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK                                     |         |
| <b><u>ITEM 8</u></b>   | 56      |
| CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA                                       |         |
| <b><u>ITEM 9</u></b>   | 56      |
| CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE           |         |
| <b><u>ITEM 9A</u></b>  | 56      |
| CONTROLS AND PROCEDURES  |         |
| <b><u>ITEM 9B</u></b>  | 57      |
| OTHER INFORMATION  |         |
| <b><u>PART III</u></b>   |         |
| <b><u>ITEM 10</u></b>  | 57      |
| DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT   |         |
| <b><u>ITEM 11</u></b>  | 59      |
| EXECUTIVE COMPENSATION   |         |
| <b><u>ITEM 12</u></b>  | 60      |
| SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS |         |
| <b><u>ITEM 13</u></b>  | 60      |
| CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS   |         |
| <b><u>ITEM 14</u></b>  | 60      |
| PRINCIPAL ACCOUNTING FEES AND SERVICES   |         |
| <b><u>PART IV</u></b>  |         |
| <b><u>ITEM 15</u></b>  | 60      |
| EXHIBITS AND FINANCIAL STATEMENT SCHEDULES   |         |
| <b><u>Signatures</u></b>   | 63      |
| <b><u>Financial Statements</u></b>   | F-1     |
| <b><u>Ex-10.18 First Amendment dated February 14, 2006 to Lease Agreement</u></b>              |         |
| <b><u>EX-23.1 Consent of Independent Registered Public Accounting Firm</u></b>                 |         |
| <b><u>Ex-31.1 Section 302 Certification of C.E.O.</u></b>                                      |         |
| <b><u>Ex-31.2 Section 302 Certification of C.F.O.</u></b>                                      |         |
| <b><u>Ex-32.1 Section 906 Certification of C.E.O.</u></b>                                      |         |
| <b><u>Ex-32.2 Section 906 Certification of C.F.O.</u></b>                                      |         |

**Table of Contents**

**PART I**

**ITEM 1. DESCRIPTION OF BUSINESS**

**Overview**

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. We have a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. We are currently conducting a Phase I clinical trial of CB001, our lead umbilical cord blood-derived stem cell therapy product candidate as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In addition to our therapeutic research and development programs, we have a reproductive health business unit that generated revenues of \$43.8 million in 2005 from sales of ViaCord, a product offering through which expectant families can preserve their baby's umbilical cord blood for possible future medical use. We are working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte<sup>sm</sup>, our investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs.

ViaCell was incorporated in the State of Delaware on September 2, 1994. Our corporate headquarters and main research facility is located in Cambridge, Massachusetts. We have processing and storage facilities in Hebron, Kentucky and an additional research and development operation in Singapore.

**Our Cellular Therapy Technology and Product Candidates**

ViaCell is dedicated to enabling the widespread application of human cells as medicine. We have focused our research and development efforts on investigating the potential therapeutic uses of umbilical cord blood-derived and adult-derived stem cells and on technology for the expansion of the populations of these cells. We are developing a pipeline of proprietary adult and umbilical cord blood-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. Below is an overview of the cell therapy area and a description of our cell therapy-related technology and product candidates.

***Stem Cell Therapy***

The human body is comprised not only of cells that have differentiated into specific tissues (such as skin, liver or blood) but also cells, known as stem cells that are not fully differentiated. As stem cells grow and proliferate, they are capable of producing both additional stem cells as well as cells that have differentiated to perform a specific function. To date, researchers have identified many different types of stem cells from many sources. These include, for example, stem cells found in umbilical cord blood and placenta, hematopoietic stem cells from bone marrow, pancreatic islet stem cells from the pancreas, neural stem cells from the brain, and embryonic stem cells from embryos. Each type of stem cell appears to have unique properties. For instance, some stem cells propagate well but are difficult to differentiate efficiently, some stem cells differentiate efficiently but are difficult to propagate, some stem cells appear to be unipotent in that they can only make one class of tissue, while others appear to be pluripotent in that they can make a variety of tissue types. Stem cells are found in different concentrations and in different locations in the body during a person's lifetime. Current scientific findings suggest that each organ and tissue in the body is formed, maintained and possibly rejuvenated to different degrees, on a more or less continual basis under normal conditions, by specific and relatively rare stem cell populations naturally present in the body.

Stem cell therapy represents an increasingly important modality in the medical and scientific community's efforts to find treatments and cures for human disease. Stem cell therapy involves the use of stem cells to replace and initiate the production of other cells and tissues that are missing or damaged due to disease or injury. For example, today, hematopoietic stem cell therapy is commonly used as a treatment for a variety of cancers to re-establish and maintain the blood and immune system by regenerating healthy, functioning bone marrow. Hematopoietic stem cell therapy is a medical procedure in which bone marrow, umbilical cord blood or processed circulating blood, all of which contain hematopoietic stem cells, are infused into the patient's circulatory system, where they find their way to the bone cavity. Once established in the bone, if the transplant

## **Table of Contents**

is successful, they begin to grow, or engraft, and produce cells of the blood and immune systems. Cells for this procedure are typically obtained from a donor, though, in some cases, the patient's own cells may be used. Hematopoietic stem cell therapy can be used to:

replace diseased bone marrow with healthy, functioning bone marrow for patients with blood diseases such as aplastic anemia;

replace bone marrow damaged by high-dose chemotherapy or radiation therapy used to treat patients with a variety of cancers such as leukemia and lymphoma; and

provide genetically healthy and functioning bone marrow to treat patients with genetic diseases such as sickle cell anemia.

According to the International Bone Marrow Transplant Registry, 45,000 hematopoietic stem cell transplants were performed worldwide in 2002. Many more patients needed transplants, but suitably compatible cells could not be found.

Current scientific and clinical research indicates that stem cells may also have promise in the treatment of diseases in addition to those currently addressed with hematopoietic stem cell therapy. Researchers are investigating the therapeutic potential of stem cells in a number of areas including in the treatment of cardiac, neurological, neuromuscular, immunological, genetic, pancreatic, liver and degenerative diseases as well as various types of cancer.

Despite the proven clinical utility of hematopoietic stem cell therapy and excitement over the potential of stem cell therapy and other cellular therapies to treat other types of diseases, significant challenges exist on the path toward widespread application, including:

*Need for HLA Matching.* Stem cell therapy is dependent on the recipient's body accepting the newly transplanted stem cells, thus facilitating the production of the targeted cells. This acceptance is contingent on the transplanted cells looking similar, at a molecular level, to the patient's own cells. Cellular similarity is measured by the presence of certain cell surface molecules known as human leukocyte antigens, or HLA. Host cells recognize the HLA pattern of the transplanted stem cells and will either accept the cells if the HLA match is close, or reject the cells if the HLA profile is not close enough. In hematopoietic stem cell transplantation, HLA mismatching can give rise to a very serious condition called graft-versus-host disease, or GVHD. GVHD is an attack by the transplanted immune cells on tissues of the host potentially resulting in severe disease, significant disability and often, in the most severe forms, death. Time consuming and expensive searches of a donor registry are often required to locate compatible donors for bone marrow or cord blood stem cell transplants. Due to these difficulties, and others, many patients seeking transplants of hematopoietic stem cells from non-related individuals do not receive stem cells.

*Harvesting Cells.* In general, harvesting sufficient quantities of stem cells from a donor or a patient is extremely difficult. For example, all current methods of obtaining hematopoietic stem cells for therapy have significant limitations. Stem cells can be collected from bone marrow through a painful, costly and invasive surgical procedure. There are not enough bone marrow donors registered and, when called upon, a large number of donors fail to follow through with the procedure. Stem cells can also be collected from blood of the circulatory system through a procedure in which drugs are injected into the donor to stimulate the movement of stem cells from the bone marrow into the blood stream, where they can be harvested and then separated from the whole blood. This procedure is time-consuming and uncomfortable for the donor. Umbilical cord blood is also rich in stem cells, but the volume of blood collected is limited. A single cord blood unit is generally too small to be suitable to treat adult patients. Stem cells can also be derived from human embryonic tissue. However, the utility of embryonic stem cells is presently technically limited and is further hampered by ethical and regulatory issues that restrict their use.

Expansion. The number of stem cells collected from any particular tissue source is typically low compared to the quantity required for therapeutic benefit. For example, bone marrow, processed



**Table of Contents**

circulating blood and umbilical cord blood are crude mixtures of largely differentiated cells with small numbers of stem cells, contributing to unpredictability in clinical responses. The likelihood and speed of successful stem cell engraftment are directly related to the number of stem cells transplanted. Consequently, the ideal approach to a successful transplant is to use a large number of stem cells. Researchers have been working for decades on methods for expanding populations of donated stem cells, but their efforts have been largely unsuccessful. Most attempts to increase the number of stem cells involve methods of growing or culturing stem cells in batches. Batch production of stem cells is generally not considered effective because differentiated cell populations outgrow stem cells and create by-products that hinder the growth and maintenance of stem cells. Few stem cells, if any, are produced using this process. The mixed populations of cells that result are also difficult to characterize, creating the possibility of clinical side effects as compared to a pure stem cell population. Furthermore, batch production of cells is expensive. Large amounts of materials and production capacity are required to accommodate large cultures that are needed given the low concentration of stem cells.

***Our Expansion Technologies*****Selective Amplification**

We have developed a proprietary technology called Selective Amplification that we use to isolate stem cells from mixtures of cells and selectively expand them in a controlled-manner. Our process uses growth factors to promote the growth of stem cell populations and a mixture of antibodies to purify them by removing unwanted differentiated cells that are produced naturally as a by-product of stem cell growth. Differentiated cells cause feedback inhibition when using conventional batch culture methodologies for growth resulting in loss of stem cells. Selective Amplification uses growth and purification techniques concurrently and iteratively to control and optimize growth of the stem cell population. Different stem cells can be grown and purified by using different combinations and concentrations of growth factors and antibodies and by selection at different time points, creating a range of potential cellular products.

The Selective Amplification process is described below:

*Purification.* We initially purify a population of cells containing targeted stem cells using a specially formulated mixture of antibodies. These antibodies bind to the surface of unwanted, differentiated cells but not to targeted stem cells. The antibodies, which have magnetic particles associated with them, link onto the surface of the differentiated cells. We then expose the cell preparation to a specially designed magnet, which removes the magnetic particles along with the antibodies and differentiated cells to which they are connected. This method of purification is referred to as negative immuno-magnetic selection because the target stem cells remain in the culture, unaffected by the antibodies or magnetic particles, while the unwanted differentiated cells are removed.

*Growth.* Following the initial purification of the target stem cell population, we place the cells into a liquid culture containing appropriate growth media. We then allow the culture to grow. During this time, the stem cells divide, producing both additional undifferentiated stem cells as well as differentiated cells.

*Re-purification.* After a specified growth period, we re-purify the target cells using negative immuno-magnetic selection. Re-purification both removes the differentiated cells and eliminates their deleterious impact on the target stem cell population.

*Repeated Cycles of Growth and Purification.* We repeat the growth and purification cycles at specified time points to optimize and control the expansion of the stem cell population and largely eliminate differentiated cells. This technique minimizes culture size and consumption of antibodies, growth factors and media, making it more cost effective than conventional cell culture techniques.

*Harvest, Characterize and Package.* After a final step of reselection and growth, the amplified target cells are harvested, characterized and packaged for use.

**Table of Contents**

The following illustration shows the difference between conventional stem cell growth methodologies and Selective Amplification.

The Selective Amplification process results in a highly characterized population of stem cells. Our lead product candidate manufactured using this technology is CB001.

We are working on other approaches to expand populations of cells in addition to Selective Amplification, including the use of Unrestricted Somatic Stem Cells as a platform for cell expansion. We believe our Selective Amplification and other technologies may have broad range potential applications not just as a potential therapeutic application, but also in cellular therapy.

***Our Product Candidates in Cellular Therapies***

**CB001**

CB001 consists of a highly enriched concentrated and purified population of hematopoietic stem cells derived from umbilical cord blood produced using Selective Amplification. CB001 is currently being studied in a Phase I clinical trial for hematopoietic stem cell reconstitution in the treatment of a variety of cancers.

**Table of Contents**

*Background.* Hematopoietic stem cell therapy is commonly used as a treatment for a variety of cancers and certain serious genetic and acquired diseases to re-establish and maintain the blood and immune system by providing or regenerating healthy, functioning bone marrow. In this type of therapy, hematopoietic stem cells are obtained typically from bone marrow, but also from umbilical cord blood or processed circulating blood, and are infused into the patient's circulatory system, where they find their way to the bone cavity. Once established in the bone, if the transplant is successful, the stem cells begin to grow, or engraft, and produce cells of the blood and immune systems. The treatment is usually undertaken in patients who are very sick and for whom there are few, if any, alternatives. Even when such a need exists, hematopoietic stem cell therapy may not be an option often because of the lack of available bone marrow donors with HLA matching cells. Umbilical cord blood is another important source of hematopoietic cells. However, a single cord blood unit is generally too small to be suitable to treat an adult patient.

CB001 is being developed as a potential source of highly purified stem cells for those for whom a suitable match from other sources is not available. We believe that an expanded umbilical cord blood-derived stem cell product like CB001 has the potential to overcome the current limitations of hematopoietic stem cell therapy by:

*Increasing the Likelihood of Locating Compatible Stem Cells.* Umbilical cord blood contains a rich supply of stem cells. With approximately 4 million births per year in the United States, cord blood represents a large, natural resource provided it can be efficiently and cost-effectively converted into standardized medicine. Most cord blood units collected, preserved and stored do not contain sufficient stem cells to treat an adult patient. We are studying whether, through Selective Amplification, we will be able to expand the number of stem cells contained in each unit so that every unit is potentially suitable to treat a patient, regardless of size. In addition to size limitations that exist with unexpanded cord blood units, HLA matching limitations exist particularly for racial minorities that are proportionally underrepresented in current donor inventories. If every cord blood unit that is collected, preserved and stored can be expanded, the likelihood of locating compatible stem cells in sufficient quantities is increased.

*Increasing the Number of Stem Cells.* We have increased hematopoietic stem cell populations by more than 100-fold, with an average of 35-fold expansion within a 14-day period. The potency of a cord blood unit has been correlated with the number of hematopoietic stem cells in the graft. The number of stem cells in an average cord blood unit are generally considered to be insufficient to engraft an adult by a factor of 2 to 10. The increase in stem cell populations that we may be able to achieve may have significance in the potential for therapeutic effect.

*Program Status.* We are currently conducting a ten patient Phase 1 clinical study of CB001. We have enrolled and completed treatment in eight of the ten patients called for in the study. The patient population eligible for participation in this trial includes children and adult patients (ages 12-60) with acute lymphocytic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, and Non-Hodgkins lymphoma. The patients receive CB001 (produced by Selective Amplification of a donor umbilical cord) plus a standard cord blood transplant (derived from a different donor) following high dose chemotherapy and radiation therapy. Patients are followed for 100 days post transplant. We expect to enroll the final two patients and complete analysis of the study data in 2006. We resumed the study in December 2005 after the United States Food and Drug Administration, or FDA, lifted a clinical hold. The FDA had placed a clinical hold on the study in September 2005 following our decision to suspend enrollment after two patients experienced acute Grade IV graft-versus-host disease, or aGVHD, a potential and common side effect in transplantation. Under the study protocol, two cases of Grade IV aGVHD called for suspension of enrollment. Both patients recovered from Grade IV GVHD, and were released from the hospital. The CB001 Phase 1 clinical study is designed primarily as a safety study. However, we may also be able to differentiate between cells coming from CB001 and cells coming from the standard cord blood transplant due to genetic differences in the two types of donor cells. As a result, we also expect to generate preliminary data on the clinical activity of CB001.

**Table of Contents****Unrestricted Somatic Stem Cells    Cardiac**

We are working to develop a proprietary type of stem cell called Unrestricted Somatic Stem Cells, or USSCs. USSCs are a pluripotent class of stem cells derived from umbilical cord blood. Scientific findings indicate that USSCs may have the ability to differentiate into many cell types, including fat, bone, cartilage and precursor neuronal cells under specified *in vitro* culture conditions. Data from animal models suggests that this cell type is also capable of differentiating in a variety of tissue types as shown by positive histo-chemical data from liver, bone, cartilage, brain and heart of transplanted animals. We are currently studying the potential for this technology in the treatment of cardiac disease.

*Background.* Acute myocardial infarction, or heart attack, occurs when the blood supply to part of the heart muscle is severely reduced or stopped. This occurs when one of the heart's arteries is blocked by an obstruction, such as a blood clot or a plaque formed by arteriosclerosis. If the blood supply is cut off for a prolonged period of time, heart muscle cells suffer irreversible injury and die. According to a statistical report from the American Heart Association (Heart Disease and Stroke Statistics – 2005 Update), there are approximately 1.2 million cases of myocardial infarction and fatal coronary heart disease each year in the United States, with a terminal outcome in about 42% of cases.

Many patients who survive develop a chronic form of heart disease called congestive heart failure, or CHF, which is associated with a progressive deterioration of the heart muscle. According to the American Heart Association, about 5 million patients suffer from CHF in the United States. Although patient survival rates have been improved by using catheters or drugs to remove thrombotic occlusions (blood vessel blockages), there is no proven therapy for repairing damaged heart tissue or generating new tissue. Scientists have theorized that stem cells may be able to play a role in tissue repair and regeneration in the heart, and may help restore heart function after a heart attack. Using rodent models, scientists conducting research in the area have generated data that suggests that adult stem cells when injected into the damaged area of the heart can lead to improved function and increased survival. In other experimental applications, scientists conducting research in the area have used preparations of stem cells isolated from a patient's own bone marrow, and have seen improvement in cardiac function. This area of investigation is still in the early stages. Scientists are working to confirm the effect of introducing stem cells to damaged areas in the heart and to determine which types of stem cells might work, how to expand the cells so that an adequate amount is delivered and how to effectively deliver the cells to the impacted area. We are studying the potential for USSCs in this area given their ability to differentiate into myogenic (endothelial and myocardiocyte) cells such as those found in cardiac muscle tissue.

*Status of Program.* We continue to conduct preclinical studies of USSCs in the cardiac area. We are focused on using animal models to confirm that USSCs have the potential to improve heart function, and on finding a catheter-based mode of administration to deliver cells in a targeted manner to the infarct region that can be applied by interventional cardiologists. If we successfully complete preclinical development, we expect to file an investigational new drug application ( IND ) with the FDA in late 2006 or early 2007.

**Pancreatic Stem Cells    Diabetes**

We are conducting an early-stage research program in collaboration with Genzyme Corporation to explore the potential for pancreatic adult stem cells in the treatment of diabetes. Type 1 diabetes, also known as juvenile-onset diabetes, is caused by destruction of the insulin-producing islet cells of the pancreas. In the absence of insulin, a sugar called glucose cannot enter the cells and accumulates in abnormally high levels in the blood. Patients with Type 1 diabetes must monitor their blood sugar levels and take insulin several times a day. In the most serious cases, doctors have had success in the treatment of Type 1 diabetes with pancreas transplants. Researchers have also experimented with use of transplanted islet cells rather than transplant of the entire pancreas. One challenge in the transplant area is the need for immune suppressive drugs to prevent rejection. A second challenge, and the one that stem cell therapy might help to address, is the lack of availability of donor organs. We are conducting early-stage research into the use of a novel population of adult stem cells isolated from donated cadaver pancreatic tissue in the treatment of Type 1 diabetes. Pancreatic stem cells have shown the ability to produce insulin in mouse models of diabetes. We are currently



## **Table of Contents**

investigating these findings with additional animal studies and working to better understand how to isolate these cells and expand them while still preserving their ability to produce insulin. Our diabetes program is based on technology that has been licensed to us by Massachusetts General Hospital.

### **Other Areas of Interest**

We expect to supplement our internal research and product development efforts through the acquisition or licensing from third parties of products and technologies that support our business strategy. We also expect to continue to look to structure high value collaborative relationships with industry leaders particularly where the involvement of a strategic partner may significantly improve the chances of commercial success or where a partner possesses the resources and expertise to develop and commercialize products for indications outside the scope of our internal development programs.

### **Our ViaCord Reproductive Health Business**

Our ViaCord Reproductive Health business unit is responsible for marketing and sales of our ViaCord product offering for the collection, testing, processing and storage of umbilical cord stem cells, and for development of ViaCyte, our product candidate for the cryopreservation of human eggs for future in vitro fertilization use.

#### ***ViaCord: Umbilical Cord Blood Preservation***

Through our ViaCord product offering, we offer expectant families the chance to preserve their baby's umbilical cord blood for possible future use by the child or potentially a related family member. Stem cells derived from umbilical cord blood are currently a treatment option for over 40 diseases, including cancers such as acute lymphoblastic leukemia and Non-Hodgkins lymphoma, certain bone marrow failure syndromes such as severe aplastic anemia and neuroblastoma, certain blood disorders such as sickle cell anemia and other diseases such as Hurler syndrome and severe combined immune deficiency, or SCID. Studies have shown that umbilical cord stem cells transplants from a person's own umbilical cord blood or a related matching donor such as a sibling have a higher survival rate and a lower incidence of GVHD, a serious potential side effect of transplants, than transplants from an unrelated donor.

Through our ViaCord product offering, we provide the following services to each customer:

*Collection.* We provide a kit that contains all of the materials necessary for collecting the newborn's umbilical cord blood at birth and packaging the unit for transportation to our laboratory. The kit also provides for collecting a maternal blood sample for later testing.

*Comprehensive Testing.* At our laboratory, we conduct several tests on the cord blood unit which are essential in the event the unit is ever needed for transplant. These tests include volume collected, number and viability of nucleated cells, sterility, blood typing and the percent of stem cells. The maternal blood sample is tested for infectious diseases.

*Processing.* At our state-of-the-art laboratory, we process the cord blood using a process designed to maximize the number of stem cells preserved.

*Cryopreservation.* After processing and testing, we freeze the cord blood unit in a controlled-manner and store it using liquid nitrogen. Published data indicates that cord blood retains viability and function for 15 years, and potentially longer, when stored in this manner.

All of our processing and storage of cord blood products is handled at our own cord blood processing and storage facility located in Hebron, Kentucky.

Our ViaCell Reproductive Health business sales and marketing organization consists of sales and marketing professionals supporting our ViaCord product. We have an expanding field sales organization, with representatives in territories which cover the largest birthing centers in the United States who educate obstetricians, child birth educators, and hospitals on the benefits of cord blood preservation. In addition, our internal marketing staff targets two primary segments: high-birthing obstetrics practices and expectant



## **Table of Contents**

families. We educate expectant families through many mediums, including targeted advertising, direct mail and web-based marketing activities.

Over the past several years, the number of families choosing to preserve their baby's umbilical cord blood has grown significantly. In 2005, we generated revenue of \$43.8 million from ViaCord compared to \$36.8 million in 2004. We currently store over 90,000 cord blood units for customers. We have established a leading position in this emerging field, with an estimated market share of approximately 24% total units stored, based on estimates by the independent organization Parent's Guide to Cord Blood Banks of total units stored in family cord blood banks (356,000 as of the end of 2005). We believe that, based on the demographic profile of our average ViaCord customer, the total available target market for the industry could grow to 30% of the approximately 4 million annual births in the United States in the next several years.

### ***ViaCyte***

We are working to leverage our ViaCord Reproductive Health business unit by developing a proprietary media intended for the cryopreservation of human oocytes. We believe that, if successfully developed, an oocyte cryopreservation product could allow a woman to have a child later in life, using one of her own younger oocytes, and may also address currently unmet needs of female cancer patients who, as a result of chemotherapy and radiation treatment, may be at risk of compromised fertility. Women diagnosed with cancer could preserve their oocytes in order to preserve their ability to have a child in the future. Oocyte cryopreservation may also be an attractive option for women (or couples) who require IVF, but who have ethical concerns about embryo cryopreservation as well as for those individuals seeking donor oocytes, but for whom the logistics of coordinating a donor-recipient cycle present a challenge.

*Background.* In the United States and elsewhere in the world, more women are choosing to have children later in life. The average age for a woman having her first child is almost 25, as compared to age 21 in 1970, according to the Center for Disease Control and Prevention. This trend is driven in part by rising birth rates for women in their 30's and 40's. Despite this trend, female fertility actually begins to decline at around age 26, and declines more rapidly after age 35. Declining oocyte viability due to the natural aging process is one of the major factors contributing to compromised fertility in women. While methods for preserving sperm and embryos are well-established and have been utilized in *in vitro* fertilization procedures for the past three decades, methods for preserving oocytes have not been widely employed due to difficulties encountered in freezing this cell. The oocyte is the largest cell in the body and, due to its large liquid volume, tends to form ice crystals during the freezing process. Formation of ice crystals can damage this cell, making it unsuitable to develop into a healthy embryo. These obstacles represent a significant barrier to the cryopreservation of oocytes for treatment of chemotherapy-treated, donor-recipient, IVF and age-related infertility patients.

*ViaCyte Product Candidate.* We have licensed a proprietary high choline cryopreservation media that is designed for use with a slow freezing technique to help protect oocytes from damage during cryopreservation. We believe that, if successfully developed, our ViaCyte cryopreservation product candidate would complement our existing ViaCord product by:

- using our existing operational infrastructure and facilities, including our cell processing and storage facility in Hebron, Kentucky where long-term storage of oocytes would be maintained; and

- utilizing our sales, marketing and clinical support staff and our current marketing channels to educate consumers and healthcare professionals, including obstetricians, gynecologists, and oncologists.

*Status of Program.* We are in discussions with the FDA on an Investigational Drug Exemption, or IDE, with the FDA to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. In response to the original 510(k) application filed by our media supplier, the FDA indicated that the media supplier had not demonstrated substantial equivalence of the media to a predicate device and, as a result, the FDA could not clear the media for commercial use. The FDA indicated that the 510(k) application could be re-submitted when additional data supporting substantial equivalence of the media to a predicate device was available. The FDA has indicated that we will need to conduct a clinical study of



ViaCyte in oocyte cryopreservation that

## **Table of Contents**

produces pregnancy, birth rate data and safety information to support the application. We are in discussions with the FDA related to the IDE and, in particular, the design and size of the trial. If we are able to reach agreement with the FDA, we expect to commence a clinical trial of our ViaCyte oocyte cryopreservation product candidate in late 2006.

### **Collaborations, Licenses and Strategic Relationships**

Our most significant collaborations, licenses and strategic relationships are described below:

#### ***Amgen***

In December 2003, we entered into a license and collaboration agreement with Amgen Inc. under which we received a royalty-free, worldwide, non-exclusive license to certain Amgen growth factors for use as reagents in producing stem cell therapy products. In August 2005, we expanded the collaboration to include an additional growth factor. Amgen has an option to collaborate with us on any product or products that incorporate a licensed Amgen growth factor or technology. Each time Amgen exercises a collaboration option, it must partially reimburse our past development costs based on a pre-determined formula, share in the future development costs, and take primary responsibility for clinical development, regulatory matters, marketing and commercialization of the product. For each collaboration product that receives regulatory approval, Amgen will pay us a cash milestone payment for the first regulatory approval for the first indication of the product in the United States. The parties will share in profits and losses resulting from the collaboration product's worldwide sales. Either we or Amgen may later opt-out of any product collaboration upon advance notice; however, we will retain our license to the Amgen growth factors if either we or Amgen opts out of any product collaboration. In the event Amgen does not exercise its option to collaborate on a particular product, we will owe Amgen a royalty on any sales of such product, if successfully developed. Under this agreement, we can purchase current Good Manufacturing Practices grade growth factors manufactured by Amgen at a specified price. Upon the mutual agreement of both parties, we also may receive a license to additional Amgen growth factors or technologies that may be useful in stem cell therapy. The agreement may be terminated by either party following an uncured material breach by the other party, by mutual consent or by Amgen in certain events involving our bankruptcy or insolvency. Unless earlier terminated, the agreement terminates on the later of the expiration of the licensed Amgen patents or when no products are being co-developed or jointly commercialized between us and Amgen or solely developed by us. The expiration of the issued licensed Amgen patents will occur no earlier than 2013, subject to extension upon the issuance of a patent based on a pending application or a renewal, reissuance, reexamination or other continuation or extension of a covered patent.

In conjunction with this license and collaboration agreement, Amgen made a \$20 million investment in our preferred stock. As part of this agreement, we may offer Amgen the right to make an additional investment of up to \$15 million in connection with a future strategic transaction by us that would further our collaboration with Amgen. Amgen also holds a warrant to purchase 560,000 shares of our common stock at \$12.00 per share as consideration for a previous license agreement that was superceded by this license and collaboration agreement.

In connection with the expansion of the collaboration agreement, we issued Amgen a warrant to purchase 200,000 shares of our common stock at an exercise price of \$7.85 per share. The warrant will vest upon the successful treatment of a human in a Phase 2 clinical trial utilizing the specific growth factor that is the subject of the amendment. The term of the warrant is seven years from the effective date of the amendment. The warrant will be recognized as in-process research and development expense when and if it vests, based on the fair value at that time.

#### ***Tyho Galileo Research Laboratory***

On September 1, 2004, we entered into a License Agreement with Tyho Galileo Research Laboratory, or Galileo, under which we received exclusive rights to a patent covering proprietary media for use in the field of oocyte cryopreservation. As part of this agreement, we also entered into a research collaboration with Galileo which is focused on the development of technologies in the field of oocyte and embryo cryopreservation. Our

## **Table of Contents**

agreement with Galileo includes funding by us of research at Galileo, annual license fees, milestone payments to Galileo upon achievement of certain events and a royalty on revenues generated from the sale of ViaCyte, our oocyte cryopreservation product candidate, if successfully developed. The agreement may be terminated by either party following an uncured breach by the other party. The license expires on a product-by-product, media-by-media and country-by-country basis as the underlying patents in such country expire (if the product or media is covered by a patent claim under the license), or ten years from the date of the first commercial sale in such country (if the product or media is not covered by a patent claim under the license). The patent licensed expires in 2017 if not extended.

### ***Genzyme***

In December 2004, we entered into a Research Agreement with Genzyme under which we provide islet stem cells from donated pancreases to Genzyme, and Genzyme conducts specified research using the islet stem cells. We have granted Genzyme a right of first negotiation to enter into an agreement with us in the field of diseases and disorders of glucose metabolism or insulin insufficiency, including diabetes, using the results of the research conducted by Genzyme. If we do not reach an agreement in such negotiations, we cannot, for a period of 12 months following such negotiations, enter into an agreement with another party on terms more favorable than those we last offered to Genzyme without first offering such terms to Genzyme. The agreement may be terminated by either party following an uncured breach by the other party or by Genzyme if it holds a good faith belief that further research efforts are not commercially practicable. Jan van Heek, former Executive Vice President of Genzyme and currently an employee of that company, is a member of our board of directors.

### ***Johns Hopkins University License***

In August 2005, we entered into a license agreement with Johns Hopkins University and Zhejiang University for an exclusive license to inventions entitled *Ex vivo* Expansion of Cord Mononuclear Cells on Umbilical Cord Blood derived Stromal Cells . This license agreement allows us to develop and market a new technology for the expansion of hematopoietic stem cells that is based on a different principle than our proprietary method of Selective Amplification. The agreement also includes annual license fees, milestone payments upon achievement of certain events, coverage of patent and legal fees and a royalty on revenues generated from the sale of a resulting product, if successfully developed. The term of the license is for 20 years and can be cancelled by us at anytime without cause with specified amount of notice.

### ***Massachusetts General Hospital***

In March 2002, we entered into a license agreement with Massachusetts General Hospital, or MGH under which we received exclusive, worldwide rights to develop and commercialize products based on patents (currently pending) covering inventions of Dr. Joel Habener pertaining to pancreatic stem cells for the treatment of diabetes. The agreement provides for the payments of milestones to MGH upon certain events and royalties based on sales of products covered by the license.

## **Intellectual Property**

The protection of our intellectual property is a strategic part of our business. We currently own or have exclusively in-licensed six US patents. Three of our owned and issued US patents are directed to methods of manufacturing target populations of cells for use as cellular medicines. These patents broadly cover the use of selection elements to select a target population of cells continuously, intermittently during, or after a culture phase. The Selective Amplification technology covered by two of these patents is core to the manufacture of our lead stem cell product candidate, CB001. These patents expire in 2015 if not extended. One of our owned and issued US patents is directed to the method of isolating and expanding hemangioblast cells from a non-fetal source. This patent expires in 2017 if not extended. Corresponding international applications are pending. One of our in-licensed US patents has been exclusively licensed from Galileo, and is directed to a method of cryopreserving human oocytes using proprietary media so that the oocytes enter into a dormant state and are then stored for future use. This patent expires in 2017 if not extended. Another of our US patents, exclusively

## **Table of Contents**

in-licensed from MGH, broadly covers methods for the treatment of type I insulin-dependent diabetes mellitus and other conditions using nestin-positive islet derived progenitor cells, or NIPs, which can be expanded and differentiated into pancreatic islet cells, i.e., insulin-producing beta cells. This patent will expire in 2020 if not extended.

We own two pending US patent applications directed to compositions and methods of using USSCs to treat a broad class of diseases. Furthermore, we own outright or have exclusively in-licensed 52 international patent applications covering a variety of areas, and have non-exclusive licenses to 30 US patents and patent applications and 86 foreign patents and patent applications, including patents covering growth factors used in our Selective Amplification process.

The patent positions of companies like ours present complex legal and factual issues and, as a result, the enforceability of our patents cannot be predicted with any certainty. Our issued patents, those licensed to us, and those that may issue to us in the future may be challenged, invalidated or circumvented, and the rights granted under our patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. There may be existing patents in the U.S. or in foreign countries or patents issued in the future that might be asserted to be infringed by our products, and that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder our ability to develop or commercialize our products. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights, or to determine the validity, scope and non-infringement of patent rights claimed by third parties to be pertinent to our activities. For example, Pharmastem Therapeutics, Inc. has filed suit against us claiming that our ViaCord cord blood preservation product offering infringes certain of Pharmastem's patents. For a description of this litigation, see Item 3 Legal Proceedings. Intellectual property litigation could create business uncertainty and consume substantial financial and human resources. Ultimately the outcome of such litigation could hinder our ability to market our products. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Expiration of patents we own or license could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

Patent rights and other proprietary rights are important in our business and for the development of our product candidates. We have sought, and intend to continue to seek patent protection for our inventions and rely upon patents, trade secrets, know-how, continuing technological innovations and in-licensing opportunities to develop and maintain a competitive advantage. In order to protect these rights, know-how and trade secrets, we typically require employees, consultants, collaborators, and advisors to enter into agreements with us, generally stating that they will not disclose any confidential information about us to third parties for a certain period of time, and will otherwise not use confidential information for anyone's benefit but ours. In the case of our employees and certain of our consultants, the agreements also provide that all inventions conceived by such persons will be our exclusive property. These agreements may not provide meaningful protection or adequate remedies in the event of breach.

### **Competition**

We are aware of products manufactured or under development by competitors that are used for the prevention or treatment of diseases and health conditions which we have targeted for product development. Stem cell therapy competitors with products that could potentially compete with CB001 include commercial and development-stage companies offering or intending to offer stem cell products derived from bone marrow, cord blood or mobilized peripheral blood, or devices or services for processing and producing cells derived from these tissues, for use in stem cell transplants. Specific competitors include Aastrom Biosciences, Celgene Corporation, Cellerant Therapeutics, Inc., Gamida-Cell Ltd. and Osiris Therapeutics Inc. In particular, Gamida-Cell, a private company based in Israel, has completed a Phase 1/2 trial of a hematopoietic stem cell product candidate made from umbilical cord blood similar to CB001 that is intended for use in hematopoietic stem cell transplants. Enrollment for this trial was completed in August 2004.



## **Table of Contents**

If successfully developed, CB001 would also face competition from the increasing availability of cord blood units and the increasing use of multiple cord transplants. If public cord blood banks are able to increase their inventories and obtain more units with a higher volume of stem cells, then public cord blood banks may be able to better compete with our potential cell therapy. In addition to these cell therapy products, competition for CB001 may be in the form of new and better non-cell based drugs to treat leukemias, lymphomas, myelomas and certain genetic diseases.

We are aware of several competitors developing stem cell therapies for the treatment of cardiac disease, including Genzyme, Bioheart Inc., Cytori Therapeutics, Osiris Therapeutics, and potentially others. Genzyme and Bioheart are developing products consisting of skeletal myoblasts isolated from muscle, expanded in culture, and injected into a patient's heart to repair dead tissue. Genzyme recently announced that it has ceased enrollment of new patients in its Phase 2 trial after its Data Monitoring Committee concluded there was a low likelihood that the trial would result in the hypothesized improvements in heart function. Bioheart is conducting a Phase 1/2 study. Osiris is conducting a Phase 1 study of its product candidate in the cardiac area which consists of mesenchymal stem cells isolated from donor bone marrow, expanded in culture. Cytori is developing adipose-tissue derived stem cells intended to be used in cardiac patients in an autologous manner and is in preclinical investigations using large animal models. Other companies, including Hydra Biosciences, have preclinical development efforts using growth factors to stimulate repair of endogenous heart tissue. In addition, many other companies are marketing or developing non-cell based drugs for the treatment of cardiac disease.

At this time, we cannot evaluate how our product candidates in cell therapy, if successfully developed, would compare technologically, clinically or commercially to any other potential cellular and non-cellular products being developed by or currently marketed by competitors because our product candidates are in the early stages of development and we cannot predict the cost, efficacy and safety of those products nor when any such products would be available for sale.

Our competitors in the cord blood preservation industry include the approximately 20 other private family cord blood banks in the United States, including Cbr Systems (Cord Blood Registry), Cryo-Cell International, California Cryo-bank, CorCell, LifeBankUSA, and New England Cord Blood Bank. Some of our competitors, including Cryo-Cell, CorCell, and LifeBankUSA, charge a lower price for their products than we do. Other competitors such as LifeBankUSA, a division of Celgene, a publicly traded corporation, may have greater financial resources than we do. There are also more than fifty public cord blood banks throughout the world, including the New York Blood Center (National Cord Blood Program), University of Colorado Cord Blood Bank, Milan Cord Blood Bank, Düsseldorf Cord Blood Bank, and others.

In 2005, President Bush signed into law the Stem Cell Therapeutic and Research Act of 2005, or the Stem Cell Therapeutic Act. The Stem Cell Therapeutic Act provides federal funding for a national system of public cord blood banks in order to increase the number of available cord blood units to at least 150,000 units. It also contains provisions designed to encourage cord blood donations from an ethnically diverse population. We expect that the Stem Cell Therapeutic Act will increase the number of public cord banks.

Our ability to compete with other private family and public cord blood banks will depend on our ability to distinguish ourselves as a leading provider of comprehensive, quality cord blood preservation products with clinical stem cell transplant experience and a research and development organization focused on the development and commercialization of cell therapies derived from cord blood. Our ability to compete with public cord blood banks will also depend on the extent to which related cord blood transplants show better efficacy and safety than unrelated cord blood transplants.

Our competitors in the development of oocyte cryopreservation include IVF centers and individual companies that already offer oocyte cryopreservation, though none has taken its product through the rigors of the FDA approval process. We are aware of approximately 20 IVF centers already offering oocyte cryopreservation, which may make it more difficult for us to establish our product if successfully developed, or to achieve a significant market share. IVF centers currently offering this service include Florida Institute for Reproductive Medicine, Stanford University, The Jones Institute for Reproductive Medicine, and Egg Bank USA (through Advanced Fertility Clinic). Companies offering oocyte cryopreservation include Extend



## **Table of Contents**

### **Fertility.**

We are in discussion with the FDA on a clinical trial of our ViaCyte oocyte cryopreservation product candidate. If we are able to reach agreement with the FDA and are successful in our development efforts, our ability to compete with these entities will depend on our ability to demonstrate the success of our oocyte cryopreservation method in producing healthy births from previously cryopreserved oocytes, as well as our ability to distinguish ourselves as a leading provider of a high quality oocyte cryopreservation product and our ability to prevent others from using our proprietary method. We expect that companies with alternative forms of media and other techniques for cryopreservation will also seek FDA approval. We anticipate that, if we are successful in our development efforts, we will face increased competition in the future from new companies and individual IVF centers that offer oocyte cryopreservation using these alternative methods.

### **Government Regulation**

#### ***Regulations Relating to ViaCell***

Virtually all of the products we develop will require regulatory approval or licensure by governmental agencies, including the FDA, prior to commercialization. We must obtain similar approvals from comparable agencies in most foreign countries. Regulatory agencies have established mandatory procedures and safety standards that apply to preclinical testing and clinical trials, as well as to the manufacture and marketing of pharmaceutical products. State, local and other authorities may also regulate pharmaceutical manufacturing facilities. This regulatory process can take many years and requires the expenditure of substantial resources.

#### ***FDA Regulation of Biologics, Drugs, and Medical Devices***

The FDA regulates human therapeutic products in one of three broad categories: biologics, drugs, or medical devices.

*Premarket Approval of Biologics and Drugs.* The FDA generally requires the following steps for premarket approval or licensure of a new biological product or new drug product:

- preclinical laboratory and animal tests to assess a drug's biological activity and to identify potential safety problems;

- submission to the FDA of an IND, which must receive FDA clearance before clinical trials may begin;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication;

- compliance with cGMP regulations and standards;

- submission to the FDA of a biologics license application, or BLA, or new drug application, or NDA, for marketing that includes adequate results of preclinical testing and clinical trials; and

FDA review of the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses.

Typically, clinical testing involves a three-phase process although the phases may overlap. Phase 1 clinical trials typically involve a small number of volunteers or patients and are designed to provide information about both product safety and the expected dose of the drug. Phase 2 clinical trials generally provide additional information on efficacy and safety in a limited patient population. Phase 3 clinical trials are generally large-scale, well-controlled studies designed to provide statistically valid proof of efficacy, as well as safety and potency. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators.

Preparing marketing applications involve considerable data collection, verification, analysis and expense. In responding to the submission of a BLA or NDA, the FDA must first accept the filing and review the BLA or NDA for a specific indication. Following review of the BLA or NDA, the FDA may request additional clinical data or deny



approval or licensure of the application if it determines that the application does not satisfy its approval criteria. On occasion, regulatory authorities may require larger or additional studies leading to unanticipated delay or expense. In addition, the manufacturing facilities must be inspected and found to be

**Table of Contents**

in full compliance with cGMP standards before approval for marketing and must continue to comply with cGMP standards post approval. Further clinical trials may be required after approval to continue to monitor safety or to gain approval to promote the use of the product for any additional indications. Our cellular therapeutic products will be regulated as biologics and subject to the above requirements.

*Premarket Clearance or Approval of Medical Devices.* Medical devices are also subject to extensive regulation by the FDA, including 510(k) clearance or Premarket Approval, or PMA, prior to commercial distribution in the United States. Depending on the risk posed by the medical device, there are two pathways for FDA marketing clearance of medical devices. For devices deemed by FDA to pose relatively less risk (Class I or Class II devices), manufacturers must submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. To obtain 510(k) clearance, the premarket notification must demonstrate that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was commercially distributed before May 28, 1976 and for which FDA has not yet called for submission of a PMA. Some low risk devices are exempt from 510(k) clearance requirements.

The other pathway, PMA approval, is required for devices deemed to pose the greatest risk (e.g., life-sustaining, life-supporting, or implantable devices) or devices deemed not substantially equivalent to a previously 510(k) cleared device or to a class III device for which PMA applications have not been called. The PMA approval pathway is much more costly, lengthy and uncertain than the 510(k) clearance pathway. A PMA applicant must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing, and labeling. As with BLA and NDA submissions, FDA must first accept the filing and review the PMA for a specific indication. FDA review of the PMA typically takes one to three years, but may last longer, especially if the FDA asks for more information or clarification of information already provided. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, requirements, which impose specific testing, control, documentation and other quality assurance procedures.

Assuming we are successful in our efforts to reach agreement with the FDA on a clinical trial design and size, and if the results of such trial are favorable, we expect to seek 510(k) clearance for our ViaCyte oocyte cryopreservation product candidate. There is no assurance, however that the FDA will agree that we meet the standards for 510(k) clearance. The FDA could at any time determine that some or all of the components used to cryopreserve the oocytes will require PMA approval, which would involve additional time and expense.

*Compliance Requirements after Licensure, Approval or Clearance.* Manufacturers of biologics, drug products and devices licensed, approved or cleared by the FDA must comply with FDA requirements for labeling, advertising, promotion, record keeping, reporting of adverse experiences and other reporting requirements. Violations of FDA or other governmental regulatory requirements during either the pre- or post-marketing stages may result in various adverse consequences.

*Adverse Event Reporting.* We are required to comply with FDA regulations on reporting of side effects and adverse effects that are reported during clinical trials and post-marketing. Regulatory authorities track this information. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use, and potentially, withdrawal or suspension of the product from the market.

*Outside the U.S.* To market a biologic drug product or device outside the United States, we will most likely have to obtain approval for manufacturing and marketing of each product or device from foreign regulatory authorities. The approval procedure varies among countries, may involve additional preclinical testing and clinical trials, and the time required may differ from that required for FDA approval or licensure. Although there is now a centralized European Union approval mechanism in place, each European country may nonetheless impose its own procedures and requirements, many of which could be time-consuming and expensive. Additionally, European approval standards for cellular therapy are still under development and consequently approval of cell therapy products in Europe may require additional data that we may not be able to satisfy.



**Table of Contents*****Regulations Relating To ViaCord***

**FDA Regulations.** We have registered ViaCord with the FDA as a cord blood preservation service, listed our products with the FDA, and are subject to FDA inspection. In addition, the FDA has recently adopted good tissue practice, or GTP, regulations that establish a comprehensive regulatory program for human cellular and tissue-based products and finalized rules for donor eligibility that became effective in May 2005. We believe that we comply with applicable regulatory requirements. These regulations do not require licensing of minimally manipulated homologous, cryopreserved hematopoietic stem cells for autologous use or use for a first or second degree blood relative. As a result, ViaCord cord blood collection kits, and the collected cells, while regulated, do not need to be licensed or cleared. The FDA could, however, in the future require us to file an IND or BLA and seek approval for the cell product kits or could impose other regulatory requirements applicable to the collection and storage of cord blood. Medical device clearance or approval for the cord blood collection kits or compliance with any new requirements that may be imposed in the future might involve the submission of a substantial volume of data and might require a lengthy substantive review. In such event, the FDA could require that we cease distributing the collection kits and require us to obtain 510(k) clearance or PMA approval prior to further distribution of the kits.

**State Regulations.** Of the states in which we provide cord blood preservation services, only New Jersey, New York, Maryland, Kentucky, Illinois and Pennsylvania currently require that cord blood services be licensed, permitted or registered. We are currently licensed, permitted or registered to operate in all of these states. If other states adopt requirements for licensing, permitting or registration of cord blood services, we would have to obtain licenses, permits or registration to continue providing services in those states.

**Privacy Laws.** Federal and state laws govern our ability to obtain and, in some cases, to use and disclose data we may need to conduct certain of our activities. Through the Health Insurance Portability and Accountability Act of 1996, or HIPAA, Congress required the Department of Health and Human Services to issue a series of regulations establishing standards for the electronic transmission of certain health information. Among these regulations were standards for the privacy of individually identifiable health information. Because ViaCell does not engage in certain electronic transactions related to reimbursement for health care and because blood and tissue procurement and banking activities are exempt, ViaCell is not a covered health care provider subject to HIPAA. Many of the health care providers and research institutions with whom we collaborate and the hospitals, obstetricians, and other healthcare providers who collect umbilical cord blood for our ViaCord customers, however, are subject to HIPAA. These entities may share identifiable patient information with ViaCell only as permitted by HIPAA (for example, with written patient authorizations which comply with certain detailed requirements). Although ViaCell is not directly subject to HIPAA, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a research collaborator or health care provider who has not satisfied HIPAA's disclosure requirements.

HIPAA does not preempt or override state privacy laws that provide even more protection for an individual's health information. The requirements of these laws could further complicate our ability to obtain necessary research data from our collaborators or patient information related to our ViaCord customers. In addition, certain state privacy and genetic testing laws may directly regulate our research activities, affecting the manner in which we use and disclose an individual's health information, potentially increasing our cost of doing business, and exposing us to liability claims. In addition, patients, research collaborators and healthcare providers may have contractual rights that further limit our ability to use and disclose individually identifiable health information. Claims that we have violated an individual's privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

**Other Regulations.** In addition to regulations enforced by the FDA and privacy law requirements, we also are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. These laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act.



## **Table of Contents**

Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we cannot assure you that accidental contamination or injury to employees and third parties from these materials will not occur. We may not have adequate insurance to cover claims arising from our use and disposal of these hazardous substances.

### **Employees**

As of December 31, 2005, we employed 211 individuals. Of our 211 employees, 202 are based in the United States, and 9 are in Singapore. All of our employees are at-will employees, other than Marc Beer, Stephen Dance, Morey Kraus, Stephan Wnendt, Mary Thistle and Anne Marie Cook, who have employment agreements. None of our employees is represented by a labor union or is covered by collective bargaining agreements. We have not experienced any work stoppages, and believe we maintain satisfactory relations with our employees.

### **ITEM 1A. RISK FACTORS THAT MAY AFFECT RESULTS**

#### **NOTE ABOUT FORWARD-LOOKING STATEMENTS**

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to the potential and anticipated results of our development programs, and our views as to the possible outcome of pending litigation and actions related to our intellectual property portfolio. We have based these forward-looking statements on our current expectations about such future events. While we believe these expectations are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those discussed in this report under this heading Risk Factors That May Affect Results . Given these risks and uncertainties, you are cautioned not to place substantial weight on forward-looking statements. The forward-looking statements included in this report are made only as of the date of this report. We do not undertake any obligation to update or revise any of these statements.

#### ***We expect to continue to incur operating losses and may never become profitable.***

We have generated operating losses since our inception. As of December 31, 2005, we had cumulative net losses of approximately \$173.4 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately \$101.6 million since our inception. We expect our losses to continue for the next several years as we make substantial expenditures to further develop and commercialize our product candidates. In particular, we expect that our rate of spending will accelerate over the next several years as a result of increased costs and expenses associated with research, clinical trials, submissions for regulatory approvals, and the expansion of clinical and commercial scale manufacturing facilities. Furthermore, we expect to make additional sales and marketing investments in the near term in our ViaCell Reproductive Health business, as we seek to expand the market for our ViaCord product offering. Our ability to become profitable will depend on many factors, including our ability to increase sales of our ViaCord product offering particularly in the face of significant competition, and our ability to establish the safety and efficacy of our product candidates, obtain necessary regulatory approvals for such product candidates and successfully commercialize the resulting products. We cannot assure you that we will ever become profitable. Factors that may affect our ability to become profitable are described in more detail elsewhere in this Risk Factors that May Affect Results Section.

#### ***We may not be able to sustain our current level of revenues or our recent growth rates.***

Revenues from ViaCord have grown significantly over the past several years, from \$7.1 million in fiscal year 2001, to \$20.1 million, \$30.9 million, \$36.8 million, and \$43.8 million in fiscal years 2002, 2003, 2004, and 2005, respectively. We believe that this is a result of our increased marketing efforts and from increased awareness by the public generally of the concept of umbilical cord blood banking. We may not be able in the

## **Table of Contents**

future, however, to sustain this growth rate nor the current level of ViaCord's revenues. The principal factors that may adversely affect our revenues include competition from other private cord blood banks, the risks of associated litigation, in particular, the pending PharmaStem litigation, the risks of operational issues and the risks of reputational damage. These and other risks that may affect our future revenues are described in more detail elsewhere in this Risk Factors That May Affect Results section. If we are unable to sustain our revenues, we may need to reduce our product development activities or raise additional funds earlier than anticipated or on unfavorable terms, and our stock price may be adversely affected.

### ***If we do not prevail in the PharmaStem litigation, we may be prevented from selling our ViaCord product, or may have to incur significant expenses.***

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 ( '681) and No. 5,192,553 ( '553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that we do not infringe these patents and that the patents are invalid.

In 2003, a jury ruled against us and the other defendants, Cbr Systems Inc, CorCell, Inc. and Cryo-Cell International Inc, who represent a majority of the family cord blood preservation industry finding that the patents were valid and enforceable, and that the defendants infringed the patents. A judgment was entered against us for approximately \$2.9 million, based on 6.125% royalties on our revenue from the processing and storage of umbilical cord blood since April 2000. In 2004, the District Court judge in the case overturned the jury's verdict and entered judgment in our favor and against PharmaStem, stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge's decision. We have appealed the jury's finding as to validity of the patents. A hearing on the appeal is scheduled for April 4, 2006.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patents No. 6,461,645 ( '645) and 6,569,427 ( '427), which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that the patents in this new action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That motion is currently stayed. We believe the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, our request was granted. The cases have been consolidated in Delaware.

The U.S. Patent and Trademark Office, or U.S. PTO, has ordered the re-examination of both the '553 method patent and the '681 composition patent at issue in the first case and the '645 and the '427 patents at issue in the second case based on prior art. A second re-examination of the '427 patent was ordered in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. Final decisions on the re-examinations have not yet been issued.

On October 6, 2005, the Delaware court granted our motion to stay all discovery in the second lawsuit pending decisions from the Federal Circuit on PharmaStem's appeal of the District Court of Delaware's ruling in the original case and from the U.S. PTO on the patent re-examinations.

In either of the pending cases, if we are ultimately found to infringe, we could have a significant damages award entered against us. If we are found to infringe or at any other time during the course of either case, including possibly if the court of appeals were to overturn the district court's non-infringement ruling, we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant us a license or to do so on economically reasonable terms, and previously informed us that it would not do so after October 15, 2004. While we do not believe this outcome is likely, in the event of an injunction, if we are not able to obtain a license under the disputed patents on economically reasonable terms or at all and we cannot operate under an equitable doctrine known as intervening rights, we will be required to stop preserving and storing cord





## **Table of Contents**

blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products. We may enter into settlement negotiations with PharmaStem regarding the litigation. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all.

A loss in either of the PharmaStem lawsuits could have a material adverse effect on our ability to generate revenues from our ViaCord product offering, which is currently our only commercialized product, and could create business uncertainty. Even if we ultimately prevail, we are likely to incur significant legal expenses during the course of the cases.

***If we are not able to successfully develop and commercialize new products, we may not generate sufficient revenues to continue our business operations.***

No company has yet been successful in its efforts to develop and commercialize a stem cell product. Stem cell products in general may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit its approval or commercial use.

Our cellular therapy product candidates are in the early stages of development. Only one of our therapeutic product candidates, CB001, has entered human clinical trials. CB001 consists of a highly enriched population of hematopoietic stem cells which are expanded from umbilical cord blood using our Selective Amplification technology. While stem cell populations expanded using our Selective Amplification technology have shown promising results in preclinical research, those results have not been obtained in humans and may not be indicative of results we may encounter in clinical trials. We may discover that manipulation of stem cells using Selective Amplification or any of our other expansion technologies changes the biological characteristics of the stem cells. For this or other reasons, therapeutic products developed with our stem cell expansion technology may fail to work as intended, even in areas where stem cell therapy is already in use. This may result from the failure of our product candidates to:

properly engraft into the recipient's body in the desired manner;

provide the intended therapeutic benefits; or

achieve benefits or a safety profile that is acceptable and better or equal to existing therapies.

Drug development in general involves a high degree of risk. We are likely to encounter hurdles and unexpected issues as we proceed in our development of any particular product candidate. For example, in the second half of 2005, the FDA put our Phase I clinical trial of CB001 on clinical hold while we assessed two cases of Grade IV aGVHD, a potential and sometimes fatal side effect of transplantation. The FDA lifted the clinical hold in December 2005. However there is no assurance that we will not encounter additional safety issues that may cause us to further delay or discontinue the trial, including additional cases of aGVHD. Several other factors could also prevent completion or cause further delay in this trial, including if we are unable to enroll the final two patients. To date, enrollment in our Phase 1 clinical trial for CB001 has been slower than anticipated and we cannot predict whether or when we will be able to enroll the final patients to complete the trial. We also may encounter hurdles related to the clinical path for CB001. For example, in improving our Selective Amplification process, the resulting product candidate may be viewed by the FDA as sufficiently different from the product candidate being used in our current Phase 1 clinical trial. If so, the FDA may require that we conduct new Phase 1 clinical trials using the product candidate manufactured using the improved process to generate appropriate safety data to support later stage clinical trials. Also, there is evidence that clinicians are increasingly using a new procedure for stem cell transplant patients involving less toxic doses of chemotherapy and radiation than used in conventional transplants. This so called mini-transplant procedure is not being used in our Phase 1 trials. If we need to redesign trials for CB001 that incorporate mini-transplants, it could require repeating earlier trials. Repeating clinical trials for any reason would significantly delay in our development efforts related to CB001.

As we obtain results and safety information from preclinical or clinical trials of our product candidates, we may elect to discontinue development or delay additional preclinical studies or clinical trials in order to

**Table of Contents**

focus our resources on more promising product candidates. There is no assurance, for example, that the results of the CB001 Phase 1 clinical trial will warrant further clinical development or ultimately prove to be safe and effective. We may also change the indication being pursued for a particular product candidate or otherwise revise the development plan for that candidate. Moreover, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical testing.

We cannot market any product candidate until regulatory agencies grant marketing approval or licensure. The industry and the FDA have relatively little experience with therapeutics based on cellular medicine generally. As a result, the pathway to regulatory approval for our stem cell-based product candidates, including CB001, may be more complex and lengthy than the pathway for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the United States, we will need to submit clinical data concerning our products and receive regulatory approval from the appropriate governmental agencies. Standards for approval outside the United States may differ from those required by the FDA. We may encounter delays or rejections if changes occur in regulatory agency policies during the period in which we develop a product candidate or during the period required for review of any application for regulatory agency approval.

The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never gain necessary approvals. Any difficulties that we encounter in developing our product candidates and in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly. If we are not able to successfully develop our product candidates and obtain regulatory approval, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

We expect that none of our cellular therapy product candidates will be commercially available for at least several years, if at all. We will need to devote significant additional research and development, financial resources and personnel to develop commercially viable products and obtain regulatory approvals.

***We may not be able to successfully develop our ViaCyte oocyte cryopreservation product candidate.***

We are in discussions with the FDA on an IDE to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. In response to the original 510(k) application filed by our media supplier, the FDA indicated that the media supplier had not demonstrated substantial equivalence of the media to a predicate device and, as a result, the FDA could not clear the media for commercial use. The FDA indicated that the 510(k) application could be re-submitted when additional data supporting substantial equivalence of the media to a predicate device were available. The FDA has indicated that we will need to conduct a clinical study of ViaCyte in oocyte cryopreservation that produces pregnancy and birth rate data to support the application. We are in discussions with the FDA related to the IDE and, in particular, the design and size of the trial. However, there is no assurance that we will be able to reach agreement with the FDA on a trial design or size that is feasible and acceptable to both the FDA and us. In addition, even if we undertake the clinical trial, there is no assurance that we will be able to show that our ViaCyte cryopreservation product is safe and effective for its intended use. While methods for preserving sperm and embryos are well-established and have been utilized in *in vitro* fertilization procedures for the past three decades, methods for cryopreserving oocytes have not been widely employed due to difficulties encountered in freezing this cell. The oocyte is the largest cell in the body and, due to its large liquid volume, tends to form ice crystals during the freezing process. Formation of ice crystals can damage this cell, making it unsuitable to develop into a healthy embryo. These obstacles represent a significant barrier to the cryopreservation of oocytes. There is no assurance that we will be able to generate the number of live births needed to show that our product candidate is effective and there is no assurance that we will not encounter unexpected safety issues. Even if we are successful in our efforts to reach agreement with the FDA on a clinical trial design and size and the results of such trial are favorable, there is no assurance that the FDA will agree that we have met the standards for 510(k) clearance. The FDA could at any time determine that some or all of the components used to cryopreserve the oocytes will require PMA approval and additional trials, which would involve additional time and expense. Even if we are successful in our efforts to



**Table of Contents**

develop and gain approval for the ViaCyte oocyte cryopreservation product candidate, the FDA could ask for post-approval safety monitoring which would entail additional expense.

***We may not be able to raise additional funds necessary to fund our operations.***

As of December 31, 2005, we had approximately \$60.5 million in cash, cash equivalents and short-term investments. In order to develop and bring our new products to market, we must commit substantial resources to costly and time-consuming research and development, preclinical testing and clinical trials. While we anticipate that our existing cash, cash equivalents and investments will be sufficient to fund our current operations for the next three years, we may need or want to raise additional funding sooner, particularly if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. We expect to attempt to raise additional funds well in advance of completely depleting our available funds.

Our future capital requirements will depend on many factors, including:

the level of cash flows from sales of our ViaCord product;

the scope and results of our research and development programs;

the clinical pathway for each of our product candidates, including the number, size, scope and cost of clinical trials required to establish safety and efficacy;

the results of litigation;

the timing of and the costs involved in obtaining regulatory approvals for our product candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug given the FDA's relatively little experience with cellular-based therapeutics;

the costs of research and development work focused on developing clinical and commercial scale processes for manufacturing cellular products and the costs of building and operating our manufacturing facilities, both in the near-term to support our clinical activities, and also in anticipation of growing our commercialization activities;

funds spent in connection with acquisitions of related technologies or businesses, including contingent payments that may be made in connection with our acquisition of Kourion Therapeutics;

the costs associated with expanding our portfolio of product candidates through licensing, collaborations or acquisitions;

the costs of maintaining, expanding and protecting our intellectual property portfolio, including litigation costs and liabilities; and

our ability to establish and maintain collaborative arrangements and obtain milestones, royalties and other payments from collaborators.

We may seek additional funding through collaborative arrangements and public or private financings. Additional funding may not be available to us on acceptable terms, or at all. If we obtain additional capital through collaborative arrangements, these arrangements may require us to relinquish greater rights to our technologies or product candidates than we might otherwise have done. If we raise additional capital through the sale of equity, or securities convertible into equity, further dilution to our then existing stockholders will result. If we raise additional capital through the incurrence of debt, our business may be affected by the amount of leverage we incur. For instance, such borrowings could subject us to covenants restricting our business activities, servicing interest would divert funds that would otherwise be available to support research and development, clinical or commercialization activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. If we are unable to obtain

adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business.

**Table of Contents*****We depend on patents and other proprietary rights that may fail to protect our business.***

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our product candidates, technologies and trade secrets. We own or have exclusive licenses to six U.S. patents and three international patents. We also own or have exclusive licenses to 14 pending applications in the United States and over 50 pending applications in foreign countries. Our pending patent applications may not issue, and we may not receive any additional patents. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the U.S. PTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. The claims of our existing U.S. patents and those that may issue in the future, or those licensed to us, may not offer significant protection of our Selective Amplification and other technologies. Our patents on Selective Amplification, in particular, are quite broad in that they cover selection and amplification of any targeted cell population. While Selective Amplification is covered by issued patents and we are not aware of any challenges to the validity of these patents, patents with broad claims tend to be more vulnerable to challenge by other parties than patents with more narrowly written claims. Our patent applications covering USSCs claim these cells as well as their use in the treatment of many diseases. It is possible that these cells could be covered by other patents or patent applications which identify, isolate or use the same cells by other markers, although we are not aware of any. Third parties may challenge, narrow, invalidate or circumvent any patents we obtain based on these applications. Interference proceedings brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management.

Competitors may infringe our patents or the patents of our collaborators or licensors. Although we have not needed to take such action to date, we may be required to file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us in a manner that does not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. For instance, our patents on Selective Amplification will expire in 2015. To the extent our product candidates based on that technology are not commercialized significantly ahead of this date, or to the extent we have no other patent protection on such products, those products would not be protected by patents beyond 2015. Without patent protection, those products might have to compete with identical products by competitors.

In an effort to protect our unpatented proprietary technology, processes and know-how as trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary informa-





## **Table of Contents**

tion and techniques or otherwise gain access to our trade secrets. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

### ***Third parties may own or control patents or patent applications that are infringed by our technologies or product candidates.***

Our success depends in part on our not infringing other parties' patents and proprietary rights as well as not breaching any licenses relating to our technologies and product candidates. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, there may be patent applications of which we are unaware that will result in issued patents in our field, and avoiding patent infringement may be difficult. We may inadvertently infringe third party patents or patent applications. These third parties could bring claims against us, our collaborators or our licensors that, even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. For example, some aspects of our Selective Amplification technology involve the use of antibodies, growth factors and other reagents that are, in certain cases, the subject of third party rights. We believe we have the rights to third party patents for use of all growth factors employed in manufacturing our current product candidates for preclinical and clinical testing, including licenses from Amgen for SCF and Flt3-L and GlaxoSmithKline for TPO mimetic. The media in which we amplify the cells is available from several commercial sources. Before we commercialize any product utilizing this technology, including CB001, we may need to obtain additional license rights to use reagents from third parties not covered by these patents or licenses. If we are not able to obtain these rights on reasonable terms or redesign our Selective Amplification process to use other reagents, we may not be able to commercialize any products, including CB001. If we must redesign our Selective Amplification process to use other reagents, we may need to demonstrate comparability in subsequent clinical trials or be required to repeat earlier clinical trials, which would be costly and time consuming.

We may be required to pay substantial damages to a patent holder in an infringement case in the event of a finding of infringement. Under some circumstances in the United States, these damages could be triple the actual damages the patent holder incurred, and we could be ordered to pay the costs and attorneys' fees incurred by the patent holder. If we have supplied infringing products to third parties for marketing, or licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for any damages they may be required to pay to the patent holder and for any losses the third parties may sustain themselves as the result of lost sales or damages paid to the patent holder. Further, if patent infringement suits are brought against us, our collaborators or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. In addition, payments under such licenses would reduce the earnings otherwise attributable to the related products.

Patent infringement cases often involve substantial legal expenses. For example, we are involved in two patent infringement lawsuits filed against us by PharmaStem. As of December 31, 2005, we have incurred total legal expenses of approximately \$7.1 million related to these cases. Depending upon the results of PharmaStem's appeal of the District Court's decision to overturn the jury verdict against us in this case, and the extent to which we are required to litigate the second lawsuit brought by PharmaStem and any related appeals, we estimate that we could incur at least an additional \$1.0 million to \$5.0 million in litigation expenses.

In addition to the two PharmaStem patent infringement lawsuits we are contesting, we are aware that PharmaStem owns an additional patent, U.S. Patent No. 6,605,275, in the umbilical cord blood preservation field, which is the field in which we currently do business with our ViaCord product and potentially might relate to our CB001 product candidate, if approved and commercialized. This patent expires in 2010. We are



## **Table of Contents**

also aware of two patents relating to compositions of purified hematopoietic stem cells and their use in hematopoietic stem cell transplantation, which could impact our stem cell therapeutics business. We believe, based on advice of our patent counsel, that we do not infringe any valid claims of this additional PharmaStem patent or of these two other patents. There is no assurance, however, that if we are sued on any of these patents we would prevail. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe these patents and are not able to obtain a license, we may not be able to operate our business.

Any successful infringement action brought against us may also adversely affect marketing of the infringing product in other markets not covered by the infringement action, as well as our marketing of other products by us based on similar technology and may also delay the regulatory approval process for future product candidates. Furthermore, we may suffer adverse consequences from a successful infringement action against us even if the action is subsequently reversed on appeal, nullified through another action or resolved by settlement with the patent holder. The damages or other remedies awarded, if any, may be significant. As a result, any infringement action against us may harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

### ***Our success will depend in part on establishing and maintaining effective strategic partnerships and collaborations.***

A key aspect of our business strategy is to establish strategic relationships in order to gain access to technology and critical raw materials, to expand or complement our research, development or commercialization capabilities, or to reduce the cost of developing or commercializing products on our own. While we are continually in discussions with a number of companies, universities, research institutions, cord blood banks and others to establish additional relationships and collaborations, we may not reach definitive agreements with any of them. Even if we enter into these arrangements, we may not be able to maintain these relationships or establish new ones in the future on acceptable terms. Furthermore, these arrangements may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, or may have other terms that are burdensome to us, and may involve the acquisition of our securities. Our partners may decide to develop alternative technologies either on their own or in collaboration with others. If any of our partners terminate their relationship with us or fail to perform their obligations in a timely manner, the development or commercialization of our technology and potential products may be substantially delayed.

### ***Our cell preservation activities are subject to regulations that may impose significant costs and restrictions on us.***

**Cord blood preservation.** The FDA has adopted GTP regulations that establish a comprehensive regulatory program for human cellular and tissue-based products. Our ViaCord product is subject to these GTP regulations. We have registered with the FDA as an umbilical cord blood preservation service, listed our products with the FDA, and we are subject to FDA inspection. We believe that we comply with the new GTP regulations as adopted, though we have not yet been inspected by the FDA. However, we may not be able to maintain this compliance or comply with future regulatory requirements that may be imposed on us, including product standards that may be developed. Moreover, the cost of compliance with government regulations may adversely affect our revenue and profitability. Regulation of our cord blood preservation services in foreign jurisdictions is still evolving.

Consistent with industry practice, the ViaCord collection kits have not been cleared as a medical device. The FDA could at any time require us to obtain PMA approval or 510(k) clearance for the collection kits, or new drug application supplement, or sNDA, approval for a drug component of the kits or file an IND/ BLA and seek approval for the cell product. Securing any necessary medical device 510(k) clearance or PMA approval for the cord blood collection kits, or sNDA approval for a drug component of the kits or BLA, may involve the submission of a substantial volume of data and may require a lengthy substantive review. The FDA also could require that we cease distributing the collection kits and require us to obtain medical device 510(k) clearance or PMA approval for the kits or sNDA approval of a drug component of the kits or BLA approval prior to further distribution of the kits on product use.



## Table of Contents

Of the states in which we provide cord blood banking services, only New Jersey, New York, Maryland, Kentucky, Illinois and Pennsylvania currently require that cord blood services be licensed, permitted or registered. We are currently licensed, permitted or registered to operate in all of these states. If other states adopt requirements for the licensing, permitting or registration of cord blood preservation services, we would have to obtain licenses, permits or registration to continue providing services in those states.

*Oocyte cryopreservation.* There are no established precedents for U.S. and international regulation of oocyte cryopreservation. The FDA has informed us that it will require a clinical study to support approval of the technology used in oocyte cryopreservation. Even if such a study is conducted, we cannot assure you that the FDA will find the data sufficient to grant 510(k) clearance.

If we conduct a clinical study and submit a new 510(k), and the FDA does not find the information adequate to support 510(k) clearance, we would need to obtain PMA approval. This requirement would substantially lengthen our planned developmental timeline and increase the costs of developing and commercializing this product candidate. We cannot assure you that this product candidate will receive either 510(k) clearance or PMA approval. We believe that the time to conduct a clinical study, prepare a new 510(k), and receive FDA clearance for our oocyte cryopreservation product candidate, will take several years.

We have not investigated the regulations for the cryopreservation of oocytes in foreign jurisdictions.

There is no assurance that we will ever be able to generate sufficient data to receive approval to market technology for the cryopreservation of oocytes.

***We have only limited experience manufacturing cell therapy product candidates, and we may not be able to manufacture our product candidates in quantities sufficient for clinical studies or for commercial scale.***

We currently produce limited quantities of stem cells using our Selective Amplification and USSC technologies. We have not built commercial scale manufacturing facilities, and have no experience in manufacturing cellular products in the volumes that will be required for later stage clinical studies or commercialization. If we successfully obtain marketing approval for any products, we may not be able to produce sufficient quantities of our products at an acceptable cost. Commercial-scale production of therapies made from live human cells involves production in small batches and management of complex logistics. Cellular therapies are inherently more difficult to manufacture at commercial-scale than chemical pharmaceuticals, which are manufactured using standardized production technologies and operational methods. We may encounter difficulties in production due to, among other things, quality control, quality assurance and component supply. These difficulties could reduce sales of our products, increase our cost or cause production delays, all of which could damage our reputation and hurt our profitability.

***We are dependent on our existing suppliers and establishing relationships with certain other suppliers for certain components of our product candidates. The loss of such suppliers or our inability to establish such relationships may delay development or limit our ability to manufacture our stem cell therapy products.***

In order to produce cells for use in clinical studies and produce stem cell products for commercial sale, certain biological components used in our production process will need to be manufactured in compliance with cGMP. To meet this requirement, we will need to maintain supply agreements with firms who manufacture these components to cGMP standards. Once we engage these third parties, we may be dependent on them for supply of cGMP grade components. If we are unable to obtain cGMP grade biological components for our product candidates, we may not be able to market our stem cell product candidates.

Certain antibodies, growth factors and other reagents are critical components used in our stem cell production process. Our Selective Amplification process currently uses components sold to us by certain manufacturers, and we need to establish relationships with other suppliers to manufacture cGMP grade products for commercial sale. We are dependent on our suppliers for such components as SCF, Flt3-L, TPO mimetic and cGMP grade antibodies conjugated with magnetic particles. Some of these components are

**Table of Contents**

currently supplied to us by Amgen, GlaxoSmithKline and Miltenyi Biotec, who are currently single-source suppliers. Other components, such as research grade materials that are suitable for production of stem cells used for research and in Phase 1 human clinical studies, are purchased as catalog products from vendors, such as StemCell Technologies and R&D Systems, with whom we do not have relationships. In order to continue our clinical trials and commercialize our Selective Amplification product candidates, we will need to establish relationships with some of these suppliers. In the event that our suppliers are unable or unwilling to produce such components on commercially reasonable terms, and we are unable to find substitute suppliers for such components, we may not be able to commercialize our stem cell product candidates. We depend on our suppliers to perform their obligations in a timely manner and in accordance with applicable government regulations. In the event that any of these suppliers becomes unwilling or unable to continue to supply necessary components for the manufacture of our stem cell products, we will need to repeat certain development work to identify and demonstrate the equivalence of alternative components purchased from other suppliers. If we are unable to demonstrate the equivalence of alternative components in a timely manner, or purchase these alternative components on commercially reasonable terms, development of our product candidates may be delayed and we may not be able to complete development of or market our stem cell product candidates.

***If our cord blood processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects would be negatively affected.***

We process and store our customers' umbilical cord blood at our facility in Hebron, Kentucky. If this facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored cord blood units. Depending on the extent of loss, such an event could reduce our ability to provide cord blood stem cells when requested, could expose us to significant liability from our cord blood banking customers and could affect our ability to continue to provide umbilical cord blood banking services.

We have a clinical manufacturing facility located in Worcester, Massachusetts that is capable of producing stem cells for Phase 1 and 2 clinical trials. We have built out a facility in Cambridge, Massachusetts that we intend to replace our Worcester facility and be capable of producing stem cells for Phase 2 and 3 clinical trials and initial commercialization. For the next several years, we expect to manufacture all of our stem cell product candidates in our new Cambridge facility. If this facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. In the event of a temporary or protracted loss of this facility or equipment, we may be able to transfer manufacturing to a third party, but the shift would likely be expensive, and the timing would depend on availability of third party resources and the speed with which we could have a new facility approved by the FDA.

While we believe that we have insured against losses from damage to or destruction of our facilities consistent with typical industry practices, if we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies. Currently, we maintain insurance coverage totaling \$21.9 million against damage to our property and equipment, and an additional \$19.0 million to cover incremental expenses and loss of profits resulting from such damage.

***Our competitors may have greater resources or capabilities or better technologies than we have, or may succeed in developing better products or develop products more quickly than we do, and we may not be successful in competing with them.***

The private umbilical cord banking business is highly competitive. In private umbilical cord blood banking, we compete with companies such as Cbr Systems, Cryo-Cell International, Inc., CorCell, Inc. and LifeBank USA. Any of these companies may choose to invest more in sales, marketing, research and product development than we have. In cord blood banking, we also compete with public cord blood banks such as the New York Blood Center (National Cord Blood Program), University of Colorado Cord Blood Bank, Milan Cord Blood Bank, Düsseldorf Cord Blood Bank, and approximately 50 other cord blood banks around the world. Public cord blood banks provide families with the option of donating their cord blood for public use.

**Table of Contents**

There is no cost to donate and, as public banks grow in size and increase in diversity, which is, for instance, the aim of the Stem Cell Therapeutic Act, the probability of finding suitably matched cells for a family member may increase, which may result in a decrease in demand for private cord blood banking. In addition, if the science of HLA typing advances, then unrelated cord blood transplantation may become safer and more efficacious, similarly reducing the clinical advantage of related cord blood transplantation.

The pharmaceutical and biotechnology businesses are also highly competitive. We compete with many organizations that are developing cell therapies for the treatment of a variety of human diseases, including companies such as Aastrom Biosciences, Cellerant, Celgene, Gamida-Cell, Genzyme, Bioheart, and Osiris. We also face competition in the cell therapy field from academic institutions and governmental agencies. We are also aware that some larger pharmaceutical and biopharmaceutical companies have programs in the cell therapy area. Some of these competitors, and future competitors, may have similar or better product candidates or technologies, greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities. Specifically, Gamida-Cell, a private company based in Israel, is developing a hematopoietic stem cell therapy product candidate similar to CB001. This product has been evaluated in a Phase 1/2 trial. Enrollment for this trial was completed in August 2004. This product candidate, and potentially others, could have equal or better efficacy than CB001 or could potentially reach the market more quickly than CB001. In addition, public cord blood banks may, as a result of a recent legislative initiative, be able to better compete with our potential cell therapy products, such as CB001. The Stem Cell Therapeutic Act provides financing for a national system of public cord blood banks to encourage cord blood donations from an ethnically diverse population. An increase in the number and diversity of publicly-available cord blood units from public banks could diminish the necessity for cord blood-derived therapeutics produced with our Selective Amplification technology.

In oocyte cryopreservation, if our ViaCyte product candidate is successfully developed and approved, we expect to compete with IVF centers, including Florida Institute for Reproductive Medicine, Stanford University, the Jones Institute for Reproductive Medicine, and Egg Bank USA (through Advanced Fertility Clinic) and individual companies offering oocyte cryopreservation, including Extend Fertility. Current and future competitors in this field, too, may have greater financial and human resources than we have, and may have similar or better product candidates or technologies, or product candidates which are brought to the market more quickly than ours. Specifically, several IVF centers (including all of those mentioned here) are already performing oocyte cryopreservation on a limited basis and Extend Fertility is offering related services, which may make it more difficult for us to establish our product candidate or achieve a significant market share.

We anticipate this competition to increase in the future as new companies enter the stem cell therapy, cord blood preservation and oocyte cryopreservation markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our product candidates obsolete.

***Due to the nature of our cell preservation activities, harm to our reputation could have a significant negative impact on our financial condition, and damage to or loss of our customers' property held in our custody could potentially result in significant legal liability.***

Our reputation among clients and the medical and birthing services community is extremely important to the commercial success of our ViaCord product. This is due in significant part to the nature of the product and service we provide. For instance, as part of our ViaCord product, we are assuming custodial care of a child's umbilical cord blood tissue entrusted to us by the parents for potential future use as a therapeutic for the child or its siblings. We believe that our reputation enables us to market ourselves as a premium provider of cord blood preservation among our competitors. While we seek to maintain high standards in all aspects of our provision of products and services, we cannot guarantee that we will not experience problems. Like family cord blood banks generally, we face the risk that a customer's cord blood unit could be lost or damaged while in transit from the collection site to our storage facility, including while the unit is in the possession of third party commercial carriers used to transport the units. There is also risk of loss or damage to the unit during the





## **Table of Contents**

preservation or storage process. Any such problems, particularly if publicized in the media or otherwise, could negatively impact our reputation, which could adversely affect our business and business prospects.

In addition to reputational damage, we face the risk of legal liability for loss of or damage to cord blood units. We do not own the cord blood units banked by our ViaCord customers; instead, we act as custodian on behalf of the child-donor's guardian. Thus loss or damage to the units would be loss or damage to the customer's property, a potentially unique, and depending on the circumstances, perhaps irreplaceable potential therapeutic. Therefore, we cannot be sure to what extent we could be found liable, in any given scenario, for damages suffered by an owner or donor as a result of harm or loss of a cord blood unit. Since we began offering the ViaCord blood preservation product in 1994, two lawsuits have been filed against us, one regarding damage to a customer's cord blood unit because of a delay in transport to our processing facility and the other regarding the total loss of the unit while in transit. Both cases were settled through mediation for amounts not material to our financial results or financial condition and were substantially covered by our insurance policies. However, we cannot assure you that any future cases could be resolved by payment of immaterial amounts for damages or that our insurance coverage will be sufficient to cover such damages.

### ***The manufacture and sale of products may expose us to product liability claims for which we could have substantial liability.***

We face an inherent business risk of exposure to product liability claims if our products or product candidates are alleged or found to have caused injury. While we believe that our current liability insurance coverage is adequate for our present commercial activities, we will need to increase our insurance coverage if and when we begin commercializing stem cell therapy products. We may not be able to obtain insurance with adequate coverage for potential liability arising from any such potential products on acceptable terms or may be excluded from coverage under the terms of any insurance policy that we obtain. We may not be able to maintain insurance on acceptable terms or at all. If we are unable to obtain insurance or any claims against us substantially exceed our coverage, then our business could be adversely impacted.

### ***If we are not able to recruit and retain qualified management and other personnel, we may fail in developing our technologies and product candidates.***

Our success is highly dependent on the retention of the principal members of our scientific, management and sales personnel. Marc D. Beer, our President and Chief Executive Officer, is critical to our ability to execute our overall business strategy. Morey Kraus, our Chief Technology Officer and co-founder, is a co-inventor of our Selective Amplification technology and has significant and unique expertise in stem cell expansion and related technologies. We maintain key man life insurance on the lives of Marc D. Beer and Morey Kraus. Additionally, we have several other employees with scientific or other skills that we consider important to the successful development of our technology. Any of our key employees could terminate his or her relationship with us at any time and, despite any non-competition agreement with us, work for one of our competitors. Furthermore, our future growth will require hiring a significant number of qualified technical, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success.

There is intense competition from other companies, universities and other research institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or achieve our business objectives.

### ***We may face difficulties in managing and maintaining the growth of our business.***

We expect to continue expanding our reproductive health business and our research and development activities. This expansion could put significant strain on our management, operational and financial resources. To manage future growth, we would need to hire, train and manage additional employees.

Prior to completing our initial public offering in January 2005, we maintained a small finance and accounting staff because we were a private company. Our new reporting obligations as a public company, as

## **Table of Contents**

well as our need to comply with the requirements of the Sarbanes-Oxley Act of 2002, the rules and regulations of the Securities and Exchange Commission and the NASDAQ National Market, place significant additional demands on our finance and accounting staff, on our financial, accounting and information systems and on our internal controls. We have increased the number of our accounting and finance personnel and have taken steps to proactively monitor our networks and to improve our financial, accounting and information systems and internal controls in order to fulfill our responsibilities as a public company and to support growth in our business. We cannot assure you that our current and planned personnel, systems procedures and controls will be adequate to support our anticipated growth or that management will be able to hire, train, retain, motivate and manage required personnel.

Our failure to manage growth effectively could limit our ability to achieve our research and development and commercialization goals or to satisfy our reporting and other obligations as a public company.

***If we acquire other businesses or technologies the transactions may be dilutive and we may be unable to integrate them successfully with our business, our financial performance could suffer.***

If we are presented with appropriate opportunities, we may acquire other businesses. We have had limited experience in acquiring and integrating other businesses. Since our incorporation in 1994, we have acquired three businesses: ViaCord in 2000, Cerebrotec, Inc. in 2001 and Kourion Therapeutics AG in 2003. The integration process following any future acquisitions may produce unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Also, in any future acquisitions, we may issue shares of stock dilutive to existing stockholders, incur debt, assume contingent liabilities, or create additional expenses related to amortizing intangible assets, any of which might harm our financial results and cause our stock price to decline. Any financing we might need for future acquisitions may be available to us only on terms that restrict our business or impose costs that increase our net loss.

***The successful commercialization of our other potential cell therapy products will depend on obtaining reimbursement for use of this product candidate from third party payers.***

If we successfully develop and obtain necessary regulatory approvals for our therapeutic product candidates, we intend to sell such products initially in the United States and the European Union. In the United States, the market for many pharmaceutical products is affected by the availability of reimbursement from third party payers such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. Our potential cellular therapy products may be relatively expensive treatments due to the higher cost of production and more complex logistics of cellular products compared with standard pharmaceuticals; this, in turn, may make it more difficult for us to obtain adequate reimbursement from third party payers, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payers may also deny coverage or offer inadequate levels of reimbursement for our potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate. In the countries of the European Union and in some other countries, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control.

Managing and reducing health care costs has been a concern generally of federal and state governments in the United States and of foreign governments. Although we do not believe that any recently enacted or presently proposed legislation should impact our business, we cannot be sure that we will not be subject to future regulations that may materially restrict the price we receive for our products. Cost control initiatives could decrease the price that we receive for any product we may develop in the future. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services, and any of our potential products may ultimately not be considered cost-effective by these payers. Any of these initiatives or developments could materially harm our business.

Although we are aware of a small fraction of ViaCord customers receiving reimbursement, we believe our ViaCord cord blood preservation product, like other private cord blood banking, is not generally subject to

## **Table of Contents**

reimbursement. However, if our potential cell therapy products are not reimbursed by the government or third party insurers, the market for those products would be limited. We cannot be sure that third party payers will reimburse sales of a product or enable us or our partners to sell the product at prices that will provide a sustainable and profitable revenue stream.

### ***We face potential liability related to the privacy of health information we obtain from research collaborators or from providers who enroll patients and collect cord blood or human oocytes.***

Our business relies on the acquisition, analysis, and storage of potentially sensitive information about individuals health, both in our research activities and in our reproductive health product and service offerings. These data are protected by numerous federal and state privacy laws.

Most health care providers, including research collaborators from whom we obtain patient information, are subject to privacy regulations promulgated under HIPAA. Although we ourselves are not directly regulated by HIPAA Privacy Rule, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider who has not satisfied HIPAA's disclosure standards. In addition, certain state privacy laws and genetic testing laws may apply directly to our operations and impose restrictions on our use and dissemination of individuals' health information. Moreover, patients about whom we obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

### ***Ethical and other concerns surrounding the use of stem cell therapy may negatively affect regulatory approval or public perception of our products and product candidates, thereby reducing demand for our products and product candidates.***

The use of embryonic stem cells for research and stem cell therapy has been the subject of debate regarding related ethical, legal and social issues. Although we do not currently use embryonic stem cells as a source for our research programs, the use of other types of human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with embryonic stem cells. The commercial success of our product candidates will depend in part on public acceptance of the use of stem cell therapy, in general, for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that stem cell therapy is unsafe, and stem cell therapy may not gain the acceptance of the public or the medical community. Adverse events in the field of stem cell therapy that may occur in the future also may result in greater governmental regulation of our product candidates and potential regulatory delays relating to the testing or approval of our product candidates. In the event that our research becomes the subject of adverse commentary or publicity, the market price for our common stock could be significantly harmed.

### ***Our business involves the use of hazardous materials that could expose us to environmental and other liability.***

We have facilities in Massachusetts, Kentucky, and Singapore that are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. In the United States, these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these regulations, we cannot assure you that accidental contamination or injury to employees and third parties from these materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

**Table of Contents**

***Volatility of Our Stock Price***

The market price for our common stock is highly volatile, and likely will continue to fluctuate due to a variety of factors, including:

- material public announcements;
- the data, positive or negative, generated from the development of our product candidates;
- setbacks or delays in any of our development programs;
- the outcome of material litigation;
- the financial results achieved by our cord blood preservation business;
- the impact of competition;
- unusual or unexpectedly high expenses;
- developments related to patents and other proprietary rights;
- market trends affecting stock prices in our industry; and
- economic or other external factors.

**ITEM 1B. *UNRESOLVED STAFF COMMENTS***

None.

**ITEM 2. *DESCRIPTION OF PROPERTY***

Our corporate headquarters in Cambridge, Massachusetts comprise approximately 26,000 square feet of office space which houses our corporate and executive functions as well as our cord blood preservation sales, customer support, marketing and administrative personnel. At the same facility we have also leased approximately 25,000 square feet of laboratory and manufacturing space for our cell therapy product candidates. In the second half of 2005, we completed the build-out of the laboratory and manufacturing space. The lease on the Cambridge facility expires in 2014.

We are currently manufacturing CB001 for our Phase 1 trial at a 9,000 square foot leased facility in Worcester, Massachusetts. We expect to complete transfer of our manufacturing operations from the Worcester facility to the Cambridge facility after completion of the CB001 Phase 1 trial. We have negotiated a short term extension of the Worcester lease to allow us to complete manufacturing for the trial. The new Cambridge manufacturing space is designed to be able to produce cells for Phase 1, 2 and 3 trials, and potentially initial commercialization if we receive marketing approval.

We operate our cord blood processing and storage facility in Hebron, Kentucky, with over 12,000 square feet of laboratory and administrative office space, under a lease extending to 2012, with two successive five-year extension options and a right of first offer to re-lease the space from the landlord at the end of the lease term. We also operate under a lease, which expires in May 2007, for approximately 3,800 square feet of laboratory space to house our research operations in Singapore. In addition, as a result of our acquisition of Kourion Therapeutics, we maintain a lease, which expires in May 2008, for approximately 15,000 square feet of laboratory and administrative space in Langenfeld, Germany. In 2005, we transferred our German operations to the United States, and closed our operations in Germany. We have sublet our German facility to a third party under a sublease that terminates in December 2006.

In the future, we may require additional facilities to expand our research and development and cord blood processing activities or for additional clinical and commercial manufacturing operations.

**Table of Contents****ITEM 3. LEGAL PROCEEDINGS**

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 ( 681) and No. 5,192,553 ( 553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that we do not infringe these patents and that the patents are invalid.

In 2003, a jury ruled against us and the other defendants, Cbr Systems Inc, CorCell, Inc. and Cryo-Cell International Inc, who represent a majority of the family cord blood preservation industry finding that the patents were valid and enforceable, and that the defendants infringed the patents. A judgment was entered against us for approximately \$2.9 million, based on 6.125% royalties on our revenue from the processing and storage of umbilical cord blood since April 2000. In 2004, the District Court judge in the case overturned the jury's verdict and entered judgment in our favor and against PharmaStem stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge's decision to the Federal Circuit for the Court of Appeals. We have appealed the jury's finding as to validity of the patents. A hearing on the appeal is scheduled for April 4, 2006.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patents No. 6,461,645 ( 645) and 6,569,427 ( 427), which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that the patents in this new action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That motion is currently stayed. We believe the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, our request was granted. The cases have been consolidated in Delaware.

The U.S. PTO has ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and 427 patents at issue in the second case based on prior art. A second re-examination of the 427 patent was ordered in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010. Final decisions on the re-examinations have not yet been issued.

On October 6, 2005, the Delaware court granted our motion to stay all discovery in the second lawsuit pending decisions from the Federal Circuit on PharmaStem's appeal of the District Court's ruling of non-infringement in the original case and from the U.S. PTO on the patent re-examinations.

In either of the pending cases, if we are ultimately found to infringe, we could have a significant damages award entered against us. If we are found to infringe or at any other time during the course of either case, including possibly if the court of appeals were to overturn the district court's non-infringement ruling, we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant us a license or to do so on economically reasonable terms, and previously informed us that it would not do so after October 15, 2004. While we do not believe this outcome is likely, in the event of an injunction, if we are not able to obtain a license under the disputed patents on economically reasonable terms or at all and we cannot operate under an equitable doctrine known as "intervening rights," we will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products. We may enter into settlement negotiations with PharmaStem regarding the litigation. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all.

On May 13, 2004, we received a First Amended Complaint filed in the Superior Court of the State of California by Kenneth D. Worth, by and for the People of the State of California, and naming as defendants a number of private cord blood banks, including us. The complaint alleges that the defendants have made

**Table of Contents**

fraudulent claims in connection with the marketing of their cord blood banking services and seeks restitution for those affected by such marketing, injunctive relief precluding the defendants from continuing to abusively and fraudulently market their services and requiring them to provide certain information and refunds to their customers, unspecified punitive and exemplary damages and attorney's fees and costs. Subsequently, we received a Notice of Ex Parte Application for Leave to Intervene filed on behalf of the Cord Blood Foundation by the same individual and seeking similar relief. On October 7, 2004, the Court orally granted a motion to strike the complaint under the California anti-SLAPP statute and dismissed the complaint as to all defendants without leave to amend. Judgment has been entered, dismissing the complaint, and plaintiff has filed a notice of appeal and a brief for the appeal and a petition for a writ of mandate. The petition has been dismissed and the appeal is proceeding. The plaintiff has settled the litigation with all defendants other than us. We are not yet able to conclude as to the likelihood that plaintiff's claims would be upheld if the judgment of dismissal were reversed on appeal, nor can we estimate the possible financial consequences should plaintiff prevail. However, we believe this suit to be without merit and intend to continue to vigorously defend ourselves.

On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against us in the United States District Court for the Northern District of California alleging false and misleading advertising by us in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. On April 13, 2005, we answered the complaint, denying Cbr's allegations, and filed counterclaims alleging false and misleading advertising by Cbr. On October 27, 2005, we entered into an agreement to settle the pending litigation with Cbr. Under terms of the agreement the companies agreed to dismiss all outstanding legal claims. There were no financial payments to be made by either party under the settlement agreement.

We have undertaken a review of our various job classifications for legal compliance under state and federal employment laws. Based on that review, we have identified certain job classifications that may be subject to possible challenge, although there is currently no such challenge pending, and for which there is a reasonable possibility that we could incur a liability, although we also believe that the present classifications can be supported and defended. It is not possible based on the current available information to reasonably estimate the scope of any potential liability.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

Table of Contents**PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS****Market for Common Equity**

Our common stock has been traded on the NASDAQ National Market System ( NASDAQ ) under the symbol VIAC since January 21, 2005. Prior to that time there was no established public trading market for our common stock. The closing share price for our common stock on March 29, 2006, as reported by NASDAQ was \$5.51.

The following table sets forth, for the periods indicated, the high and low sales prices of our Common Stock on NASDAQ.

|   | Price per Share |         |
|---|-----------------|---------|
|   | High            | Low     |
| <b>For the Year Ended December 31, 2005</b> |                 |         |
| First Quarter (from January 21, 2005)       | \$ 14.60        | \$ 6.75 |
| Second Quarter                              | 11.39           | 5.42    |
| Third Quarter                               | 11.51           | 4.97    |
| Fourth Quarter                              | 6.37            | 4.66    |

The following table sets forth information concerning our equity compensation plans as of December 31, 2005.

**Equity Compensation Plan Information**

| Plan Category  | Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights | Weighted Average Exercise Price of Outstanding Options, Warrants and Rights | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plan |
|--|---|---|---|
|  |   |   | (Excluding Securities Referenced in Column (a))   |
|  | (a)   |   |   |
| Equity compensation plans approved by security holders | 3,930,694   | \$ 2.77   | 2,080,738   |

**Holders**

As of March 29, 2006, there were 140 stockholders of record of our common stock.

**Dividends**

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

**Sales of Unregistered Securities**

During 2005, we issued 688,014 shares of common stock to employees, former employees, and consultants upon option exercises for compensation for services provided, for an aggregate sale price of approximately \$1.2 million. There were no underwriters employed in connection with any of these transactions. Each option grant and stock

issuance was deemed exempt from registration under the Securities Act of 1933, as amended, or the Securities Act under Rule 701 promulgated there under, because the security was offered and sold pursuant to either a written compensatory plan or a written contract relating to compensation and made pursuant to an offer made prior to our initial public offering.



**Table of Contents**

**Use of Proceeds from Registered Securities.**

We registered shares of our common stock in connection with our initial public offering under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-114209) in connection with our initial public offering was declared effective by the SEC on January 19, 2005. The offering commenced as of January 20, 2005. 8,625,000 shares of our common stock registered were sold in the offering. The offering did not terminate before any securities were sold. We completed the offering on January 26, 2005. Credit Suisse and UBS Investment Bank were the managing underwriters.

All 8,625,000 shares of our common stock registered in the offering were sold, with an initial public offering price per share of \$7.00. The aggregate purchase price of the offering was \$60,375,000, of a maximum potential registered aggregate offering price of \$92,000,000. The net offering proceeds to us after deducting total related expenses were approximately \$53,300,000.

No payments for the above expenses nor other payments of proceeds were made directly or indirectly to (i) any of our directors, officers or their associates, except as described below (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds of the initial public offering, after payment of approximately \$15.5 million for all outstanding principal and interest on promissory notes held by funds affiliated with MPM Asset Management LLC, the manager of which served on our board of directors until June 9, 2005, are invested in investment grade securities with the weighted average days to maturity of the portfolio less than six months and no security with an effective maturity in excess of 12 months. To date, apart from the payment of promissory notes of \$15.5 million, we have not used any of the net proceeds from the initial public offering and there has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act.

**Table of Contents****ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

In the tables below, we provide you with our selected historical financial data. We have prepared this information using the audited consolidated financial statements for the five years ended December 31, 2005. When you read this summary historical financial data, it is important that you read along with it the consolidated financial statements and related notes to the financial statements appearing elsewhere in this report and Management's Discussion and Analysis of Financial Condition and Results of Operations. Historical results are not necessarily indicative of the results that may be expected in the future.

**Years Ended December 31,**

**2005                      2004                      2003(1)                      2002                      2001**

**(In thousands, except share and per share data)**

**Consolidated Statement of Operations****Data:**

|          |    |        |    |        |    |        |    |        |    |       |
|----------|----|--------|----|--------|----|--------|----|--------|----|-------|
| Revenues | \$ | 44,443 | \$ | 38,274 | \$ | 31,880 | \$ | 20,375 | \$ | 7,298 |
|----------|----|--------|----|--------|----|--------|----|--------|----|-------|

**Operating expenses:**

Cost of processing and storage  
revenues:(2)

|              |  |       |  |       |  |       |  |       |  |       |
|--------------|--|-------|--|-------|--|-------|--|-------|--|-------|
| Direct costs |  | 8,278 |  | 7,364 |  | 7,141 |  | 5,877 |  | 3,070 |
|--------------|--|-------|--|-------|--|-------|--|-------|--|-------|

|                            |  |  |  |         |  |       |  |  |  |  |
|----------------------------|--|--|--|---------|--|-------|--|--|--|--|
| Royalty (recovery) expense |  |  |  | (3,258) |  | 3,258 |  |  |  |  |
|----------------------------|--|--|--|---------|--|-------|--|--|--|--|

Total cost of processing and  
storage revenues

|  |       |       |        |       |       |
|--|-------|-------|--------|-------|-------|
|  | 8,278 | 4,106 | 10,399 | 5,877 | 3,070 |
|--|-------|-------|--------|-------|-------|

|                          |        |        |        |        |       |
|--------------------------|--------|--------|--------|--------|-------|
| Research and development | 13,359 | 15,134 | 13,226 | 11,429 | 6,978 |
|--------------------------|--------|--------|--------|--------|-------|

|                     |        |        |        |        |       |
|---------------------|--------|--------|--------|--------|-------|
| Sales and marketing | 24,702 | 19,322 | 20,959 | 16,578 | 9,349 |
|---------------------|--------|--------|--------|--------|-------|

|                            |        |        |        |        |       |
|----------------------------|--------|--------|--------|--------|-------|
| General and administrative | 12,193 | 13,468 | 15,222 | 10,920 | 7,086 |
|----------------------------|--------|--------|--------|--------|-------|

|                          |  |  |        |       |     |
|--------------------------|--|--|--------|-------|-----|
| In-process technology(3) |  |  | 23,925 | 5,889 | 594 |
|--------------------------|--|--|--------|-------|-----|

|                             |       |       |       |       |       |
|-----------------------------|-------|-------|-------|-------|-------|
| Stock-based compensation(4) | 2,163 | 3,429 | 3,232 | 6,464 | 4,490 |
|-----------------------------|-------|-------|-------|-------|-------|

|               |     |       |  |  |  |
|---------------|-----|-------|--|--|--|
| Restructuring | 305 | 2,945 |  |  |  |
|---------------|-----|-------|--|--|--|

|                          |        |        |        |        |        |
|--------------------------|--------|--------|--------|--------|--------|
| Total operating expenses | 61,000 | 58,404 | 86,963 | 57,157 | 31,567 |
|--------------------------|--------|--------|--------|--------|--------|

|                |          |          |          |          |          |
|----------------|----------|----------|----------|----------|----------|
| Operating loss | (16,557) | (20,130) | (55,083) | (36,782) | (24,269) |
|----------------|----------|----------|----------|----------|----------|

|                                |       |       |       |     |       |
|--------------------------------|-------|-------|-------|-----|-------|
| Interest (expense) income, net | 1,880 | (967) | (385) | 744 | 2,136 |
|--------------------------------|-------|-------|-------|-----|-------|

**Income taxes**

|          |    |          |    |          |    |          |    |          |    |          |
|----------|----|----------|----|----------|----|----------|----|----------|----|----------|
| Net loss | \$ | (14,677) | \$ | (21,097) | \$ | (55,468) | \$ | (36,038) | \$ | (22,133) |
|----------|----|----------|----|----------|----|----------|----|----------|----|----------|

Net loss attributable to common  
stockholders

|    |          |    |          |    |          |    |          |    |          |
|----|----------|----|----------|----|----------|----|----------|----|----------|
| \$ | (15,663) | \$ | (34,168) | \$ | (64,884) | \$ | (44,182) | \$ | (28,753) |
|----|----------|----|----------|----|----------|----|----------|----|----------|

Net loss per common share, basic and  
diluted

|    |        |    |         |    |         |    |         |    |         |
|----|--------|----|---------|----|---------|----|---------|----|---------|
| \$ | (0.44) | \$ | (12.62) | \$ | (24.63) | \$ | (17.60) | \$ | (12.22) |
|----|--------|----|---------|----|---------|----|---------|----|---------|

Weighted average shares used in  
computing net loss per common share,  
basic and diluted

|            |           |           |           |           |
|------------|-----------|-----------|-----------|-----------|
| 35,777,308 | 2,707,219 | 2,634,096 | 2,510,632 | 2,352,468 |
|------------|-----------|-----------|-----------|-----------|



**Table of Contents****As of December 31**

**2005                      2004                      2003                      2002                      2001**

**(In thousands, except share and per share data)**

**Consolidated Balance Sheet Data:**

|  |           |           |           |           |           |
|--|-----------|-----------|-----------|-----------|-----------|
| Cash, cash equivalents, short- and long-term investments | \$ 60,544 | \$ 28,585 | \$ 46,832 | \$ 29,188 | \$ 53,787 |
| Working capital  | 60,946    | 14,437    | 22,857    | 25,407    | 46,062    |
| Total assets   | 94,230    | 61,091    | 78,161    | 56,119    | 70,981    |
| Long-term debt obligations, including current portion    | 1,627     | 18,736    | 19,238    | 5,173     | 1,586     |
| Redeemable convertible preferred stock                   |           | 175,173   | 162,141   | 110,912   | 101,268   |
| Total stockholders' equity (deficit)                     | 56,010    | (160,957) | (130,151) | (70,487)  | (38,749)  |

- (1) We acquired Kourion Therapeutics in September 2003, and our financial results for the year ended December 31, 2003 include the results of Kourion Therapeutics' operations for the three months ended December 31, 2003. Had we included the results of Kourion Therapeutics' operations for the full fiscal year 2003, we would have reported additional revenues, operating expenses and net loss of \$0.6 million, \$2.8 million and \$2.1 million, respectively.
- (2) In October 2003, a jury awarded PharmaStem a royalty of \$2.9 million on our cord blood processing and storage revenues based on a claim of patent infringement. As a result, we recorded an expense of \$3.3 million, included in cost of processing and storage revenues, in 2003 to cover our exposure to PharmaStem. In 2004, the Delaware district court overturned the jury verdict. Based on the district court's ruling, we reversed the entire royalty accrual in 2004.
- (3) In-process technology expense for the year ended December 31, 2003 included \$22.1 million, being the fair value of technology acquired in the purchase of Kourion Therapeutics, and \$1.8 million in respect of technology acquired from Amgen and GlaxoSmithKline. The expense in the years ended December 31, 2002 and 2001 represented the fair value of warrants related to technology licensed from Amgen of \$5.9 million and stock options granted to Genzyme for a research collaboration valued at \$0.6 million, respectively.
- (4) Stock-based compensation expense represents the amortization of the excess of the fair value on the date of grant of the stock underlying the options granted to employees over the exercise price and the expense related to the fair value of options granted to non-employees. Total stock-based compensation for employees and non-employees for the periods reported, and the allocation of these expenses to operating expenses, is as follows:

**Years Ended December 31,**

**2005                      2004                      2003                      2002                      2001**

**(In thousands)**

|   |       |       |       |       |       |
|---|-------|-------|-------|-------|-------|
| Cost of processing and storage revenues | \$ 20 | \$ 32 | \$ 7  | \$ 20 | \$    |
| Research and development                | 294   | 896   | 1,073 | 2,489 | 2,249 |
| Sales and marketing                     | 207   | 175   | 414   | 670   | 222   |
| General and administrative              | 1,642 | 2,083 | 1,738 | 3,283 | 2,019 |

|                                |          |          |          |          |          |
|--------------------------------|----------|----------|----------|----------|----------|
| Restructuring                  | 243      |          |          |          |          |
| Total stock-based compensation | \$ 2,163 | \$ 3,429 | \$ 3,232 | \$ 6,464 | \$ 4,490 |

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

The following discussion and analysis by our management of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes appearing at the end of this report. This discussion and other parts of this report contain forward-looking

## **Table of Contents**

statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the Risk Factors That May Affect Results section of this report.

### **Overview**

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. We have a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. We are currently conducting a Phase I clinical trial of CB001, our lead umbilical cord blood-derived stem cell therapy product candidate as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In addition to our therapeutic research and development programs, we have a reproductive health business unit that generated revenues of \$43.8 million in 2005 from sales of ViaCord, a product offering through which expectant families can preserve their baby's umbilical cord blood for possible future medical use. We are working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte<sup>sm</sup>, our investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs.

Our management currently uses consolidated financial information in determining how to allocate resources and assess performance. We have determined that we conduct operations in one business segment. The majority of our revenues since inception have been generated in the United States, and the majority of our long-lived assets are located in the United States.

### ***Revenues***

Our current revenues are derived primarily from fees charged to families for the preservation and storage of a child's umbilical cord blood collected at birth. These fees consist of an initial fee for collection, processing and freezing of the umbilical cord blood and an annual storage fee. The annual storage fee provides a growing annuity of future revenue as the number of stored umbilical cords increases. Our revenues are recorded net of discounts and rebates that we offer our customers under certain circumstances from time to time. Our revenues have increased substantially over the last several years as cord blood banking has gained increased popularity; however, we are unable to predict our future revenues from our umbilical cord blood business. We offer our customers the opportunity to pay their fees directly to us or to finance them with a third party credit provider. The majority of our customers owe their fees directly to us, accordingly we assume the risk of losses due to unpaid accounts. We maintain a reserve for doubtful accounts to allow for this exposure and consider the amount of this reserve to be adequate at December 31, 2005.

We are in ongoing litigation with PharmaStem Therapeutics over PharmaStem's claims that our cord blood preservation business infringes certain of PharmaStem's patents. In the second half of 2004, the Delaware District Court overturned a jury verdict of infringement against us in such suit. As a result of this ruling, we do not expect the PharmaStem litigation to have a materially adverse impact on our net sales, revenues or income from continuing operations. However, PharmaStem has appealed the court's decision and has also filed a new suit claiming that we infringe additional patents. Should we ultimately lose the appeal, or the additional ongoing litigation with PharmaStem, it could have a material adverse effect on our net sales, revenues or income from continuing operations, including, possibly, resulting in an injunction preventing us from operating our cord blood preservation business.

In addition to the revenues generated by our ViaCord product, we recorded revenues in the periods presented from grant agreements with both the Governments of Singapore and Germany. We maintain a research facility in Singapore. We closed our German research facility in December 2004, and have transitioned the research activities performed there to the United States. As a result, revenues from grants in Germany have ceased as of December 31, 2004.

**Table of Contents*****Operating Expenses***

Cost of processing and storage revenues reflects the cost of transporting, testing, processing and storing umbilical cord blood at our cord blood processing facility in Hebron, Kentucky, as well as, for certain periods, an accrual of a royalty to PharmaStem relating to ongoing patent infringement litigation. Our cost of processing and storage revenues also includes expenses incurred by third party vendors relating to the transportation of cord blood to our processing facility and certain assay testing performed by a third party on the cord blood before preservation. Other variable costs include collection materials, labor, and processing and storage supplies, while other fixed costs include rent, utilities and other general facility overhead expenses. Cost of processing and storage revenues does not include costs associated with our grant revenue. Such costs are included in research and development expense.

We recorded a royalty expense of \$3.3 million in 2003 following an unfavorable jury verdict in the PharmaStem litigation in October 2003. In 2004, the District Court overturned the jury verdict. Based on the judge's ruling, we reversed the entire royalty accrual in 2004 and have not recorded any royalties since such date. PharmaStem has appealed the District Court's ruling. PharmaStem has also filed a new lawsuit claiming that we infringe additional patents. Pending a decision on the appeal and further action by the court on the new litigation, we do not intend to record a royalty expense in future periods, since we believe PharmaStem's claims are without merit. It is possible that the final outcome of these litigations could result in damages payable for infringement of PharmaStem's patents, at a higher or lower amount than previously awarded by the jury in Delaware. Should this occur, our financial position and results of operations could be materially affected. We may enter into settlement negotiations with PharmaStem regarding the litigation. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts by us to PharmaStem, or what those amounts might be.

Our research and development expenses consist primarily of costs associated with the continued development of our lead stem cell product candidate, CB001, our expansion technologies, including Selective Amplification, our other cellular therapy product candidates and ViaCyte, our oocyte cryopreservation product candidate. These expenses represent both clinical development costs and costs associated with non-clinical support activities such as toxicological testing, manufacturing, process development and regulatory services. The cost of our research and development staff is the most significant category of expense, however we also incur expenses for external service providers, including preclinical studies and consulting expenses. The major expenses relating to our CB001 clinical trial include external services provided for outside quality control testing, clinical trial monitoring, data management, and fees relating to the general administration of the clinical trial. Other direct expenses relating to our CB001 clinical trial include site costs and the cost of the cord blood.

We expect that research and development expenses will increase in the foreseeable future as we add personnel, expand our clinical trial activities and increase our discovery research and clinical and regulatory capabilities. The amount of these increases is difficult to predict due to the uncertainty inherent in our research, development and manufacturing programs and activities, the timing and scope of our clinical trials, the rate of patient enrollment in our clinical trials, and the detailed design of future clinical trials. In addition, the results from our clinical trials, as well as the results of trials of similar therapeutics under development by others, will influence the number, size and duration of planned and unplanned trials. On an ongoing basis, we evaluate the results of our product candidate programs, all of which are currently in early stages. Based on these assessments, for each program, we consider options including, but not limited to, terminating the program, funding continuing research and development with the eventual aim of commercializing products, or licensing the program to third parties.

Our sales and marketing expenses relate to our ViaCell Reproductive Health business. The majority of these costs relate to our sales force and support personnel, as well as telecommunications expense related to our call center. We also incur external costs associated with advertising, direct mail, promotional and other marketing services. We expect that sales and marketing expenses will increase in the foreseeable future as we expand our sales and marketing efforts.

**Table of Contents**

Our general and administrative expenses include our costs related to the finance, legal, human resources, business development, investor relations and corporate governance areas. These costs consist primarily of expenses related to our staff, as well as external fees paid to our legal and financial advisors, business consultants and others. We expect that these costs will increase in future years as we expand our business activities and as we incur additional costs associated with being a publicly-traded company.

In September 2004, we restructured our operations to reduce operating expenses and concentrate resources on our ViaCord product offering and three key products and product candidates. As a result, we recorded a \$1.7 million restructuring charge related to employee severance, contractual termination fees and the write down of excess equipment. In December 2004 we restructured our German operations and sub-leased our German facility to a third party. As a result we recorded a restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility costs of \$1.1 million and \$0.1 million related to a contract termination fee. The majority of the facility related costs consists of the write off of the leasehold improvements and fixed assets in our German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future lease payments receivable from the sub-lessee.

We are finalizing discussions with the German grant authorities regarding repayment of part of certain grants made to our German subsidiary in 2003 and 2004. We were notified that approximately \$500,000 in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. As a result, we reserved an additional \$410,000 during the year ended December 31, 2005 for our estimated liability under this grant. The additional reserves resulted in reversals of grant revenue of approximately \$105,000 for the year ended December 31, 2005. In addition, we reclassified approximately \$200,000 of accrued restructuring reserves to reduce outstanding grants receivable. In February 2006 we were notified by the State of North-Rhine-Westfalia, Germany that it plans on performing an audit of the State's economic grants throughout its territory, including the grant to Kourion. It is possible that the grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany, however we consider this possibility to be remote. As of December 31, 2005 we had received approximately \$3.6 million in cumulative grant proceeds from the German grant authorities.

**Results of Operations**

*Years Ended December 31, 2005, 2004 and 2003 (amounts in millions, year over year changes based on rounded amounts in millions)*

|                                       | 2005    | 2004    | 2003    | \$ Change<br>2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|---------------------------------------|---------|---------|---------|------------------------------|--------------------------------|------------------------------|--------------------------------|
| Processing revenues                   | \$ 36.1 | \$ 31.7 | \$ 27.8 | \$ 4.4                       | 14%                            | \$ 3.9                       | 14%                            |
| Storage revenues                      | 7.7     | 5.1     | 3.1     | 2.6                          | 51%                            | 2.0                          | 65%                            |
| Total processing and storage revenues | 43.8    | 36.8    | 30.9    | 7.0                          | 19%                            | 5.9                          | 19%                            |
| Grant and contract revenues           | 0.6     | 1.5     | 1.0     | (0.9)                        | (60)%                          | 0.5                          | 50%                            |
| Total revenues                        | \$ 44.4 | \$ 38.3 | \$ 31.9 | \$ 6.1                       | 16%                            | \$ 6.4                       | 20%                            |

The increases in processing revenues of \$4.4 million or 14% from 2004 to 2005 and \$3.9 million or 14% from 2003 to 2004 are due primarily to an increase in the total number of umbilical cords processed, as well as a slight



increase in the average selling price for processing. The increase in storage revenues of \$2.6 million or 51% from 2004 to 2005 and \$2.0 million or 65% from 2003 to 2004 are due primarily to increases in the number of umbilical cords stored, as well as a slight increase in the average selling price for storage.

The decrease in grant and contract revenues of \$0.9 million or 60% from 2004 to 2005 was primarily due to the decrease of \$1.1 million in grant revenues from German grant authorities following cessation of our operations in Germany in 2004 and a decrease in contract revenues derived from research activities in the

**Table of Contents**

United States of \$0.2 million. These decreases were partially offset by an increase in grant revenues from the Government of Singapore of \$0.4 million. The increase in grant and contract revenues of \$0.5 million or 50% from 2003 to 2004 was primarily due to the inclusion of German grant revenue of \$0.6 million attributable to the acquisition of Kourion Therapeutics on September 30, 2003.

|   | 2005   | 2004   | 2003    | \$ Change<br>2004 to<br>2005 | % Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | % Change<br>2003 to<br>2004 |
|---|--------|--------|---------|------------------------------|-----------------------------|------------------------------|-----------------------------|
| Cost of processing and storage revenues:      |        |        |         |                              |                             |                              |                             |
| Direct costs                                  | \$ 8.3 | \$ 7.4 | \$ 7.1  | \$ 0.9                       | 12%                         | \$ 0.3                       | 4%                          |
| Royalty expense                               |        | (3.3)  | 3.3     | 3.3                          | 100%                        | (6.6)                        | (200)%                      |
| Total cost of processing and storage revenues | \$ 8.3 | \$ 4.1 | \$ 10.4 | \$ 4.2                       | 102%                        | \$ (6.3)                     | (61)%                       |

The increases in direct costs of \$0.9 million or 12% from 2004 to 2005 and \$0.3 million or 4% from 2003 to 2004 were due primarily to increases in variable expenses related to the increased number of umbilical cords processed and number of umbilical cords stored. These variable expenses relate to transportation of the cord blood and materials for related collection and testing of the umbilical cord blood. The royalty expense of \$3.3 million in 2003 was due to our accrual of \$3.3 million in connection with the PharmaStem lawsuit, to cover our cumulative royalty expense from August 2000 through December 31, 2003 following the jury verdict that was announced in October 2003. The jury verdict of infringement was overturned by the District Court judge in the second half of 2004 and a credit to royalty expense of \$3.3 million was recorded in 2004.

While PharmaStem has appealed the District Court's ruling, we continue to believe that the lawsuit is without merit and, in light of the judge's ruling, have determined that no royalty accrual or expense is required.

|                                | 2005    | 2004    | 2003    | \$ Change<br>2004 to<br>2005 | % Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | % Change<br>2003 to<br>2004 |
|--------------------------------|---------|---------|---------|------------------------------|-----------------------------|------------------------------|-----------------------------|
| Clinical development           | \$ 9.4  | \$ 7.9  | \$ 7.3  | \$ 1.5                       | 19%                         | \$ 0.6                       | 8%                          |
| Pre-clinical programs          | 0.7     | 3.5     | 2.1     | (2.8)                        | (80)%                       | 1.4                          | 67%                         |
| Basic research                 | 2.5     | 3.0     | 3.1     | (0.5)                        | (17)%                       | (0.1)                        | (3)%                        |
| Other R&D                      | 0.8     | 0.7     | 0.7     | 0.1                          | 14%                         |                              | 0%                          |
| Total research and development | \$ 13.4 | \$ 15.1 | \$ 13.2 | \$ (1.7)                     | (11)%                       | \$ 1.9                       | 14%                         |

Clinical development expense is related primarily to outside services and clinical trial expenses for CB001. The increases in clinical development expense of \$1.5 million or 19% from 2004 to 2005 and \$0.6 million or 8% from 2003 to 2004 reflected the increasing cost of conducting the Phase I clinical trial that commenced in late 2003.

The decrease in costs associated with preclinical programs of \$2.8 million or 80% from 2004 to 2005 was primarily due to the closure of our German research operations in December 2004, and the discontinuation of our muscular dystrophy program in September 2004. These changes resulted in lower ongoing employee and facility

related costs. The increase in costs associated with preclinical programs of \$1.4 million or 67% from 2003 to 2004 was primarily due to a complete year of expenses for our German research operations following the acquisition of Kourion Therapeutics in September 2003.

The decrease in basic research expense was primarily related to the reduced facility and employee-related costs associated with the closure of our Cambridge research facility as we consolidated our general research activities into our Singapore research center. Other research and development expense related primarily to our umbilical cord blood processing and storage business.

**Table of Contents**

|                     | 2005    | 2004    | 2003    | \$ Change<br>2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|---------------------|---------|---------|---------|------------------------------|--------------------------------|------------------------------|--------------------------------|
| Sales and marketing | \$ 24.7 | \$ 19.3 | \$ 21.0 | \$ 5.4                       | 28%                            | \$ (1.7)                     | (8)%                           |

The increase in sales and marketing expenses of \$5.4 million or 28% from 2004 to 2005 was primarily related to increased staffing within both the internal and external sales organization and increased external marketing program spending to strengthen our market presence. The decrease in sales and marketing expenses of \$1.7 million or 8% from 2003 to 2004 was primarily due to cost savings attributed to a reduction in the number of internal sales employees following the implementation of call center automation technology.

|                            | 2005    | 2004    | 2003    | \$ Change<br>2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|----------------------------|---------|---------|---------|------------------------------|--------------------------------|------------------------------|--------------------------------|
| General and administrative | \$ 12.2 | \$ 13.5 | \$ 15.2 | \$ (1.3)                     | (10)%                          | \$ (1.7)                     | (11)%                          |

The decrease in general and administrative expenses of \$1.3 million or 10% from 2004 to 2005 was primarily due to a decrease in employee related costs of \$0.9 million as a result of our restructuring in September 2004 as well as a decrease in consulting costs of \$0.6 million, and a decrease in litigation expenses of \$0.7 million relating to the PharmaStem lawsuit, partially offset by increased accounting fees and outside service fees of \$0.4 million and increased insurance premiums of \$0.5 million associated with being a public company.

The decrease in general and administrative expenses of \$1.7 million or 11% from 2003 to 2004 was due primarily to the decrease in litigation expenses of \$2.3 million, relating to the PharmaStem lawsuit, a decrease in transaction costs of \$0.7 million relating to the acquisition of Kourion Therapeutics in September 2003, and a reduction in bad debt expense of \$0.3 million due to continued improvements in our collection efforts in 2004. These decreases were offset by additional consulting costs related to our ViaCyt program of \$0.3 million, an increase in general legal costs of \$0.3 million, an increase of \$0.3 million relating to additional accounting and audit fees related to quarterly reviews in preparation for our IPO, and increased employee related costs of \$0.7 million, primarily due to employee severance and payroll increases related to exiting employees.

|                       | 2005 | 2004 | 2003    | \$ Change<br>2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|-----------------------|------|------|---------|------------------------------|--------------------------------|------------------------------|--------------------------------|
| In-process technology | \$   | \$   | \$ 23.9 | \$                           | N/A                            | \$ (23.9)                    | (100)%                         |

No in-process technology expenses were incurred in 2004 and 2005. The expense in 2003 consisted primarily of the portion of the Kourion Therapeutics purchase price allocated to acquired in-process technology, representing \$22.1 million. In addition, \$1.7 million represented the stem cell growth factor technology licensed from Amgen, and \$0.1 million related to technology licensed from GlaxoSmithKline.

\$ Change

\$ Change

|                          | 2005   | 2004   | 2003   | 2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | 2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|--------------------------|--------|--------|--------|-----------------|--------------------------------|-----------------|--------------------------------|
| Stock-based compensation | \$ 2.2 | \$ 3.4 | \$ 3.2 | \$ (1.2)        | (35)%                          | \$ 0.2          | 6%                             |

Stock-based compensation expense is primarily due to the amortization of the excess of the fair value on the date of the grant of the stock underlying the options granted to employees, over the exercise price. The amortization is based on the vesting period of the related options and relates primarily to options granted prior to our IPO. During the year ended December 31, 2005, we did not grant any options with exercise prices less than fair market value on the date of grant.

In July 2005, our Board of Directors approved an increase, from 90 days to three years, in the amount of time allowed for non-employee directors to exercise vested options following termination of service to ViaCell. As a result of this modification of the option terms, we recorded \$0.8 million of stock-based compensation expense in the year ended December 31, 2005. We will record stock-based compensation expense related to the unamortized deferred compensation associated with this option modification of approximately \$0.2 million in the years 2006 through 2008 based on respective vesting schedules associated with each modified option grant. The amount of stock-based compensation actually recognized in future periods could decrease if options for which accrued but unvested compensation has been recorded are forfeited.

**Table of Contents**

The net decrease in stock-based compensation expense from 2004 to 2005 was primarily related to the amortization of the deferred compensation account since no new options were granted with exercise prices less than fair market value in 2005, partially offset by the additional stock-based compensation expense related to the modified option terms. The increase in stock-based compensation expense from 2003 to 2004 was primarily due to \$0.2 million of additional stock-based compensation expense incurred in 2004 related to the modification of employee options to extend the option exercise period for employees terminated in our restructuring.

In December 2004, the Financial Accounting Standards Board ( FASB ) released SFAS No. 123(R) -*Share-Based Payment*. This new accounting standard requires all forms of stock compensation given to employees, including stock options, to be reflected as an expense in our financial statements. Public companies must adopt the standard by their first annual fiscal period beginning after June 15, 2005. We intend to apply the revised standard in the annual period beginning January 1, 2006. Although we have not finalized our analysis, we expect that the adoption of the revised standard will result in higher operating expenses and higher net loss per share.

|               | 2005   | 2004   | 2003 | \$ Change<br>2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|---------------|--------|--------|------|------------------------------|--------------------------------|------------------------------|--------------------------------|
| Restructuring | \$ 0.3 | \$ 2.9 | \$   | \$ (2.6)                     | (90)%                          | \$ 2.9                       | 100%                           |

In September 2004 we restructured our operations to reduce operating expenses and concentrate our resources on four key products and product candidates. As a result, we recorded a \$1.7 million restructuring charge related to employee severance, contractual termination fees and the write down of excess equipment. In December 2004 we restructured our German operations and sub-leased our German facility to a third party. As a result we recorded a restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility costs of \$1.1 million and \$0.1 million related to a contract termination fee. The majority of the facility related costs consisted of the write off of the leasehold improvements and fixed assets in our German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future lease payments receivable from the sub-lessee.

In November 2005, the sub-lessee verbally gave notice of their intent to not extend the sublease past December 31, 2006. The sub-lessee has prepaid rent through December 2006.

In 2005 we were notified that approximately \$0.5 million in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. As a result, we recorded restructuring expense of \$0.3 million in 2005 to reserve for this liability. In February 2006 we were notified by the State of North-Rhine-Westfalia, Germany that it plans on performing an audit of the state's economic grants granted throughout its territory, including the grant to Kourion. It is also possible that the German grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by them for research performed in Germany, however we consider this possibility to be remote. As of December 31, 2005, we had received approximately \$3.6 million in grant proceeds from the German grant authorities.

|                  | 2005   | 2004     | 2003     | \$ Change<br>2004 to<br>2005 | %<br>Change<br>2004 to<br>2005 | \$ Change<br>2003 to<br>2004 | %<br>Change<br>2003 to<br>2004 |
|------------------|--------|----------|----------|------------------------------|--------------------------------|------------------------------|--------------------------------|
| Interest income  | \$ 2.2 | \$ 0.5   | \$ 0.3   | \$ 1.7                       | 340%                           | \$ 0.2                       | 67%                            |
| Interest expense | (0.3)  | (1.5)    | (0.7)    | 1.2                          | 80%                            | (0.8)                        | (114)%                         |
|                  | \$ 1.9 | \$ (1.0) | \$ (0.4) | \$ 2.9                       | 290%                           | \$ (0.6)                     | (150)%                         |

Total interest income  
(expense), net

Interest income is earned primarily from the investment of our cash in short-term securities and money market funds. The increase in interest income of \$1.7 million or 340% from 2004 to 2005 primarily relates to increased average investment balances resulting from a higher cash balance available for investment following our initial public offering in January 2005, as well as an increase in interest rates. The decrease in interest expense of \$1.2 million or 80% from 2004 to 2005 relates primarily to the reduction of interest on the related party notes payable, which were paid in full following the closing of our IPO in January 2005.

**Table of Contents**

In the years 2004 and 2003, interest income was earned from the investment of our cash in short and long term securities and money market funds. The changes in the amount of interest income recorded in 2004 and 2003 are primarily due to the changes in our average cash balance during those periods. In the years 2004 and 2003, interest expense relates to interest payable on our credit facility and, in 2004, \$1.1 million of interest expense was recorded on the \$14.0 million note we issued in connection with the acquisition of Kourion.

**Liquidity and Capital Resources**

From inception through December 31, 2005, we have raised \$192.0 million in common and preferred stock issuances, which includes \$53.3 million in net proceeds from our IPO in January 2005. We used approximately \$15.5 million of these net proceeds to repay in full related party notes of \$14.0 million, and accrued interest thereon of \$1.5 million. As of December 31, 2005, we had approximately \$60.5 million in cash, cash equivalents and investments, which we believe is sufficient to meet our anticipated liquidity needs for at least the next three years.

Table excerpted from our Consolidated Statements of Cash Flows (in millions):

|   | Years Ended December 31, |           |           | \$ Change       | \$ Change       |
|---|--------------------------|-----------|-----------|-----------------|-----------------|
|   | 2005                     | 2004      | 2003      | 2004 to<br>2005 | 2003 to<br>2004 |
| Net cash used in operating activities               | \$ (1.4)                 | \$ (15.1) | \$ (22.5) | \$ 13.7         | \$ 7.4          |
| Net cash provided by (used in) investing activities | (9.1)                    | (15.2)    | 9.5       | 6.1             | (24.7)          |
| Net cash provided by (used in) financing activities | 37.1                     | (1.7)     | 36.4      | 38.8            | (38.1)          |
| Cash and cash equivalents, end of period            | \$ 33.1                  | \$ 6.7    | \$ 39.0   | \$ 26.4         | \$ (32.3)       |

Net cash used in operating activities was \$1.4 million for the year ended December 31, 2005, a decrease of 91% from the \$15.1 million used in 2004. Net cash used in operating activities decreased 33% in 2004 compared to the \$22.5 million used in 2003. For the year ended December 31, 2005, the \$1.4 million cash used by operations was primarily due to our net loss of \$14.7 million, reduced by non-cash expenses of \$4.9 million, cash received by us for reimbursement from our landlord related to the build-out of our laboratory facility in Cambridge of \$2.4 million, net increases in deferred rent of \$0.9 million and net increases in deferred revenue of \$5.5 million, offset by a net increase in working capital (accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses) of \$0.4 million. The increase in deferred rent was due to prepaid rent received by us from a sublease tenant in Germany. The increase in deferred revenue of \$5.5 million related to sales of long-term pre-paid storage contracts, as well as advances received in connection with our grant program with the Government of Singapore. The decrease in the net cash used in operations in 2004 was primarily related to the increased revenue from our cord blood preservation business, a reduction in operating expenses primarily relating to legal litigation costs related to PharmaStem and the refund to us of the \$2.9 million royalty escrow payment following the judge's ruling in the second half of 2004 in the PharmaStem litigation that overturned a previous jury finding of infringement.

Net cash used in investing activities for the year ended December 31, 2005 was \$9.1 million. Net cash used in investing activities was \$15.2 million in 2004 as compared to net cash provided of \$9.5 million in 2003. For the year ended December 31, 2005, \$36.5 million of U.S. Government and high-rated corporate securities matured and \$42.1 million was invested in similar securities. We also invested approximately \$3.9 million in property and equipment for the year ended December 31, 2005. Approximately \$2.5 million of the total spent on property and equipment during the year ended December 31, 2005 related to the build-out of our manufacturing facility and laboratory in Cambridge, which was completed in August 2005. We expect that this facility will give us the capacity to complete Phase 2 and Phase 3 clinical trials and proceed to initial commercialization of CB001, if successfully developed. We expect to need to build or acquire another manufacturing facility in order to fully commercialize CB001 and our other product candidates, if successfully developed. The timing and cost of such a facility is not known at this time, however the cost is likely to be substantial. We also received proceeds of \$0.4 million related to the return of a security deposit which secured our long-term debt obligations.





**Table of Contents**

In 2004, \$22.7 million of US Government and high-rated corporate securities matured and \$36.7 million was reinvested in similar securities. In 2003, \$15.8 million of similar investments matured during 2003 and \$9.7 million was reinvested. In addition, we acquired approximately \$2.4 million and \$1.8 million in property and equipment in 2004 and 2003, respectively. Of our investments in property and equipment, approximately \$1.1 million and \$1.9 million consisted of laboratory equipment in 2004 and 2003, respectively. The remaining investments in property and equipment consisted of computer equipment, software and furniture and fixtures. In 2004, we also received proceeds of \$0.4 million related to the return of a security deposit which secured our long-term debt obligations. In 2002, certain property and equipment additions were financed with the proceeds of a credit facility. In 2003, we replaced that credit facility with the \$5.0 million credit facility from General Electric Capital Corporation. As a result of replacing the original credit facility, we were able to reduce the amount of cash required to be held as collateral for the amount borrowed with the result that our restricted cash balance was reduced by \$0.8 million and \$3.2 million in 2004 and 2003, respectively.

Net cash provided by financing activities in 2005 was \$37.1 million. Net cash used in financing activities amounted to \$1.7 million in 2004 and net cash provided by financing activities amounted to \$36.4 million in 2003. For the year ended December 31, 2005, the net cash provided by financing activities included net proceeds from our IPO of \$53.3 million, as well as proceeds of \$1.1 million relating to exercised stock options. These proceeds were partially reduced by the amount of cash used to repay related party notes of approximately \$15.5 million related to the acquisition of Kourion Therapeutics and to make repayments of \$1.8 million on our long-term debt obligations.

The net cash provided by financing activities in 2003 included the proceeds from the issuance of redeemable convertible preferred stock of \$36.9 million. In 2003, we issued promissory notes totaling \$14.0 million to former stockholders of Kourion Therapeutics in connection with our acquisition of that company in September 2003. In 2002, certain property and equipment additions were financed with the proceeds of a credit facility. In 2003, we replaced that credit facility with the \$5.0 million credit facility from General Electric Capital Corporation. In 2004 no additional financing occurred, however we repaid \$1.6 million on our credit facility, as well as \$0.2 million related to capital lease obligations, offset by proceeds from common stock option exercises of \$0.1 million.

We anticipate that our current cash, cash equivalents and investments will be sufficient to fund our operations for at least the next three years. However, our forecast for the period of time during which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more clinical trials, or other aspects of our operations.

**Commitments and Contingencies**

The table below summarizes our commitments and contingencies at December 31, 2005 (in millions and does not include our accounts payable and accrued expenses):

| <b>Contractual Obligations</b>       | <b>Total</b>   | <b>Less Than One Year</b> | <b>One to Three Years</b> | <b>Four to Five Years</b> | <b>After Five Years</b> |
|--------------------------------------|----------------|---------------------------|---------------------------|---------------------------|-------------------------|
| Operating lease obligations          | \$ 17.9        | \$ 2.2                    | \$ 4.1                    | \$ 4.1                    | \$ 7.5                  |
| Capital lease obligations            | 0.2            | 0.1                       | 0.1                       |                           |                         |
| Short and long-term debt(1)          | 1.5            | 1.5                       |                           |                           |                         |
| Consulting agreements                | 0.8            | 0.5                       | 0.1                       | 0.1                       | 0.1                     |
| License agreements(2)                | 3.1            | 0.6                       | 0.5                       | 0.6                       | 1.4                     |
| Contingent purchase price(3)         | 8.2            |                           | 3.0                       |                           | 5.2                     |
| <b>Total contractual obligations</b> | <b>\$ 31.7</b> | <b>\$ 4.9</b>             | <b>\$ 7.8</b>             | <b>\$ 4.8</b>             | <b>\$ 14.2</b>          |



## **Table of Contents**

(1) Includes interest and principal obligations.

(2) We have included several patent license agreements for technologies that are in early stages of development. While we are currently making license payments under some of these agreements, we can cancel each of these agreements at any time without further financial obligation. Of the \$3.1 million payable under license agreements, \$1.9 million relates to these cancelable agreements.

(3) See Notes 3 and 9 to our consolidated financial statements.

We provide our ViaCord customers with a product guarantee under which we agree that we will pay \$25,000 to defray the costs associated with the original collection and storage and identification and procurement of an alternative stem cell source, if medically indicated, in the event that the customer's cord blood is used in a stem cell transplant and fails to engraft. To date, we have not experienced any claims under the guarantee program and we maintain reserves against possible claims in amounts we believe are adequate to protect us against potential liabilities arising under the program. However, we do not maintain insurance to cover these potential liabilities. If we were to become subject to significant claims under this program in excess of the amount we have reserved, our financial results and financial condition could be adversely affected.

In September 2004, we launched an indemnification program offering protection to physicians from patent litigation actions taken against them by PharmaStem Therapeutics, Inc. Under this program, we agreed to pay reasonable defense costs resulting from such litigation, providing that the physician allowed us to manage his or her defense. In addition, we agreed to indemnify the physician against all potential financial liability resulting from such litigation, and we agreed to pay additional remuneration of \$100,000 should PharmaStem prevail in any patent infringement action against the physician. In order to qualify for this indemnification, the physician is required to comply with certain requirements, including returning a signed acknowledgement form regarding the particulars of the indemnification program. We recorded a reserve associated with this program in our financial statements in the quarter ended September 30, 2004. The reserve was equal to the estimated fair value of the indemnifications in place re-evaluated as of December 31, 2004 in accordance with FASB Interpretation No. 45, *Guarantors' Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, (FIN 45). We further re-evaluated this reserve at December 31, 2005 and concluded that no change in the reserve was necessary. To date, no claims have been made under this program. We may record additional charges if more physicians participate in this program.

Other than outstanding warrants exercisable for up to 3,212,083 shares of our common stock at December 31, 2005, we have no off balance sheet arrangements, as defined by Item 303(a)(4) of the SEC's Regulation S-K. Please see note 11 of our consolidated financial statements for a description of the warrants.

### ***Loan Obligation***

In October 2003, we entered into a \$5.0 million loan agreement with General Electric Capital Corporation. Borrowings under this agreement bear interest at 6.9% percent per annum and are collateralized by our fixed assets. Payments of principal and interest are due monthly through October 2006, and approximately \$1.5 million remained outstanding under this loan as of December 31, 2005. In accordance with the terms of the loan, we are required to maintain a cash deposit of approximately \$0.9 million with the lender as additional collateral. This deposit is classified within prepaid expenses and other current assets in our consolidated balance sheet.

### ***Lease Obligations***

We entered into a new operating lease commitment in December 2003 to consolidate our headquarters and US laboratory facilities in one location in Cambridge, Massachusetts. In February 2006, we amended this lease agreement for the rent of an additional 7,600 feet of office space. Rent expense on the office portion of this lease commenced in April 2004 and the rent on the laboratory facilities commenced in November 2004,

**Table of Contents**

for a term of ten years. Our office rent under this lease was \$0.4 million per year for the first two years of the lease, increasing to \$0.6 million in 2006, and to \$0.7 million in 2007 and through the remainder of the lease. The increase in the lease obligation is related to additional rent expense for an additional 7,600 square feet of office space beginning in February 2006. Our laboratory rent under this lease is \$1.0 million per year for the first two years of the lease, increasing to \$1.1 million per year for the next four years, and increasing to \$1.2 million through the remainder of the lease. Approximately \$2.5 million of the total spent on property and equipment during the year ended December 31, 2005 related to the build-out of our manufacturing facility and laboratory in Cambridge, Massachusetts, which was completed in August 2005. Our lease agreement provided for an allowance from our landlord of approximately \$2.5 million to offset these capital improvements, which was received in full in 2005. In connection with this operating lease commitment, we entered into a letter of credit with a commercial bank in December 2003 for \$1.4 million collateralized by certificates of deposit that are classified as restricted cash on our balance sheet.

In April 2002, we entered into a lease commitment for a facility located in Hebron, Kentucky used for the processing and storage of umbilical cord blood. This is a ten-year lease that commenced in June 2002, with renewal rights and a right of first offer. The annual rent is approximately \$0.1 million per year.

As part of our acquisition of Kourion Therapeutics in September 2003, we assumed an operating lease in Langenfeld, Germany that commenced in June 2003, consisting of laboratory and office space. This lease has a term of five years, with a right to one-year extensions each year for an additional five years ending in 2013, with an annual rent of approximately \$0.3 million per year. Effective January 1, 2005, we entered into an agreement with a third party to sub-lease our German facility, including our clean room and other laboratory equipment, for two years, with options to extend the sub-lease through the end of our maximum lease term in 2013. The sub-lease also includes an option under which the sub-lessee can purchase the clean room and equipment for a pre-determined price, in exchange for a reduction in rent. In addition, should the sub-lessee choose not to extend the sub-lease beyond the initial two year period, the sub-lessee must pay us a termination penalty of approximately \$240,000.

In November 2005, the sub-lessee verbally gave notice of its intent to not extend the sublease past December 31, 2006. The sublessee has prepaid rent through December 2006.

In February 2002, we entered into a lease commitment for our research facility in Singapore. This lease has a five-year term that commenced in May 2002 with an annual rent of approximately \$0.1 million per year.

***Acquisition of Kourion Therapeutics***

**Promissory Notes.** As part of our acquisition of Kourion Therapeutics in September 2003, we issued promissory notes totaling \$14.0 million in aggregate principal amount to entities affiliated with MPM Asset Management LLC, maturing September 30, 2007 and bearing interest at a rate of 8% per annum payable in arrears in cash accruing on the unpaid principal balance of the notes, compounded annually and payable on the maturity date subject to their terms. The notes were repaid in January 2005 following the initial public offering of our common stock.

**Milestones.** There are potential future payments totaling up to \$12.0 million payable to former shareholders of Kourion Therapeutics if certain USSC-related product development milestones are achieved. The milestone payments are payable in cash or stock valued at its fair market value at the time of issuance at the election of each shareholder. Also, in our acquisition of Kourion Therapeutics, we issued and deposited 241,481 shares of our Series I preferred stock (which automatically converted into common stock upon the completion of our IPO) into an escrow account, which we agreed would be released immediately following a change in control of the Company, should this event occur prior to September 30, 2006. If this event occurs, we would also issue to certain former shareholders of Kourion Therapeutics an additional 289,256 shares of our common stock. If there is no change in control prior to September 30, 2006, the escrowed shares will be returned to us and the contingent shares will never issue.

**Table of Contents*****License Agreements***

On September 1, 2004, we entered into a license agreement with Tyho Galileo Research Laboratory for exclusive rights to US Patent No. 5,985,538 in the field of oocyte cryopreservation. As part of this agreement, we also entered into a research collaboration with Galileo that is focused on the development of technologies in the field of oocyte and embryo cryopreservation. This project includes research funding by us totaling \$207,000 in the first year of the agreement and \$225,000 in the second year of the agreement as well as a license fee of \$50,000, milestones totaling \$24,000 and a royalty on revenues generated from the sale of ViaCyte, our oocyte cryopreservation product candidate, if successfully developed and commercialized.

***Other Arrangements******Amgen Collaboration Agreement***

In December 2003, we entered into a license and collaboration agreement with Amgen under which we received a royalty-free, worldwide, non-exclusive license to certain Amgen growth factors for use as reagents in producing stem cell therapy products. In August 2005, we expanded the collaboration to include an additional growth factor. Amgen has an option to collaborate with us on any product or products that incorporate a licensed Amgen growth factor or technology. Each time Amgen exercises a collaboration option, it must partially reimburse our past development costs based on a predetermined formula, share in the future development costs, and take primary responsibility for clinical development, regulatory matters, marketing and commercialization of the product. For each collaboration product that receives regulatory approval, Amgen will pay us a cash milestone payment for the first regulatory approval for the first indication of the product in the United States. The parties will share in profits and losses resulting from the collaboration product's worldwide sales. Either we or Amgen may later opt-out of any product collaboration upon advance notice; however, we will retain our license to the Amgen growth factors if either we or Amgen opts out of any product collaboration. In the event Amgen does not exercise its option to collaborate on a particular product, we will owe Amgen a royalty on any sales of such product, if successfully developed. Under this agreement, we can purchase cGMP grade growth factors manufactured by Amgen at a specified price. Upon the mutual agreement of both parties, we also may receive a license to additional Amgen growth factors or technologies that may be useful in stem cell therapy.

In January 2005, we entered into development and supply agreements with Miltenyi Biotec GmbH. The development agreement provides for the development by Miltenyi of a cGMP cell separation kit for us consisting of various antibodies conjugated with magnetic particles to be used in our proprietary Selective Amplification process for the development and commercialization of certain of our cellular therapy product candidates. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the cell separation kit, including making various filings with the U.S. Food and Drug Administration, or FDA. We are obligated to pay Miltenyi up to \$950,000 for development work. As of December 31, 2005, we had paid \$700,000 relating to the development of the product, and are recognizing expense as the work is performed over the development period. For the year ended December 31, 2005, we recognized \$950,000 of expenses related to this development agreement. The remaining payment of \$250,000 relates to a milestone to be paid upon filing the master files for the cell separation kit with the FDA. The agreement terminates on the earlier of the expiration of both parties' obligations under the development agreement or January 24, 2007.

The supply agreement with Miltenyi provides for the exclusive supply of the cell separation kits to us by Miltenyi. The initial term of the supply agreement is for seven years. We have agreed to purchase at least \$1.3 million of cell separation kits within the first year after the process development program has been completed. We also have certain minimum annual purchase requirements starting in fiscal 2007 which will apply if our investigational product for hematopoietic stem cell transplantation, CB001, continues in clinical trials or is commercialized. In January 2006, we paid the first installment of approximately \$625,000 for a quantity of the cell separation kits to be used in our research.

We are a party to various agreements in addition to those previously discussed, including license, research collaboration, consulting and employment agreements and expect to enter into additional agreements in the

## **Table of Contents**

future. We may require additional funds for conducting clinical trials and for preclinical research and development activities relating to our product candidates, as well as for the expansion of our cord blood preservation facility, construction of a cellular therapy manufacturing facility, acquisitions of technologies or businesses, the establishment of partnerships and collaborations complementary to our business and the expansion of our sales and marketing activities.

### **Net Operating Loss Carryforwards**

At December 31, 2005, we had federal and state net operating loss carryforwards of approximately \$82.8 million and \$75.3 million, respectively. These carryforwards begin expiring in 2009 and 2006, respectively. We also had federal and state credit carryforwards of approximately \$3.3 million and \$1.6 million, respectively, which begin expiring in 2009 and 2013, respectively. The Internal Revenue Code places certain limitations on the annual amount of net operating loss carryforwards that can be utilized if certain changes in our ownership occur. The Company also has foreign net operating loss carryforwards of \$14.9 million. The carryforwards expire through 2024 and are subject to review and possible adjustment. Ownership changes, as defined in the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income.

### **Legal Proceedings**

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 ( '681) and No. 5,192,553 ( '553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that we do not infringe these patents and that the patents are invalid.

In 2003, a jury ruled against us and the other defendants, Cbr Systems Inc, CorCell, Inc. and Cryo-Cell International Inc, who represent a majority of the family cord blood preservation industry finding that the patents were valid and enforceable, and that the defendants infringed the patents. A judgment was entered against us for approximately \$2.9 million, based on 6.125% royalties on our revenue from the processing and storage of umbilical cord blood since April 2000. In 2004, the District Court judge in the case overturned the jury's verdict stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge's decision. We have appealed the jury's finding as to validity of the patents. A hearing on the appeal is scheduled for April 4, 2006.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patents No. 6,461,645 ( '645) and 6,569,427 ( '427), which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that the patents in this new action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That motion is currently stayed. We believe the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, our request was granted. The cases have been consolidated in Delaware.

The U.S. Patent and Trademark Office (U.S. PTO) has ordered the re-examination of both the '553 method patent and the '681 composition patent at issue in the first case and the '645 and '427 patents at issue in the second case based on prior art. A second re-examination of the '427 patent was ordered in order to determine whether certain claims of the '427 patent should expire in 2008, rather than in 2010. Final decisions on the re-examinations have not yet been issued.

On October 6, 2005, the Delaware court granted our motion to stay all discovery in the second lawsuit pending decisions from the Federal Circuit on PharmaStem's appeal of the District Court's ruling of non-infringement in the original case and from the U.S. PTO on the patent re-examinations.

**Table of Contents**

In either of the pending cases, if we are ultimately found to infringe, we could have a significant damages award entered against us. If we are found to infringe or at any other time during the course of either case, including possibly if the court of appeals were to overturn the district court's non-infringement ruling, we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant us a license or to do so on economically reasonable terms, and previously informed us that it would not do so October 15, 2004. While we do not believe this outcome is likely, in the event of an injunction, if we are not able to obtain a license under the disputed patents on economically reasonable terms or at all and we cannot operate under an equitable doctrine known as "intervening rights," we will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products. We may enter into settlement negotiations with PharmaStem regarding the litigation. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all.

On May 13, 2004, we received a First Amended Complaint filed in the Superior Court of the State of California by Kenneth D. Worth, by and for the People of the State of California, and naming as defendants a number of private cord blood banks, including us. The complaint alleges that the defendants have made fraudulent claims in connection with the marketing of their cord blood banking services and seeks restitution for those affected by such marketing, injunctive relief precluding the defendants from continuing to abusively and fraudulently market their services and requiring them to provide certain information and refunds to their customers, unspecified punitive and exemplary damages and attorney's fees and costs. Subsequently, we received a Notice of Ex Parte Application for Leave to Intervene filed on behalf of the Cord Blood Foundation by the same individual and seeking similar relief. On October 7, 2004, the Court orally granted a motion to strike the complaint under the California anti-SLAPP statute and dismissed the complaint as to all defendants without leave to amend. Judgment has been entered, dismissing the complaint, and plaintiff has filed a notice of appeal and a brief for the appeal and a petition for a writ of mandate. The petition has been dismissed and the appeal is proceeding. The plaintiff has settled the litigation with all defendants other than us. We are not yet able to conclude as to the likelihood that plaintiff's claims would be upheld if the judgment of dismissal were reversed on appeal, nor can we estimate the possible financial consequences should plaintiff prevail. However, we believe this suit to be without merit and intend to continue to vigorously defend ourselves.

On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against us in the United States District Court for the Northern District of California alleging false and misleading advertising by us in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. On April 13, 2005, we answered the complaint, denying Cbr's allegations, and filed counterclaims alleging false and misleading advertising by Cbr. On October 27, 2005, we entered into an agreement to settle the pending litigation with Cbr. Under terms of the agreement the companies agreed to dismiss all outstanding legal claims. There were no financial payments to be made by either party under the settlement agreement.

We have undertaken a review of our various job classifications for legal compliance under state and federal employment laws. Based on that review, we have identified certain job classifications that may be subject to possible challenge, although there is currently no challenge pending, and for which there is a reasonable possibility that we could incur a liability, although we also believe that the present classifications can be supported and defended. It is not possible based on the current available information to reasonably estimate the scope of any potential liability.

**Critical Accounting Estimates**

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the





## **Table of Contents**

carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies include:

revenue recognition;

accounting for accounts receivable;

accounting for royalty expense in connection with the PharmaStem litigation;

accounting for research and development expenses;

accounting for our product guarantee program; and

accounting for our physician indemnification program.

*Revenue Recognition.* Our revenues are currently generated principally through our umbilical cord blood preservation and storage activities.

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 101, (SAB 101) as amended by SAB 104, and Emerging Issues Task Force (EITF) Issue No. 00-21 for all revenue transactions entered into in fiscal periods beginning after June 30, 2003.

We receive fees for collecting, testing, freezing and storing of cord blood units and recognize revenue upon the successful completion of these processes. Storage revenue is deferred and recognized over the storage period.

We analyze our multiple element arrangements entered into after June 30, 2003 to determine whether the elements can be separated and accounted for individually as separate units of accounting in accordance with EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*. We recognize fees received from collecting, testing and freezing processes (collectively known as processing ) as revenue if it has stand alone value to the customer and the fair value of the undelivered storage services can be determined. The Company has concluded that the collection, testing and freezing service has stand alone value to the customer. The fair value of processing service cannot be determined but the Company has objective evidence of fair value of the undelivered storage. The fair value of the storage is equal to the annual storage fee charged to customers. We defer the fair value of the revenue related to the future storage of the unit and recognize the remainder of the revenue under the residual method.

*Accounting for accounts receivable.* Accounts receivable consists of amounts primarily due from our ViaCord customers that have used the ViaCord product. Accounts receivable are stated at amounts due from customers, net of an allowance for doubtful accounts. We determine the allowance by considering receivables that are past due, our previous loss history, and the customers' current ability to pay its obligations. We write off accounts receivable when they become uncollectible and payments subsequently received on such accounts receivable are credited to the allowance for doubtful accounts.

*Accounting for royalty expense in connection with the PharmaStem litigation.* Cost of revenues in 2003 includes a royalty to PharmaStem relating to a claim for patent infringement. We are currently in litigation with PharmaStem regarding this claim. We recorded a royalty expense of approximately \$3.3 million in 2003 following a jury verdict in October 2003 which found infringement. This expense included a royalty of approximately \$2.9 million on revenues from cord blood preservation through October 29, 2003, plus an accrual of 6.125% of subsequent revenues through December 31, 2003. We also recorded an expense of \$0.5 million for the three months ended March 31, 2004, also based on 6.125% of revenues. In the second half of 2004, the court overturned the jury verdict finding that PharmaStem had not shown infringement. Based on the judge's ruling we reversed the entire royalty accrual of \$3.8 million in the quarter ended June 30, 2004. PharmaStem has appealed the court's decision. Pending further action by the courts, we do not intend to record a royalty expense in future periods, since we believe the claim is without merit. It is possible that the final outcome of this litigation, as well as the final outcome of the second patent infringement lawsuit brought by PharmaStem, could result in damages payable at a higher or lower amount than previously awarded by the Delaware jury. Should this occur or should an injunction be issued at any time in either

case, our financial position and results of operations could be materially affected. We may enter into settlement negotiations with

**Table of Contents**

PharmaStem regarding our litigation. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts by us to PharmaStem, or what those amounts might be.

*Accounting for research and development expenses.* Our research and development expenses primarily consist of costs associated with product development for CB001, the development of Selective Amplification and our other stem cell therapy technologies and our oocyte cryopreservation program. These expenses represent both clinical development costs and the costs associated with non-clinical support activities such as toxicological testing, manufacturing, process development and regulatory consulting services. Clinical development costs represent internal costs for personnel, external costs incurred at clinical sites and contracted payments to third party clinical research organizations to perform certain clinical trials. We also report the costs of patent licenses in research and development expense as they directly relate to our ongoing research programs. Our product candidates do not currently have regulatory approval; accordingly, we expense the license fees and related milestone payments when we incur the liability. We accrue research and development expenses for activities occurring during the fiscal period prior to receiving invoices from clinical sites and third party clinical research organizations. We accrue external costs for clinical studies based on the progress of the clinical trials, including patient enrollment, progress by the enrolled patients through the trial, and contracted costs with clinical sites. We record internal costs primarily related to personnel in clinical development and external costs related to non-clinical studies and basic research when incurred. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. We expect that expenses in the research and development category will increase for the foreseeable future as we add personnel, expand our clinical trial activities and increase our discovery research capabilities. The amount of the increase is difficult to predict due to the uncertainty inherent in the timing of clinical trial initiations, progress in our discovery research program, the rate of patient enrollment and the detailed design of future trials. In addition, the results from our trials, as well as the results of trials of similar drugs under development by others, will influence the number, size and duration of both planned and unplanned trials.

*Accounting for our product guarantee program.* In November 2002, we began providing our customers a product guarantee under which we agree to pay \$25,000 to defray the costs associated with the original collection, storage of cord blood, and procurement of an alternative stem cell source, if medically indicated, in the event the customer's cord blood is used in a stem cell transplant and fails to engraft. We have never experienced any claims under the guarantee program nor have we incurred costs related to these guarantees. We do not maintain insurance for this guarantee program and therefore we maintain reserves to cover our estimated potential liabilities. We account for the guarantee as a warranty obligation and recognize the obligation in accordance with SFAS No 5, *Accounting for Contingencies*. Our reserve balance is based on the \$25,000 maximum payment, multiplied by the number of units covered by the guarantee, multiplied by the expected transplant rate, multiplied by the expected engraftment failure rate. We determine the expected usage and engraftment failure rate by analyzing data from our existing bank of cords, cords stored in published private and public banks and the related historical usage and failure rates in our bank and other private and public cord banks. We determine the estimated expected usage and engraftment failure rates based on an analysis of our historical usage and failure rates and the historical usage and failure rates in other private and public cord banks based on published data. Our estimates of expected usage and engraftment failure could change as a result of changes in actual usage rates or failure rates and such changes would require an adjustment to our established reserves. The historical usage and failure rates have been very low and a small increase in the number of transplants or engraftment failures could cause a significant increase in the estimated rates used in determining our reserve. In addition, the reserve will increase as additional cord units are stored which are subject to the product guarantee. We have reserves recorded under this program in the amounts of \$92,000, \$73,000 and \$43,000 as of December 31, 2005, 2004, and 2003, respectively.

*Accounting for our physician indemnification program.* In September 2004, we launched an indemnification program protecting physicians from patent litigation actions taken against them by PharmaStem Therapeutics, Inc. Under this program we agreed to pay reasonable defense costs resulting from such litigation, providing that the physicians allowed us to manage their defense. In addition, we agreed to pay all



**Table of Contents**

damages resulting from such litigation, and we agreed to pay an additional \$100,000 to the physicians if PharmaStem prevails in any patent infringement litigation against the physician. In order to qualify for this indemnification the physicians are required to comply with certain requirements including returning a signed acknowledgement form around the particulars of the indemnification program. We have recorded a reserve associated with this program of \$51,000 in our December 31, 2005 and 2004 financial statements in compliance with FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). The reserve is equal to the estimated fair value of the indemnification arrangements entered into as of December 31, 2005 and 2004. We have determined the reserve through a probability model based on assumptions related to the likelihood of legal ramifications, and the extent of those ramifications, applicable under this program for the potential professional fees, damages, and remunerations related to the agreements executed as of December 31, 2005 and 2004. These assumptions involve judgment by management and are subject to change as additional physicians enroll in the program, if the actual amount of patent litigation and related defense costs exceed our estimates or if PharmaStem's patents are overturned by the US Patent office. We believe PharmaStem has no legal basis to pursue patent litigation against physicians who assist in collecting cord blood on behalf of our customers. However, our assumptions contemplate a wide range of possible outcomes including the possibility of PharmaStem pursuing and prevailing in such patent litigation, although we believe the likelihood of this is remote.

**Recent Accounting Pronouncements**

On December 16, 2004, the Financial Accounting Standards Board ( FASB ) released SFAS No. 123(R) *Share-Based Payment*. This new accounting standard requires all forms of stock compensation, including stock options, to be reflected as an expense in our financial statements. Public companies must adopt the standard by their first annual fiscal period beginning after June 15, 2005. We intend to apply the revised standard in the annual period beginning January 1, 2006. Although we have not finalized our analysis, we expect that the adoption of the revised standard will result in higher operating expenses and higher net loss per share. We will most likely use the modified prospective method in which compensation cost is recognized beginning with the effective date of this new accounting pronouncement (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123(R) that remain unvested on the effective date. Note 2 to the consolidated financial statements shows the pro forma impact on net loss and net loss per common share as if we had historically applied the fair value recognition provisions of SFAS No. 123 to stock-based employee awards.

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes*, and supersedes FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*-an amendment of APB Opinion No. 28. SFAS 154 requires retrospective application to prior periods financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the provisions of the SFAS 154 will have a significant impact on our results of operations.

**Table of Contents**

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

**Quantitative and Qualitative Disclosures About Market Risks**

***Investment Risk***

We own financial instruments that are sensitive to market risks as part of our investment portfolio. We use this investment portfolio to preserve our capital until it is required to fund operations, including our research and development activities. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the duration of investments. We invest in highly-rated commercial paper with maturities of less than two years and money market funds. None of these market-risk sensitive instruments is held for trading purposes. We do not own derivative financial instruments in our investment portfolio.

***Foreign Exchange Risk***

Transactions by our German and Singapore subsidiaries are recorded in euros and Singapore dollars, respectively. Exchange gains or losses resulting from the translation of these subsidiaries' financial statements into US dollars are included as a separate component of stockholders' equity (deficit). We hold euro-based and Singapore dollar-based currency accounts to mitigate foreign currency transaction risk. Since both the revenues and expenses of these subsidiaries are denominated in euros and Singapore dollars, the fluctuations of exchange rates may adversely affect our results of operations, financial position and cash flows.

***Interest Rate Risk***

We invest our cash in a variety of financial instruments, principally securities issued by the US government and its agencies, investment grade corporate and money market instruments. These investments are denominated in US dollars. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

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

Our consolidated financial statements are annexed to this report beginning on page F-1.

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

None.

**ITEM 9A. *CONTROLS AND PROCEDURES***

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2005 and, based on their evaluation, our principal executive officer and principal financial officer have concluded that these controls and procedures are effective. Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Table of Contents****ITEM 9B. OTHER INFORMATION**

None.

**PART III****ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information required with respect to directors is incorporated herein by reference to the information contained in the definitive proxy statement for our 2006 Annual Meeting of Stockholders (the Proxy Statement). The information with respect to our audit committee financial expert is incorporated herein by reference to the information contained in the section captioned Audit Committee of the Proxy Statement.

We have adopted a Code of Business Conduct and Ethics for our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and employees. Our Code of Business Conduct and Ethics is available in the Governance section of the Investor Information section of our website at [www.viacellinc.com](http://www.viacellinc.com). We intend to disclose any amendments to, or waivers from, our Code of Business Conduct and Ethics on our website. Stockholders may request a free copy of the Code of Business Conduct and Ethics by writing to us at ViaCell, Inc., 245 First Street, Cambridge, Massachusetts 02142, Attention: Investor Relations.

Information about compliance with Section 16(a) of the Exchange Act appears under Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement. That portion of the Proxy Statement is incorporated by reference into this report.

**MANAGEMENT****Executive Officers and Key Employees**

Set forth below is information regarding our executive officers and key employees as of March 29, 2006.

| <b>Name</b>                | <b>Age</b> | <b>Positions</b>  |
|----------------------------|------------|---|
| <b>Executive Officers:</b> |            |   |
| Marc D. Beer               | 41         | President, Chief Executive Officer and Director                     |
| Stephen G. Dance           | 55         | Senior Vice President, Finance and Chief Financial Officer          |
| Anne Marie Cook            | 44         | Senior Vice President, Legal and General Counsel                    |
| Mary T. Thistle            | 46         | Senior Vice President, General Manager, ViaCell Reproductive Health |
| Stephan Wnendt, Ph.D       | 43         | Senior Vice President, Research and Development                     |
| <b>Key Employee:</b>       |            |   |
| Morey Kraus                | 47         | Vice President and Chief Technical Officer                          |

***Executive Officers***

**Marc D. Beer.** Mr. Beer joined us as our President and Chief Executive Officer and a member of the board in April 2000. Until January 2004, he also served as our Chairman of the Board. From 1996 until April 2000, he was a senior manager at Genzyme Corporation most recently serving in the role of Vice President, Global Marketing. Mr. Beer has more than 15 years experience in profit and loss management, and research and development program management in therapeutic, surgical, and in vitro diagnostic systems businesses. Mr. Beer also serves as a Director of RenaMed, a private company. Mr. Beer has a B.S. from Miami University (Ohio).



## **Table of Contents**

*Stephen G. Dance.* Mr. Dance joined us as Senior Vice President, Finance and Chief Financial Officer in January 2004. From April 1999 until December 2003, he served as Senior Vice President, Finance at SangStat Medical Corporation, a biotechnology company, adding the additional title of Chief Financial Officer in December 2002. Previously, Mr. Dance spent one year with Plantronics, Inc., a telecommunications company, where he was responsible for worldwide financial accounting, reporting and planning activities. Prior to that, he spent 15 years with Syntex Corporation, a pharmaceuticals company, which was subsequently acquired by Roche. Mr. Dance holds a CPA (California) and FCA (United Kingdom) qualification in accounting and spent seven years with Deloitte & Touche in both the United Kingdom and the United States. He received his B.A. degree in French at the University of Leeds in England.

*Anne Marie Cook.* Ms. Cook has served as Senior Vice President, Legal and General Counsel since September 2005. Prior to joining ViaCell, Ms. Cook spent thirteen years at Biogen Idec Inc., most recently as Vice President, Chief Corporate Counsel. Prior to joining Biogen Idec, Inc., she was in private practice at Testa, Hurwitz & Thibault, where she represented both private and public corporations and venture capital limited partnerships. Ms. Cook holds a Bachelor of Science degree in Biology from Tufts University and graduated Summa Cum Laude from the University of Notre Dame Law School.

*Mary T. Thistle.* Ms. Thistle joined ViaCell in October 2000 as Vice President, Financial and Corporate Planning and Treasurer, before becoming Vice President, ViaCord Operations in 2002. In October 2004, she was appointed Senior Vice President and General Manager of ViaCell Reproductive Health. Prior to joining ViaCell, Ms. Thistle spent four years at the accounting firm of Yoshida, Croyle & Sokolski where she provided audit, tax and management consulting services to various companies, including Viacord. Ms. Thistle also held a variety of financial positions at S.R.T, a subsidiary of Thermo Electron and Nashua Corporation as well as Deloitte & Touche. Ms. Thistle has a B.S. in accounting from the University of Massachusetts.

*Stephan Wnendt, Ph.D.* Dr. Wnendt has served as Senior Vice President, Research and Development since October 2004 and, prior to that, as our Senior Vice President, European Operations since September 2003. He joined our company following our acquisition of Kourion Therapeutics, where he was Executive Officer and Chairman of the Management Board since March 2003. Prior to Kourion Therapeutics, Dr. Wnendt was Vice President of Biopharmaceutical Development and General Manager of JOMED GmbH, now Abbott Vascular Instruments GmbH from November 2000 to February 2003. Previously, Dr. Wnendt worked for nine years in various positions in research management with Grunenthal, an international pharmaceutical company. Dr. Wnendt is Assistant Professor at the University of Technology in Aachen, Germany, and received a Diploma in Biochemistry from the Free University of Berlin and a Ph.D. from the University of Technology, Berlin.

### ***Key Employee***

*Morey Kraus.* Mr. Kraus is the co-founder of ViaCell, has served as our Vice President and Chief Technology Officer since April 2000, and also serves on our medical and scientific advisory board. From September 1994 until March 2000, Mr. Kraus served as our Chairman and Chief Executive Officer. Prior to founding ViaCell, Mr. Kraus was a Ph.D. candidate at Worcester Polytechnic Institute in an interdisciplinary Bioprocess Engineering Program combining chemical engineering and biology. Mr. Kraus has a B.A. in religion from American University.

### **Medical and Scientific Advisory Board**

Our medical and scientific advisory board provides specific expertise in areas of research and development relevant to our business and meets with our scientific and management personnel from time to time to discuss our present and long-term research and development activities. Our medical and scientific advisory board members are:

*Graham Molineux.* Dr. Molineux has been a scientific advisor since November 2005. He is currently Director of Hematology and Oncology Research at Amgen Inc. Before joining Amgen in 1994 he spent nearly twenty years at the Paterson Institute for Cancer Research at Christie Hospital in

## **Table of Contents**

Manchester, England. He trained at University of Manchester specializing in stem cell biology. Dr. Molineux received his Ph.D. from the University of Manchester Institute of Science and Technology, a MS in Experimental Immunology and Oncology and a BSc from Liverpool University.

*Barbara E. Bierer, M.D.* Dr. Bierer has been a member of our scientific advisory board since 2001 and has served on our Board of Directors since June 2005. Dr. Bierer is the Senior Vice President for Research at Brigham and Women's Hospital in Boston and Professor of Medicine and Pediatrics at Harvard Medical School. Previously, she was the Chief of the Laboratory of Lymphocyte Biology at the National Heart, Lung and Blood Institute at the National Institutes of Health (NIH) in Bethesda, MD. She also served as the Director of Pediatric Stem Cell Transplantation at the Dana-Farber Cancer Institute and The Children's Hospital in Boston and was Professor of Pediatrics at Harvard Medical School. A graduate of Harvard Medical School, she specializes in immunology and stem cell transplantation.

*George Daley, M.D., Ph.D.* Dr. Daley has been one of our scientific consultants since 1998 and Co-Chairman of our medical and scientific advisory board since 2000. He is currently an Associate Professor in the Division of Pediatric Hematology/Oncology, Children's Hospital and Dana Farber Cancer Institute, Boston and the Department of Biological Chemistry and Molecular Pharmacology, Harvard Medical School. Previously, Dr. Daley was a Whitehead Fellow at the Whitehead Institute for Biomedical Research and an Assistant Professor of Medicine and staff member in Hematology/ Oncology at the Massachusetts General Hospital from 1995 to 2003. He is board certified in Internal Medicine and Hematology. Dr. Daley has a Bachelor's degree magna cum laude from Harvard University, a Ph.D. in biology from the Massachusetts Institute of Technology and an M.D. summa cum laude from Harvard University.

*Leonard I. Zon, M.D.* Dr. Zon has been a member of our medical and scientific advisory board since February 2002. Dr. Zon is an attending physician in hematology at Children's Hospital Boston and in Oncology at Dana-Farber Cancer Institute. He is an Associate in Medicine-Hematology/Oncology, at Children's Hospital and Professor of Pediatric Medicine at Harvard Medical School. He is also an Investigator for Howard Hughes Medical Institute. Dr. Zon is board certified in Medical Oncology and Hematology. He received a B.S. degree in chemistry and natural sciences from Muhlenberg College and an M.D. degree from Jefferson Medical College. He subsequently did an internal medicine residency at New England Deaconess Hospital and a fellowship in medical oncology at Dana-Farber Cancer Institute. His postdoctoral research was in the laboratory of Stuart Orkin.

*Kurt Gunter, M.D.* Dr. Gunter has been a member of our medical and scientific advisory board since September 2005. He is currently Vice President, Clinical & Medical Affairs/ Government Relations at ZymeQuest, Inc., a private company focused on blood conversion products for use in blood transfusion medicine. He also serves as an industry representative on the FDA's Cellular, Tissue and Gene Therapies Advisory Committee. Previously, he was Senior Vice President, Clinical and Regulatory Affairs and Government Relations at ViaCell, Inc. and served as Vice President, Clinical and Regulatory Affairs at Transkaryotic Therapies, Inc. Before joining the biotechnology industry, Dr. Gunter was Director of Stem Cell Processing, Hematology and Blood Donor Center in the Department of Laboratory Medicine at Children's National Medical Center in Washington, D.C. Dr. Gunter has also held positions at the FDA's Center for Biologics Evaluation and Research, including Acting Deputy Director for the Division of Cellular and Gene Therapies and Chief of the Cytokine and Cell Biology Branch. Dr. Gunter is board-certified in clinical and anatomical pathology and transfusion medicine. He has a B.S. from Stanford University and a M.D. from the University of Kansas School of Medicine.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to the Proxy Statement under the heading Executive Compensation.

**Table of Contents****ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information about security ownership of certain beneficial owners and management appears under the heading Principal Stockholders in the Proxy Statement, which portion of the Proxy Statement is incorporated by reference into this report.

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

The information required by this item is incorporated by reference to the Proxy Statement under the heading Certain Relationships and Related Transactions.

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

The information required by this item is incorporated by reference to the Proxy Statement under the heading Ratification of the Selection of Our Independent Registered Public Accounting Firm.

**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are being filed as part of this report:

*(1) Consolidated Financial Statements*

The following consolidated financial statements of ViaCell, Inc. are filed as part of this report.

|   | <b>Page Number in<br/>This Form 10-K</b> |
|---|--|
| Report of Independent Registered Public Accounting Firm   | F-2                                      |
| Consolidated Balance Sheets                               | F-3                                      |
| Consolidated Statements of Operations                     | F-4                                      |
| Consolidated Statements of Comprehensive Loss             | F-5                                      |
| Consolidated Statements of Stockholders' Equity (Deficit) | F-6                                      |
| Consolidated Statements of Cash Flows                     | F-7                                      |
| Notes to Consolidated Financial Statements                | F-8                                      |

*(2) Financial Statement Schedules*

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

*(b) Exhibits*

| <b>Exhibit No.</b> | <b>Description of Document</b>  |
|--------------------|---|
| 3.1(1)             | Sixth Amended and Restated Certificate of Incorporation.  |
| 3.2(1)             | Amended and Restated By-laws.   |
| 4.1(1)             | Specimen Stock Certificate.   |
| 4.2(7)             | Form of Warrant to purchase Common Stock, together with a list of holders.  |
| 4.3(1)             | Warrant issued to Amgen Inc. on April 9, 2002 to purchase 560,000 shares Common Stock.  |
| 4.4(8)             | Form Warrant issued to former investors in the Company's Series J convertible preferred stock on January 26, 2005 to purchase up to a total aggregate amount of 2,190,000 shares of |

common stock.

10.1(6) Amended and Restated 1998 Equity Incentive Plan.\*\*

**Table of Contents**

| <b>Exhibit No.</b> | <b>Description of Document</b>   |
|--------------------|--|
| 10.1.2(8)          | Form of Nonstatutory Stock Option Certificate.**   |
| 10.1.3(8)          | Form of Incentive Stock Option Certificate.**  |
| 10.2(7)            | Letter Agreement dated June 7, 2001 between ViaCell and Chris Adams.**   |
| 10.3(7)            | Letter Agreement dated May 2, 2000 between ViaCell and Marc Beer.**  |
| 10.4(7)            | Letter Agreement dated May 14, 2001 between ViaCell and Kurt Gunter.**   |
| 10.5(7)            | Letter Agreement dated April 11, 2000 between ViaCell and Morey Kraus.**   |
| 10.6(1)            | Letter Agreement dated September 12, 2003 between ViaCell and Jan van Heek.**  |
| 10.7(1)            | Letter Agreement dated November 4, 2003 between ViaCell and Vaughn M. Kailian.**   |
| 10.8(7)            | Letter Agreement dated December 15, 2002 between ViaCell and Paul Hastings.**  |
| 10.9(1)            | Stock Purchase Agreement dated September 30, 2003 by and among ViaCell, Kourion Therapeutics AG and the shareholders of Kourion Therapeutics signatory thereto.            |
| 10.10(3)           | Amendment to Stock Purchase Agreement dated October 25, 2004 by and among ViaCell, Kourion Therapeutics AG and the shareholders of Kourion Therapeutics signatory thereto. |
| 10.11.1(1)         | Form of Promissory Note issued by ViaCell to General Electric Capital Corporation.   |
| 10.11.2(1)         | Master Security Agreement dated October 16, 2003 by and between ViaCell and General Electric Capital Corporation, as amended by an Amendment dated October 16, 2003.       |
| 10.11.3(1)         | Form of Security Deposit Pledge Agreement by and between ViaCell and General Electric Capital Corporation.   |
| 10.12 (1)          | Non-Exclusive License Agreement dated January 1, 2003 between ViaCell and SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Glaxo Group Limited.                    |
| 10.13 (1)          | Collaboration Agreement dated December 23, 2003 between ViaCell and Amgen Inc.   |
| 10.14 (1)          | License Agreement dated March 15, 2002 between ViaCell Endocrine Science, Inc. and the General Hospital Corporation, d/b/a Massachusetts General Hospital.                 |
| 10.15 (1)          | License Agreement dated August 1, 2002 between ViaCell and Massachusetts Institute of Technology.  |
| 10.16(1)           | Lease Agreement dated April 12, 2002 between ViaCell and Dugan Financing LLC.  |

Edgar Filing: VIACELL INC - Form 10-K

|            |  |
|------------|--|
| 10.17(1)   | Lease Agreement dated December 22, 2003 between ViaCell and MA-Riverview/245 First Street, LLC.  |
| 10.18      | First Amendment dated February 14, 2006 to Lease Agreement dated December 22, 2003 between ViaCell and MA-Riverview/245 First Street, LLC. |
| 10.19(1)   | Letter Agreement dated March 11, 2004 between ViaCell and Stephen Dance.**   |
| 10.20 (3)  | License Agreement dated September 1, 2004 between Tyho Galileo Research Laboratory, LLC and ViaCell, Inc.                                  |
| 10.21 (5)  | Research Agreement dated December 13, 2004 between Genzyme Corporation and ViaCell.  |
| 10.22(6)   | Letter Agreement dated December 29, 2004 from ViaCell to Stephan Wnendt.**   |
| 10.23(8)   | Letter Agreement dated October 10, 2004 from ViaCell to Mary Thistle.**  |
| 10.24 (9)  | Development Agreement between ViaCell, Inc. and Miltenyi Biotec GmbH, dated January 24, 2005   |
| 10.25 (9)  | Supply Agreement between ViaCell, Inc. and Miltenyi Biotec GmbH, dated January 24, 2005  |
| 10.26 (10) | Amendment No. 1 to Collaboration Agreement between ViaCell, Inc. and Amgen, Inc., dated August 29, 2005                                    |
| 10.27(10)  | Warrant Purchase Agreement between ViaCell, Inc. and Amgen, Inc., dated August 29, 2005  |
| 10.28(10)  | Purchase Warrant issued to Amgen, Inc., dated August 29, 2005  |
| 10.29 (10) | Exclusive License Agreement among Johns Hopkins University, Zheijiang University and ViaCell, Inc., dated August 29, 2005                  |
| 10.30(10)  | Letter Agreement dated August 1, 2005 from ViaCell to Anne Marie Cook.**   |
| 21.1(1)    | Subsidiaries of ViaCell.   |

**Table of Contents**

| <b>Exhibit No.</b> | <b>Description of Document</b>   |
|--------------------|--|
| 23.1               | Consent of PricewaterhouseCoopers LLP                                  |
| 31.1               | Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer. |
| 31.2               | Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer. |
| 32.1               | Section 1350 Certification of Chief Executive Officer.                 |
| 32.2               | Section 1350 Certification of Chief Financial Officer.                 |

  

- (1) Incorporated by reference to the Company's registration statement on Form S-1 (No. 333-114209) filed with the Securities and Exchange Commission (the SEC) on April 5, 2004.
- (2) Incorporated by reference to the Company's Amendment No. 1 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on May 25, 2004.
- (3) Incorporated by reference to the Company's Amendment No. 3 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on October 26, 2004.
- (4) Incorporated by reference to the Company's Amendment No. 4 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on December 15, 2004.
- (5) Incorporated by reference to the Company's Amendment No. 5 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on December 27, 2004.
- (6) Incorporated by reference to the Company's Amendment No. 6 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on January 3, 2005.
- (7) Incorporated by reference to the Company's registration statement on Form S-1 (No. 333-81650) filed with the SEC on January 30, 2002.
- (8) Incorporated by reference to the Company's annual report on Form 10-K (No. 0-51110) filed with the SEC on March 31, 2005.
- (9) Incorporated by reference to the Company's quarterly report on Form 10-Q (No. 0-51110) filed with the SEC on May 13, 2005.
- (10) Incorporated by reference to the Company's quarterly report on Form 10-Q (No. 0-51110) filed with the SEC on November 14, 2005.

This exhibit has been filed separately with the Commission pursuant to an application for confidential treatment. The confidential portions of this exhibit have been omitted and are marked by an asterisk.

\*\* Indicates a management contract or compensatory plan.

**Table of Contents****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.

ViaCell, Inc.  
By /s/ Marc D. Beer

Marc D. Beer  
Chief Executive Officer

Date: March 31, 2006

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the following capacities on March 31, 2006.

| <b>Signature</b>  | <b>Title</b>   | <b>Date</b>    |
|---|--|----------------|
| <u>/s/ Marc D. Beer</u><br>Marc D. Beer                   | Chief Executive Officer and Director<br>(Principal Executive Officer)                        | March 31, 2006 |
| <u>/s/ Stephen G. Dance</u><br>Stephen G. Dance           | Chief Financial Officer<br>(Principal Financial Officer and<br>Principal Accounting Officer) | March 31, 2006 |
| <u>/s/ Vaughn M. Kailian</u><br>Vaughn M. Kailian         | Director   | March 31, 2006 |
| <u>/s/ James Sigler</u><br>James Sigler                   | Director   | March 31, 2006 |
| <u>/s/ Paul Blake</u><br>Paul Blake                       | Director   | March 31, 2006 |
| <u>/s/ Paul Hastings</u><br>Paul Hastings                 | Director   | March 31, 2006 |
| <u>/s/ Denise Pollard-Knight</u><br>Denise Pollard-Knight | Director   | March 31, 2006 |
| <u>/s/ James Tullis</u><br>James Tullis                   | Director   | March 31, 2006 |



|                    |          |                |
|--------------------|----------|----------------|
| /s/ Jan van Heek   | Director | March 31, 2006 |
| <hr/>              |          |                |
| Jan van Heek       |          |                |
| /s/ Barbara Bierer | Director | March 31, 2006 |
| <hr/>              |          |                |
| Barbara Bierer     |          |                |

**Table of Contents**

**Index to Consolidated Financial Statements  
ViaCell, Inc.**

|  | <b>Page</b> |
|--|-------------|
| <u>Report of Independent Registered Public Accounting Firm</u>   | F-2         |
| <u>Consolidated Balance Sheets</u>                               | F-3         |
| <u>Consolidated Statements of Operations</u>                     | F-4         |
| <u>Consolidated Statements of Comprehensive Loss</u>             | F-5         |
| <u>Consolidated Statements of Stockholders' Equity (Deficit)</u> | F-6         |
| <u>Consolidated Statements of Cash Flows</u>                     | F-7         |
| <u>Notes to Consolidated Financial Statements</u>                | F-8         |

F-1

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of ViaCell, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows present fairly, in all material respects, the financial position of ViaCell, Inc. and its subsidiaries at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 31, 2006

**Table of Contents**

**ViaCell, Inc.**  
**Consolidated Balance Sheets**

|  | As of December 31,               |           |
|--|----------------------------------|-----------|
|  | 2005                             | 2004      |
|  | (In thousands except share data) |           |
| ASSETS   |                                  |           |
| Current assets:  |                                  |           |
| Cash and cash equivalents  | \$ 33,138                        | \$ 6,746  |
| Short-term investments   | 27,406                           | 21,339    |
| Accounts receivable, less allowances of \$1.1 million and \$1.2 million in 2005 and 2004, respectively                                       | 13,736                           | 10,808    |
| Prepaid expenses and other current assets  | 2,679                            | 4,766     |
| Restricted cash  | 162                              | 162       |
| Total current assets   | 77,121                           | 43,821    |
| Property and equipment, net  | 8,702                            | 6,738     |
| Goodwill   | 3,621                            | 3,621     |
| Intangible assets, net   | 2,823                            | 3,025     |
| Long-term investments  |                                  | 500       |
| Restricted cash  | 1,932                            | 1,953     |
| Other assets   | 31                               | 1,433     |
| Total assets   | \$ 94,230                        | \$ 61,091 |
| LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)  |                                  |           |
| Current liabilities:   |                                  |           |
| Current portion of long-term debt obligations  | \$ 1,543                         | \$ 1,742  |
| Accounts payable   | 1,141                            | 1,271     |
| Accrued expenses   | 7,706                            | 7,490     |
| Notes payable to related party   |                                  | 15,422    |
| Deferred revenue   | 5,785                            | 3,459     |
| Total current liabilities  | 16,175                           | 29,384    |
| Deferred revenue   | 9,930                            | 6,729     |
| Deferred rent  | 3,876                            | 1,035     |
| Contingent purchase price  | 8,155                            | 8,155     |
| Long-term debt obligations, net of current portion   | 84                               | 1,572     |
| Total liabilities  | 38,220                           | 46,875    |
| Redeemable convertible preferred stock (at redemption value) authorized 30,396,809 shares in 2004, issued and outstanding 25,628,075 in 2004 |                                  | 175,173   |
| Commitments and contingencies (Note 9)   |                                  |           |
| Stockholders' equity (deficit):  |                                  |           |

Edgar Filing: VIACELL INC - Form 10-K

|  |               |               |
|--|---------------|---------------|
| Convertible preferred stock, \$0.01 par value; authorized 428,191 shares; issued and outstanding 182,857 shares (liquidation preference of \$245,000) in 2004                                      |               | 2             |
| Preferred stock, \$0.01 par value; authorized 5,000,000 shares in 2005   |               |               |
| Common stock, \$0.01 par value; authorized 100,000,000 and 80,000,000 shares in 2005 and 2004, respectively; issued and outstanding 38,117,725 and 2,763,961 shares in 2005 and 2004, respectively | 381           | 28            |
| Additional paid-in capital   | 229,955       |               |
| Deferred compensation  | (1,087)       | (2,530)       |
| Accumulated deficit  | (173,443)     | (158,766)     |
| Accumulated other comprehensive income   | 204           | 309           |
| <br>Total stockholders' equity (deficit)   | <br>56,010    | <br>(160,957) |
| <br>Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)   | <br>\$ 94,230 | <br>\$ 61,091 |

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

F-3

**Table of Contents**

**ViaCell, Inc.**  
**Consolidated Statements of Operations**

|  | <b>Years Ended December 31,</b>                       |                    |                    |
|--|---|--------------------|--------------------|
|  | <b>2005</b>   | <b>2004</b>        | <b>2003</b>        |
|  | <b>(In thousands except share and per share data)</b> |                    |                    |
| Processing and storage revenues  | \$ 43,775   | \$ 36,805          | \$ 30,884          |
| Grant and contract revenues  | 668   | 1,469              | 996                |
| <b>Total revenues</b>  | <b>44,443</b>   | <b>38,274</b>      | <b>31,880</b>      |
| Operating expenses:  |   |                    |                    |
| Cost of processing and storage revenues:   |   |                    |                    |
| Direct costs   | 8,278   | 7,364              | 7,141              |
| Royalty (recovery) expense   |   | (3,258)            | 3,258              |
| <b>Total cost of processing and storage revenues</b>                             | <b>8,278</b>  | <b>4,106</b>       | <b>10,399</b>      |
| Research and development   | 13,359  | 15,134             | 13,226             |
| Sales and marketing  | 24,702  | 19,322             | 20,959             |
| General and administrative   | 12,193  | 13,468             | 15,222             |
| In-process technology  |   |                    | 23,925             |
| Stock-based compensation(1)  | 2,163   | 3,429              | 3,232              |
| Restructuring  | 305   | 2,945              |                    |
| <b>Total operating expenses</b>  | <b>61,000</b>   | <b>58,404</b>      | <b>86,963</b>      |
| <b>Loss from operations</b>  | <b>(16,557)</b>                                       | <b>(20,130)</b>    | <b>(55,083)</b>    |
| Interest income (expense):   |   |                    |                    |
| Interest income  | 2,216   | 530                | 348                |
| Interest expense   | (336)   | (1,497)            | (733)              |
| <b>Total interest income (expense), net</b>                                      | <b>1,880</b>  | <b>(967)</b>       | <b>(385)</b>       |
| <b>Net loss</b>  | <b>(14,677)</b>                                       | <b>(21,097)</b>    | <b>(55,468)</b>    |
| Accretion on redeemable convertible preferred stock                              | (986)   | (13,071)           | (9,416)            |
| <b>Net loss attributable to common stockholders</b>                              | <b>\$ (15,663)</b>                                    | <b>\$ (34,168)</b> | <b>\$ (64,884)</b> |
| Net loss per share:  |   |                    |                    |
| Net loss per common share, basic and diluted                                     | \$ (0.44)   | \$ (12.62)         | \$ (24.63)         |
| Weighted average shares used in basic and diluted net loss per share computation | 35,777,308  | 2,707,219          | 2,634,096          |

(1) Allocation of stock-based compensation expense is as follows:

**Years Ended December 31,**

**2005      2004      2003**

|  | <b>(In thousands)</b> |              |              |
|--|-----------------------|--------------|--------------|
| Cost of processing and storage revenues    | \$ 20                 | \$ 32        | \$ 7         |
| Research and development                   | 294                   | 896          | 1,073        |
| Sales and marketing                        | 207                   | 175          | 414          |
| General and administrative                 | 1,642                 | 2,083        | 1,738        |
| Restructuring                              |                       | 243          |              |
| <br>Total stock-based compensation expense | <br>\$ 2,163          | <br>\$ 3,429 | <br>\$ 3,232 |

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

F-4

---

**Table of Contents**

**ViaCell, Inc.**  
**Consolidated Statements of Comprehensive Loss**

|   | <b>Years Ended December 31,</b> |             |             |
|---|---------------------------------|-------------|-------------|
|   | <b>2005</b>                     | <b>2004</b> | <b>2003</b> |
|   | <b>(In thousands)</b>           |             |             |
| Net loss                                | \$ (14,677)                     | \$ (21,097) | \$ (55,468) |
| Foreign currency translation adjustment | (105)                           | (175)       | 484         |
| Comprehensive loss                      | \$ (14,782)                     | \$ (21,272) | \$ (54,984) |

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

F-5

---



Table of Contents

**ViaCell, Inc.**  
**Consolidated Statements of Stockholders Equity (Deficit)**

|   | <b>Preferred Stock</b> |                  | <b>Common Stock</b> |                  | <b>Additional</b>      | <b>Deferred</b>     | <b>Accumulated</b> | <b>Other</b>                | <b>Total</b>                         |
|---|------------------------|------------------|---------------------|------------------|------------------------|---------------------|--------------------|-----------------------------|--------------------------------------|
|   | <b>Shares</b>          | <b>Par Value</b> | <b>Shares</b>       | <b>Par Value</b> | <b>Paid-In Capital</b> | <b>Compensation</b> | <b>Deficit</b>     | <b>Comprehensive Income</b> | <b>Stockholders Equity (Deficit)</b> |
| (In thousands except share data)        |                        |                  |                     |                  |                        |                     |                    |                             |                                      |
| Balance, December 31, 2002              | 182,857                | \$ 2             | 2,558,574           | \$ 26            | \$ 8,822               | \$ (6,126)          | \$ (73,211)        | \$                          | \$ (70,487)                          |
| Stock option exercises                  |                        |                  | 101,280             | 1                | 53                     |                     |                    |                             | 54                                   |
| Issuance of stock warrant               |                        |                  |                     |                  | 1,450                  |                     |                    |                             | 1,450                                |
| Accretion of redeemable preferred stock |                        |                  |                     |                  | (9,416)                |                     |                    |                             | (9,416)                              |
| Non-employee stock compensation         |                        |                  |                     |                  | 251                    |                     |                    |                             | 251                                  |
| Deferred compensation                   |                        |                  |                     |                  | 804                    | (804)               |                    |                             |                                      |
| Amortization of deferred compensation   |                        |                  |                     |                  | (527)                  | 3,508               |                    |                             | 2,981                                |
| Net loss                                |                        |                  |                     |                  |                        |                     | (55,468)           |                             | (55,468)                             |
| Translation adjustment                  |                        |                  |                     |                  |                        |                     |                    | 484                         | 484                                  |
| Balance, December 31, 2003              | 182,857                | \$ 2             | 2,659,854           | \$ 27            | \$ 1,437               | \$ (3,422)          | \$ (128,679)       | \$ 484                      | \$ (130,151)                         |
| Stock option exercises                  |                        |                  | 89,915              | 1                | 107                    |                     |                    |                             | 108                                  |
| Accretion of redeemable preferred stock |                        |                  |                     |                  | (4,081)                |                     | (8,990)            |                             | (13,071)                             |
| Non-employee stock compensation         |                        |                  | 14,192              |                  | 415                    |                     |                    |                             | 415                                  |
| Deferred compensation                   |                        |                  |                     |                  | 2,882                  | (2,882)             |                    |                             |                                      |
| Forfeiture of stock options             |                        |                  |                     |                  | (413)                  | 413                 |                    |                             |                                      |
|   |                        |                  |                     |                  | 774                    |                     |                    |                             | 774                                  |

|   |           |      |            |        |            |              |              |        |    |           |  |
|---|-----------|------|------------|--------|------------|--------------|--------------|--------|----|-----------|--|
| Modification of stock options   |           |      |            |        |            |              |              |        |    |           |  |
| Amortization of deferred compensation                                 |           |      |            |        | (1,121)    | 3,361        |              |        |    | 2,240     |  |
| Net loss  |           |      |            |        |            |              | (21,097)     |        |    | (21,097)  |  |
| Translation adjustment  |           |      |            |        |            |              |              | (175)  |    | (175)     |  |
| Balance, December 31, 2004  | 182,857   | \$ 2 | 2,763,961  | \$ 28  | \$         | \$ (2,530)   | \$ (158,766) | \$ 309 | \$ | (160,957) |  |
| Stock option exercises  |           |      | 685,157    | 7      | 1,157      |              |              |        |    | 1,164     |  |
| Initial public offering   |           |      | 8,625,000  | 86     | 56,062     |              |              |        |    | 56,148    |  |
| Initial public offering costs   |           |      |            |        | (2,899)    |              |              |        |    | (2,899)   |  |
| Accretion of redeemable preferred stock                               |           |      |            |        | (986)      |              |              |        |    | (986)     |  |
| Conversion of redeemable convertible preferred stock (Series A and B) | (182,857) | (2)  | 182,857    | 2      |            |              |              |        |    |           |  |
| Conversion of redeemable convertible preferred stock (Series C and K) |           |      | 25,628,075 | 256    | 175,903    |              |              |        |    | 176,159   |  |
| Issuance of common stock upon exercise of warrants, net               |           |      | 229,818    | 2      | (2)        |              |              |        |    |           |  |
| Non-employee stock compensation                                       |           |      | 2,857      |        | 20         |              |              |        |    | 20        |  |
| Deferred compensation, net  |           |      |            |        | 700        | 1,443        |              |        |    | 2,143     |  |
| Net loss  |           |      |            |        |            |              | (14,677)     |        |    | (14,677)  |  |
| Translation adjustment  |           |      |            |        |            |              |              | (105)  |    | (105)     |  |
| Balance, December 31, 2005  |           | \$   | 38,117,725 | \$ 381 | \$ 229,955 | \$ \$(1,087) | \$ (173,443) | \$ 204 | \$ | 56,010    |  |

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

F-6

---

**Table of Contents**

**ViaCell, Inc.**  
**Consolidated Statements of Cash Flows**

|  | <b>Years Ended December 31,</b> |                 |                 |
|--|---------------------------------|-----------------|-----------------|
|  | <b>2005</b>                     | <b>2004</b>     | <b>2003</b>     |
|  | <b>(In thousands)</b>           |                 |                 |
| <b>Cash flows from operating activities:</b>   |                                 |                 |                 |
| Net loss   | \$ (14,677)                     | \$ (21,097)     | \$ (55,468)     |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b>       |                                 |                 |                 |
| Depreciation and amortization  | 2,110                           | 2,577           | 2,518           |
| Stock-based compensation   | 2,163                           | 3,429           | 3,232           |
| Reserve for bad debt   | 515                             | 248             | 777             |
| Non-cash charge for acquired in-process R & D  |                                 |                 | 23,925          |
| Non-cash interest expense on related party notes   | 88                              | 1,142           | 280             |
| Loss on write-down of fixed assets   | 17                              | 2,155           |                 |
| Tenant improvement allowance   | 2,437                           | 1,004           |                 |
| Other  | 17                              | 29              | 4               |
| <b>Changes in assets and liabilities, excluding the effect of acquisition:</b>           |                                 |                 |                 |
| Accounts receivable  | (3,276)                         | (3,376)         | (2,034)         |
| Prepaid expenses and other current assets  | 2,853                           | (615)           | (2,267)         |
| Accounts payable   | (115)                           | (2,192)         | 415             |
| Accrued expenses   | 34                              | (2,542)         | 4,630           |
| Deferred revenue   | 5,527                           | 4,092           | 1,498           |
| Deferred rent  | 873                             | 31              |                 |
| <b>Net cash used in operating activities</b>   | <b>(1,434)</b>                  | <b>(15,115)</b> | <b>(22,490)</b> |
| <b>Cash flows from investing activities:</b>   |                                 |                 |                 |
| Purchases of property and equipment  | (3,923)                         | (2,393)         | (1,826)         |
| Proceeds from maturities of investments  | 36,532                          | 22,682          | 15,813          |
| Purchase of investments  | (42,099)                        | (36,697)        | (9,688)         |
| Proceeds from return of security deposits on debt obligations                            | 414                             | 403             |                 |
| Decrease in restricted cash  |                                 | 732             | 3,210           |
| (Increase) decrease in long-term other assets  | 7                               | 85              | (1,751)         |
| Cash acquired in acquisition, net of acquisition costs                                   |                                 |                 | 3,738           |
| <b>Net cash provided by (used in) investing activities</b>                               | <b>(9,069)</b>                  | <b>(15,188)</b> | <b>9,496</b>    |
| <b>Cash flows from financing activities:</b>   |                                 |                 |                 |
| Proceeds from issuance of redeemable convertible preferred stock, net                    |                                 |                 | 36,887          |
| Proceeds from exercise of stock options  | 1,164                           | 108             | 43              |
| Net proceeds from sale of common stock in initial public offering, net of offering costs | 53,249                          |                 |                 |
| Proceeds from credit facilities  |                                 |                 | 5,000           |
| Repayments on credit facilities  | (1,674)                         | (1,562)         | (5,452)         |
| Repayment of notes payable to related party, including accrued interest                  | (15,510)                        |                 |                 |
| Payments on capital lease principal  | (86)                            | (267)           | (49)            |

|  |           |          |           |
|--|-----------|----------|-----------|
| Net cash provided by (used in) financing activities  | 37,143    | (1,721)  | 36,429    |
| Effect of change in exchange rates on cash           | (248)     | (238)    | 334       |
| Net increase (decrease) in cash and cash equivalents | 26,392    | (32,262) | 23,769    |
| Cash and cash equivalents, beginning of period       | 6,746     | 39,008   | 15,239    |
| Cash and cash equivalents, end of period             | \$ 33,138 | \$ 6,746 | \$ 39,008 |

Supplemental disclosures of cash flow information and non cash transactions:

|  |        |        |        |
|--|--------|--------|--------|
| Interest paid  | \$ 273 | \$ 325 | \$ 260 |
| Income taxes paid  | 153    | 73     | 9      |
| Acquisitions (Note 3)  |        |        | 28,705 |
| Accretion of redeemable convertible preferred stock                | 986    | 13,071 | 9,416  |
| Equipment purchased under capital lease, net of disposals (Note 2) | 56     | 140    | 155    |

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

**Table of Contents**

**ViaCell, Inc.**  
**Notes to Consolidated Financial Statements**

**1. Organization and Nature of Business**

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. The Company has a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. The Company is currently conducting a Phase I clinical trial of CB001, its lead umbilical cord blood-derived stem cell therapy product candidate as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In addition to the Company's therapeutic research and development programs, it has a reproductive health business unit that generated revenues of \$43.8 million in 2005 from sales of ViaCord, a service offering through which expectant families can preserve their baby's umbilical cord blood for possible future medical use. The Company is working to leverage its commercial infrastructure and product development capabilities by developing ViaCyte<sup>sm</sup>, its investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs.

ViaCell was incorporated in the State of Delaware on September 2, 1994. The Company's corporate headquarters and main research facility is located in Cambridge, Massachusetts. The Company has processing and storage facilities in Hebron, Kentucky and an additional research and development operation in Singapore.

On September 30, 2003, ViaCell acquired the outstanding shares of Kourion Therapeutics AG ( "Kourion" ) in a purchase business combination. Under the terms of the agreement, shareholders of Kourion exchanged all of their outstanding shares for a \$14 million note and 549,854 shares of ViaCell's Series I convertible preferred stock. As potential additional consideration, the Company issued 241,481 additional shares of Series I convertible preferred stock to an escrow account and reserved 289,256 shares of Series I convertible preferred stock for possible issuance in the future (Note 3).

The Company restructured its operations in September and December 2004 to reduce operating expenses and concentrate its resources on four key products and product candidates, and related business initiatives (Note 14).

On January 26, 2005 the Company completed its initial public offering ( "IPO" ). The Company issued 8,625,000 shares at \$7.00 per share resulting in net proceeds to the Company of approximately \$53,249,000 after underwriters' discounts and offering expenses. As a result of the IPO, all shares of the Company's preferred stock immediately converted into 25,810,932 shares of common stock. On January 26, 2005, the Company paid in full the related party note of \$15,509,760, which included all outstanding principal and interest owed at that date.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. Certain reclassifications of prior year amounts have been made to conform with current year presentation.

***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 disclosure 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.

Table of Contents

**ViaCell, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**

***Cash, Cash Equivalents and Investments***

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Investments with remaining maturities of 12 months or less are classified as short-term investments. Investments with maturities greater than 12 months are classified as long-term investments. Investments in debt securities are classified as either held-to-maturity or available-for-sale based on facts and circumstances at the time of purchase. Investments for which the Company has the positive intent and ability to hold to maturity are classified as held-to-maturity investments and are reported at amortized cost plus accrued interest. As of each balance sheet date presented all investments are classified as cash and cash equivalents or held-to-maturity. To date, the Company has not recorded any realized gains or losses on the sale of investments. The following table is in thousands.

|  | December 31, 2005 |               |                      | December 31, 2004 |               |                      |
|--|-------------------|---------------|----------------------|-------------------|---------------|----------------------|
|  | Amortized<br>Cost | Fair<br>Value | Unrealized<br>(Loss) | Amortized<br>Cost | Fair<br>Value | Unrealized<br>(Loss) |
| Cash and cash equivalents                    |                   |               |                      |                   |               |                      |
| Money market accounts                        | \$ 29,807         | \$ 29,807     | \$                   | \$ 3,613          | \$ 3,613      | \$                   |
| Government securities                        | 1,432             | 1,432         |                      | 1,485             | 1,485         |                      |
| Cash   | 1,899             | 1,899         |                      | 1,648             | 1,648         |                      |
| Total cash and cash equivalents              | 33,138            | 33,138        |                      | 6,746             | 6,746         |                      |
| Short-term investments                       |                   |               |                      |                   |               |                      |
| Commercial paper                             | 27,406            | 27,362        | (44)                 | 21,339            | 21,262        | (77)                 |
| Long-term investments                        |                   |               |                      |                   |               |                      |
| Commercial paper                             |                   |               |                      | 500               | 498           | (2)                  |
| Total investments                            | 27,406            | 27,362        | (44)                 | 21,839            | 21,760        | (79)                 |
| Total cash, cash equivalents and investments | \$ 60,544         | \$ 60,500     | \$ (44)              | \$ 28,585         | \$ 28,506     | \$ (79)              |

In connection with Company's commitments under various agreements (Notes 8 and 9) and one of the Company's operating bank accounts, the Company issued letters of credit totaling \$1.9 million collateralized by certificates of deposit totaling \$1.9 million that are classified as restricted cash on the accompanying consolidated balance sheet.

During 2005, the Company revised the classification for certain items, including security deposits and restricted cash, in the Company's Consolidated Statements of Cash Flows. These changes are now presented as investing activities. The revised classifications have also been reflected in the comparative prior year amounts for purposes of consistency.

***Revenue Recognition***

The Company recognizes revenue from cord blood processing and storage fees in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*. The Company receives fees for collecting, testing, freezing and storing of cord blood units. Once the cord blood units are collected, tested, screened and successfully meet all of the required attributes, the Company freezes the units and stores them in a cryogenic

freezer. Upon successful completion of collection, testing, screening and freezing services, the Company recognizes revenue from the processing fees.

F-9

---



**Table of Contents**

**ViaCell, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

When evaluating multiple element arrangements subsequent to July 1, 2003, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ). EITF 00-21 requires the following criteria to be met for an element to represent a separate unit of accounting:

- a) The delivered items have value to a customer on a standalone basis;
- b) There is objective and reliable evidence of the fair value of the undelivered items; and
- c) Delivery or performance is probable and within the control of the vendor for any delivered items that have a right of return.

The Company has concluded that the collection, testing and freezing service has stand-alone value to the customer and that the Company has objective evidence of fair value of the undelivered storage services. The fair value of the storage services is based on the annual storage fee charged to customers on a stand-alone basis.

The Company charges an initial fee which covers collection, testing, freezing and, typically, one year of storage. The Company defers the fair value of the revenue related to the future storage and recognizes the remainder of the revenue under the residual method. The adoption of EITF 00-21 did not impact the Company's revenue recognition model.

Revenue recognized from the collection, testing and freezing of cord blood units was approximately \$36,098,000, \$31,737,000, and \$27,768,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

Revenue from storage fees is recognized over the contractual period on a straight-line basis and amounted to approximately \$7,677,000, \$5,068,000, and \$3,116,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Deferred revenue of \$15,715,000 and \$10,187,000 at December 31, 2005 and 2004, respectively, consist primarily of the unearned portions of annual storage fees and deposits paid by customers prior to completion of our processing service. Deferred revenue at December 31, 2005 and 2004 also included approximately \$731,000 and \$154,000, respectively, of unearned revenue related to the Company's economic development grant with Singapore.

The Company recognizes shipping costs billed to customers as revenues and records a corresponding amount as cost of processing and storage revenues.

In February 2002, the EITF released EITF Issue No. 01-09 (EITF 01-09), *Accounting for Consideration Given by a Vendor*, to a customer (including a reseller of the vendor's products). EITF 01-09 states that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement, rather than a sales and marketing expense. The Company conducts rebate programs for its customers and the total amount of these rebates was \$130,000, \$334,000, and \$783,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The rebates have been recorded as a reduction in processing revenue for the years ended December 31, 2005, 2004, and 2003.

Revenues from short-term research contracts are recognized over the contract period as services are provided. Revenues from research contracts amounted to \$0, \$192,000, and \$363,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

**Table of Contents**

**ViaCell, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

The Company recognized approximately \$668,000, \$1,277,000, and \$633,000 in grant revenue in the years ended December 31, 2005, 2004, and 2003, respectively, under grants from the Economic Development Boards of Singapore and Germany. Under these grant agreements, the Company is reimbursed for certain defined expenses.

***Accounts Receivable***

Accounts receivable consists of amounts primarily due from customers for cord blood processing and storage revenues. Accounts receivable are stated at amounts due from customers, net of an allowance for doubtful accounts. The Company determines the allowance by considering receivables that are past due, our previous loss history, and the customers' current ability to pay its obligations. The Company writes off accounts receivable when they become uncollectible and any payments subsequently received on reserved accounts receivable are credited to the allowance for doubtful accounts.

***Cost of Processing and Storage Revenues***

Cost of processing and storage revenues reflects the cost of transporting, testing, processing and storing cord blood at the Company's cord blood processing facility in Hebron, Kentucky, as well as a royalty to PharmaStem Therapeutics, Inc. relating to ongoing patent infringement litigation. We recorded a royalty expense of \$3.3 million in 2003 following an unfavorable jury verdict in the PharmaStem litigation in October 2003. In 2004, the District Court overturned the jury verdict. Based on the judge's ruling, we reversed the entire royalty accrual in 2004 and have not recorded any royalties since such date. PharmaStem has appealed the District Court's ruling. PharmaStem has also filed a new lawsuit claiming that we infringe additional patents (Note 9). Pending a decision on the appeal and further action by the court on the new litigation, we do not intend to record a royalty expense in future periods, since we believe PharmaStem's claims are without merit.

Costs incurred related to grant and contract revenues are included in research and development expense.

***Advertising Costs***

Costs of media advertising are expensed at the time the advertising takes place and are classified as sales and marketing expense. Advertising costs totaled approximately \$3,100,000, \$2,515,000, and \$1,815,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

***Research and Development Expenses***

Research and development expenses, which are comprised of costs incurred in performing research and development activities including wages and related employee benefits, clinical trial costs, contract services, supplies, facilities and overhead costs, are expensed as incurred.

***In-process Technology***

The Company expenses costs of purchased technology used in its ongoing research and development activities in the period of purchase if management believes the technology has not yet reached technical feasibility and has no alternative future use.

***Foreign Currency Translation***

The financial statements of the Company's German subsidiary, Kourion, are translated in accordance with Statement of Financial Accounting Standards (SFAS) No. 52, *Foreign Currency Translation*. The functional currency of Kourion is the local currency (euro), and accordingly, all assets and liabilities of the foreign subsidiary are translated using the exchange rate at the balance sheet date except for capital accounts

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

which are translated at historical rates. Revenues and expenses are translated at average rates during the period. Adjustments resulting from the translation from the financial statements of Kourion into US dollars are excluded from the determination of net loss and are recorded in accumulated other comprehensive income within stockholders equity. Foreign currency transaction gains and losses are reported in the accompanying consolidated statements of operations and are immaterial to the results of operations.

***Income Taxes***

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets may be reduced by a valuation allowance to reduce deferred tax assets to the amounts expected to be realized.

***Property and Equipment***

Property and equipment are initially recorded at cost and depreciated over the estimated useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the estimated useful life of the asset or the lease term, if shorter. The Company accounts for internal-use software and web-site development costs in accordance with Statement of Position 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use* and classifies such costs as software within property and equipment.

Useful lives are as follows:

| <b>Asset Classification</b>   | <b>Estimated Useful Life</b> |
|-------------------------------|------------------------------|
| Software                      | 2-3 years                    |
| Laboratory equipment          | 5-10 years                   |
| Office and computer equipment | 3-5 years                    |
| Leasehold improvements        | Life of lease                |
| Furniture and fixtures        | 5-7 years                    |

Maintenance and repairs are charged to expense as incurred. When assets are impaired or otherwise disposed of, the cost of these assets and the related accumulated depreciation and amortization are eliminated from the balance sheet and any resulting gains or losses are included in operations in the period of disposal.

***Fair Value of Financial Instruments***

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, capital lease obligations, equipment loans and notes payable to related party. The carrying value of the short-term financial instruments approximates fair value due to short maturities and the carrying value of the long-term financial instruments approximate fair value based on current rates offered to the Company for debt with similar maturities.

***Goodwill and Other Intangible Assets***

The Company's intangible assets consist of:  
goodwill;

employment contracts;

**Table of Contents**

**ViaCell, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**

customer lists; and

trademarks.

SFAS No. 142, *Goodwill and Other Intangible Assets* requires that periodic tests of goodwill's impairment be performed and that other intangibles be amortized over their useful lives unless these lives are determined to be indefinite. SFAS No. 142 requires that goodwill be tested annually for impairment under a two-step impairment process or whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

The Company amortizes other intangible assets using the straight-line method over useful lives of 3 years for employment agreements, 20 years for trademarks, and 10 years for customer lists.

***Accounting for the Impairment of Long-Lived Assets***

The Company periodically evaluates its long-lived assets for potential impairment under SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The Company performs these evaluations whenever events or changes in circumstances suggest that the carrying amount of an asset or group of assets is not recoverable. Indicators of potential impairment include but are not limited to:

- a significant change in the manner in which an asset is used;

- a significant decrease in the market value of an asset;

- a significant adverse change in its business or the industry in which it is sold; and

- a current period operating cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the asset.

If management believes an indicator of potential impairment exists, it tests to determine whether impairment recognition criteria in SFAS No. 144 have been met. The Company charges impairments of the long-lived assets to operations if its evaluations indicate that the carrying values of these assets are not recoverable.

***Concentration of Credit Risk and Other Risks and Uncertainties***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, short-term investments, restricted cash and accounts receivable. At December 31, 2005 and 2004, substantially all of the Company's cash, cash equivalents and short-term investments were invested in highly rated financial institutions and consisted of money market funds and highly-rated commercial paper.

At December 31, 2005 and 2004, the Company had cash balances at certain financial institutions in excess of federally insured limits. However, the Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company provides most of its services to consumers. Concentration of credit risk with respect to trade receivable balances are limited due to the diverse number of customers comprising the Company's customer base.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

The Company performs ongoing evaluations of its receivable balances and maintains reserves for potential credit loss. At December 31, the Company's allowance for doubtful accounts receivable consisted of the following (in thousands):

|   | <b>Balance at<br/>Beginning<br/>of<br/>Period</b> | <b>Additions<br/>to<br/>Costs and<br/>Expenses</b> | <b>Deductions</b> | <b>Balance at<br/>End of<br/>Period</b> |
|---|---|--|-------------------|---|
| <b>Allowance for doubtful accounts receivable</b> |   |  |                   |   |
| December 31, 2005                                 | \$ 1,197  | 515  | (644)             | \$ 1,068                                |
| December 31, 2004                                 | \$ 1,044  | 248  | (95)              | \$ 1,197                                |
| December 31, 2003                                 | \$ 269  | 777  | (2)               | \$ 1,044                                |

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the successful development and commercialization of products, clinical trial uncertainty, fluctuations in operating results and financial risks, potential need for additional funding, protection of proprietary technology and patent risks, compliance with government regulations, dependence on key personnel and collaborative partners, competition, technological and medical risks, customer demand, supply risk, management of growth and effectiveness of marketing by the Company and by third parties.

The Company's cord blood collection, testing and processing activities are currently subject to Food and Drug Administration (FDA) regulations requiring infectious disease testing. In the future, the Company may have to list its cord blood preservation products with the FDA. The Company also may be subject to inspection by the FDA.

***Redeemable Convertible Preferred Stock***

The carrying value of redeemable convertible preferred stock was increased by periodic accretions, including cumulative dividends, so that the carrying amount will equal the redemption amount at the earliest redemption date. These increases were effected through charges to additional paid-in capital to the extent there are any, and, thereafter, to accumulated deficit.

***Stock-Based Compensation***

The Company uses the intrinsic value method of Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees*, and related interpretations in accounting for its employee stock options, and presents disclosure of pro forma information required under Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* and SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*—an amendment of FASB Statement No. 123.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which require that such equity instruments be recorded at their fair value on the measurement date. The measurement of stock-based compensation may be subject to periodic adjustment as the underlying equity instruments vest.

During the year ended December 31, 2005, the Company did not issue any stock options to employees with an exercise price below fair market value. During the years ended December 31, 2005, 2004, and 2003, the Company recorded amortization of deferred compensation related to stock options granted to employees and non-employee directors and charges related to the modification of existing grants of approximately \$2.1 million, \$3.0 million, and \$3.0 million, respectively (Note 12). At December 31, 2005 and December 31,



**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

2004, approximately \$1.1 million and \$2.5 million, respectively, of deferred stock-based compensation related to stock options remained unamortized.

During the years ended December 31, 2005, 2004, and 2003, the Company recorded stock-based compensation expense of approximately \$20,000, \$415,000 and \$251,000, respectively, related to stock options granted to non-employees.

Had all employee stock-based compensation expense been determined using the fair value method and amortized on a straight-line basis over the vesting period of the related stock options consistent with SFAS No. 123, the pro forma net loss per share would have been as follows (table in thousands, except per share data):

|   | <b>Years Ended December 31</b> |             |             |
|---|--------------------------------|-------------|-------------|
|   | <b>2005</b>                    | <b>2004</b> | <b>2003</b> |
| Net loss attributable to common stockholders as reported  | \$ (15,663)                    | \$ (34,168) | \$ (64,884) |
| Add: employee stock-based compensation expense included in reported net loss                                    | 2,143                          | 3,014       | 2,981       |
| Deduct: total employee stock-based compensation expense determined under fair value based method for all awards | (4,630)                        | (5,175)     | (4,257)     |
| Pro forma net loss attributable to common stockholders  | \$ (18,150)                    | \$ (36,329) | \$ (66,160) |
| Basic and diluted net loss per share as reported  | \$ (0.44)                      | \$ (12.62)  | \$ (24.63)  |
| Pro forma basic and diluted net loss per share  | \$ (0.51)                      | \$ (13.42)  | \$ (25.12)  |

The Company has computed the pro forma disclosures required under SFAS No. 123 for all stock options granted to employees and directors of the Company as of December 31, 2005, 2004 and 2003 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The weighted average assumptions used for the years ended December 31 are as follows:

|                                 | <b>December 31,</b> |             |             |
|---------------------------------|---------------------|-------------|-------------|
|                                 | <b>2005</b>         | <b>2004</b> | <b>2003</b> |
| Risk-free interest rate         | 3.92%               | 2.86%       | 2.00%       |
| Expected life                   | 5 years             | 5 years     | 5 years     |
| Expected volatility             | 100%                | 100%        | 100%        |
| Dividend yield                  | 0%                  | 0%          | 0%          |
| Per share grant date fair value | \$ 6.26             | \$ 8.00     | \$ 8.15     |

During 2004, all stock options were granted to employees at an exercise price of \$5.00 per share. This was lower than the fair market value used for purposes of recording stock-based compensation expense during 2004 in anticipation of the Company's initial public offering, which occurred in January 2005.

***Segment Information***

The Company's management currently uses consolidated financial information in determining how to allocate resources and assess performance. The Company may organize its business into more discrete business units when and if it generates significant revenues from the sale of stem cell therapies. For these reasons, the Company has determined that it conducts operations in one business segment.

F-15

---



**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

The following table presents total long-lived tangible assets by geographic areas as of December 31, 2005 and 2004, respectively (in thousands):

|                                       | <b>December 31,<br/>2005</b> | <b>December 31,<br/>2004</b> |
|---------------------------------------|------------------------------|------------------------------|
| Long-lived assets, net                |                              |                              |
| United States                         | \$ 8,430                     | \$ 6,310                     |
| Germany                               |                              | 88                           |
| Singapore                             | 272                          | 340                          |
| Total long-lived tangible assets, net | \$ 8,702                     | \$ 6,738                     |

The following table presents revenues by geographic area for the period ended December 31, 2005 and 2004, respectively (in thousands):

|                | <b>December 31,<br/>2005</b> | <b>December 31,<br/>2004</b> |
|----------------|------------------------------|------------------------------|
| United States  | \$ 43,812                    | \$ 36,997                    |
| Germany        | (101)                        | 990                          |
| Singapore      | 732                          | 287                          |
| Total Revenues | \$ 44,443                    | \$ 38,274                    |

***Comprehensive Loss***

Comprehensive loss is comprised of net loss and certain changes in stockholders' equity that are excluded from net loss. The Company includes foreign currency translation adjustments for Kourion in comprehensive loss.

***Net Loss Per Common Share***

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares consist of the common shares issuable upon the exercise of stock options and warrants and the conversion of convertible preferred stock (using the if-converted method). Potentially dilutive common shares are excluded from the calculation if their effect is anti-dilutive.

The following sets forth the computation of basic and diluted net loss per share (in thousands):

|  | <b>Years Ended December 31,</b> |             |               |
|--|---------------------------------|-------------|---------------|
|  | <b>2005</b>                     | <b>2004</b> | <b>2003</b>   |
| Basic and diluted net loss per share                 |                                 |             |               |
| Net loss attributable to common stockholders         | \$ (15,663)                     | \$ (34,168) | \$ \$(64,884) |
| Weighted average number of common shares outstanding | 35,777                          | 2,707       | 2,634         |

|                                      |           |            |            |
|--------------------------------------|-----------|------------|------------|
| Basic and diluted net loss per share | \$ (0.44) | \$ (12.62) | \$ (24.63) |
|--------------------------------------|-----------|------------|------------|

F-16

---

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

The following potentially dilutive securities were excluded because their effect was antidilutive:

|                             | <b>Years Ended December 31,</b> |             |             |
|-----------------------------|---------------------------------|-------------|-------------|
|                             | <b>2005</b>                     | <b>2004</b> | <b>2003</b> |
| Options                     | 3,746,395                       | 4,222,211   | 4,374,160   |
| Warrants                    | 3,349,455                       | 1,428,750   | 1,413,906   |
| Convertible preferred stock | 1,433,941                       | 25,810,932  | 25,810,932  |

***Recent Accounting Pronouncements***

On December 16, 2004, the Financial Accounting Standards Board ( FASB ) released SFAS No. 123(R) *Share-Based Payment*. This new accounting standard requires all forms of stock compensation, including stock options, to be reflected as an expense in the Company's financial statements. Public companies must adopt the standard by their first annual fiscal period beginning after June 15, 2005. The Company intends to apply the revised standard in the annual period beginning January 2006. Although the Company has not finalized its analysis, it expects that the adoption of the revised standard will result in higher operating expenses and higher net loss per share. The Company most likely will use the modified prospective method in which compensation cost is recognized beginning with the effective date of this new accounting pronouncement (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date of this new accounting pronouncement and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123(R) that remain unvested on the effective date. Note 2 to the consolidated financial statements shows the pro forma impact on net loss and net loss per common share as if the Company had historically applied the fair value recognition provisions of SFAS No. 123 to stock-based employee awards.

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes*, and supersedes FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*-an amendment of APB Opinion No. 28. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the provisions of the SFAS 154 will have a significant impact on our results of operations.

**3. Acquisitions*****Acquisition of Kourion Therapeutics AG***

In September 2003, the Company acquired all the outstanding common shares of Kourion in a taxable exchange for 549,854 shares of Series I convertible preferred stock, valued at approximately \$4.4 million. The Company also issued promissory notes to a related party totaling \$14.0 million in principal amount to funds affiliated with the former holders of all outstanding preferred shares of Kourion and incurred acquisition-related costs totaling \$2.1 million.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

As potential additional consideration, the Company issued 241,481 additional shares of Series I convertible preferred stock to an escrow account (escrow shares) and reserved 289,256 shares of Series I convertible preferred stock (contingent shares) for possible issuance in the future. All convertible preferred stock immediately converted to common stock upon the completion of the Company's initial public offering. The escrowed shares will be released, and the contingent shares will issue, upon a change in control if that event occurs prior to September 30, 2006, otherwise the escrow shares will revert back to the Company and the contingent shares will never issue. If the contingent shares issue upon a change in control, the recipients of these shares will be issued an additional number of shares equal to 8% of the initial number of contingent shares issued compounded annually from the acquisition closing date to the date of issuance.

Under the acquisition agreement, the Company is also obligated to make payments to Kourion's former shareholders if certain Unrestricted Somatic Stem Cells (USSCs)-related programs assumed in the acquisition achieve certain milestones by specified dates. Should all these milestones be achieved, including final FDA approval of the developed products, the Company would have to pay a total of \$12.0 million, either in stock or cash at each shareholder's option.

The fair value of the net assets acquired from Kourion exceeded the total consideration paid by ViaCell, resulting in negative goodwill of approximately \$8.2 million. Because the acquisition involved contingent consideration, the Company was required to recognize additional purchase consideration equal to the lesser of the negative goodwill of \$8.2 million or the maximum amount of contingent consideration of \$16.2 million. Accordingly, contingent purchase price totaling \$8.2 million has been included in the Company's determination of the total purchase price. The total contingent consideration consists of the \$12.0 million of potential milestone payments to the Kourion shareholders, the 241,481 escrow shares with a face value as of the date of acquisition of \$1.9 million and the 289,256 contingent shares with a face value as of the date of acquisition of \$2.3 million. The entire contingent consideration of \$8.2 million included in purchase price has been included as a non-current liability since the escrowed and contingent shares will only be issued if there is a change of control of the Company prior to September 30, 2006, and the milestone payments are less likely to be paid.

The acquisition has been accounted for as a purchase and, accordingly, the results of operations of Kourion subsequent to September 2003 are included in the Company's consolidated statement of operations (in thousands):

The aggregate purchase price of \$28,705,000 consists of the following:

|                                      |                  |
|--------------------------------------|------------------|
| Series I convertible preferred stock | \$ 4,400         |
| Note payable to related party        | 14,000           |
| Acquisition costs                    | 2,150            |
| Contingent consideration             | 8,155            |
| <b>Total purchase price</b>          | <b>\$ 28,705</b> |

The aggregate purchase price was allocated as follows:

|                           |          |
|---------------------------|----------|
| Cash and cash equivalents | \$ 4,563 |
| Other current assets, net | 1,125    |
| Property and equipment    | 1,432    |
| Other assets              | 139      |
| Current liabilities       | (513)    |
| Capital lease obligation  | (141)    |
| In-process technology     | 22,100   |

Total net assets acquired

\$ 28,705

F-18

---

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

Upon consummation of the Kourion acquisition, the Company immediately expensed to in-process technology \$22.1 million, representing a portion of the fair value allocated to in-process research and development ( IPR&D ).

The Company believes that this charge represents a reasonably reliable estimate of the future benefits attributed to purchased IPR&D. The value assigned to IPR&D was composed of the projected value of the two Kourion preclinical drug development projects. The valuation was determined using the income approach. Potential revenue and drug development expenses were projected through 2021 based on management's estimates. Specifically, management estimated that the development of the Kourion programs through clinical trials to commercial viability will take approximately eight years and cost in excess of \$31.0 million. The discounted cash flow method was applied to the projected cash flows, adjusted for the probability of success using a discount rate of 23%. The discount rate takes into consideration the uncertainty surrounding successful development and commercialization of the IPR&D. The technology that the Company acquired in the transaction with Kourion is at an early stage and will require several more years of development before a therapeutic product can be developed and commercialized. Given the risks inherent in the clinical development and regulatory approval process, it is possible that no commercial product will ever result from this technology.

**4. Property and Equipment**

Property and equipment consisted of (in thousands):

|   | <b>December 31,</b> |             |
|---|---------------------|-------------|
|   | <b>2005</b>         | <b>2004</b> |
| Software  | \$ 3,098            | \$ 2,700    |
| Laboratory equipment                            | 5,230               | 4,674       |
| Office and computer equipment                   | 2,611               | 1,867       |
| Leasehold improvements                          | 5,267               | 3,130       |
| Furniture and fixtures                          | 767                 | 717         |
| Construction in progress                        | 8                   | 380         |
| Property and equipment, gross                   | 16,981              | 13,468      |
| Less: accumulated depreciation and amortization | (8,279)             | (6,730)     |
| Property and equipment, net                     | \$ 8,702            | \$ 6,738    |

At December 31, 2005 and 2004 the net book value of property and equipment serving as collateral under loan agreements amounted to \$1,485,000 and \$3,159,000, respectively.

At December 31, 2005 and 2004, equipment held under capital leases totaled \$492,126 and \$474,776, and accumulated depreciation related to this leased equipment totaled approximately \$299,133 and \$250,909, respectively.

Depreciation and amortization expense on property and equipment totaled approximately \$1,909,000, \$2,413,000, and \$2,256,000 in the years ended December 31, 2005, 2004, and 2003.

**5. Long-Lived Assets and Goodwill**

Intangible assets consist of a trademark and goodwill. Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, was amortized on a straight-line basis over its useful life of ten years prior to January 1, 2002.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

Amortization of intangible assets was approximately \$202,000, \$250,000, and \$261,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

At December 31, 2005 and 2004, ViaCell's goodwill and intangible assets consisted of the following (in thousands):

|                                | <b>December 31,</b> |             |
|--------------------------------|---------------------|-------------|
|                                | <b>2005</b>         | <b>2004</b> |
| Goodwill                       | \$ 3,621            | \$ 3,621    |
| Intangible assets              |                     |             |
| Trademark                      | \$ 4,400            | \$ 4,400    |
| Employment agreements          | 288                 | 288         |
| Less: accumulated amortization | (1,865)             | (1,663)     |
| Intangible assets, net         | \$ 2,823            | \$ 3,025    |

The Company expects amortization of these intangible assets to be approximately \$202,000 annually through 2019, at which point they will be fully amortized.

**6. Accrued Expenses**

At December 31, 2005 and 2004, accrued expenses consisted of the following (in thousands):

|                                 | <b>December 31,</b> |             |
|---------------------------------|---------------------|-------------|
|                                 | <b>2005</b>         | <b>2004</b> |
| Payroll and payroll related     | \$ 1,541            | \$ 1,016    |
| Management incentive            | 881                 | 723         |
| Professional fees               | 1,206               | 2,026       |
| Accrued marketing               | 1,260               | 913         |
| Accrued restructuring (Note 14) | 632                 | 907         |
| Deferred rent, current          | 619                 | 238         |
| Accrued taxes                   | 537                 | 647         |
| Other                           | 1,030               | 1,020       |
| Accrued expenses                | \$ 7,706            | \$ 7,490    |

**7. Income Taxes**

Loss before income taxes is as follows for the years ended December 31 (in thousands):

|             |             |             |
|-------------|-------------|-------------|
| <b>2005</b> | <b>2004</b> | <b>2003</b> |
|-------------|-------------|-------------|

Edgar Filing: VIACELL INC - Form 10-K

|                                |             |             |             |
|--------------------------------|-------------|-------------|-------------|
| Domestic                       | \$ (13,104) | \$ (16,019) | \$ (52,299) |
| Foreign                        | (1,573)     | (5,078)     | (3,169)     |
| Total Loss Before Income Taxes | \$ (14,677) | \$ (21,097) | \$ (55,468) |

F-20

---



**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

The Company's effective tax rate for the years ended December 31 varies from the statutory rate as follows:

|                               | <b>Years Ended December 31,</b> |             |             |
|-------------------------------|---------------------------------|-------------|-------------|
|                               | <b>2005</b>                     | <b>2004</b> | <b>2003</b> |
| US Statutory rate             | 34.00%                          | 34.00%      | 34.00%      |
| State taxes, net              | (0.66)%                         | 3.70%       | 2.00%       |
| Foreign rate differential     | 0.02%                           | 1.80%       | 0.40%       |
| Benefit of tax credits        | 4.37%                           | 2.60%       | 1.30%       |
| Change in valuation allowance | (34.41)%                        | (36.80)%    | (14.80)%    |
| Stock-based compensation      | (1.41)%                         | (5.10)%     | (8.10)%     |
| In process R&D                | 0.00%                           | 0.00%       | (14.70)%    |
| Other                         | (1.03)%                         | (0.20)%     | (0.10)%     |
| Change in local tax rate      | (1.89)%                         | 0.00%       | 0.00%       |
| Effective tax rate            | (1.01)%                         | 0.00%       | 0.00%       |

The Company accounts for income taxes under SFAS No. 109, Accounting for Income Taxes. Under SFAS No. 109, deferred tax assets or liabilities are computed based on the differences between the financial statement and income tax bases of assets and liabilities using the enacted tax rates. Deferred income tax expense or credits are based on changes in the asset or liability from period to period. The components of net deferred tax assets (liabilities) are described in the following table:

|                              | <b>Years Ended December 31,</b> |             |
|------------------------------|---------------------------------|-------------|
|                              | <b>2005</b>                     | <b>2004</b> |
| Deferred tax assets:         |                                 |             |
| Operating loss carryforwards | \$ 37,323                       | \$ 35,436   |
| Tax credit carryforwards     | 4,315                           | 3,484       |
| Stock-based compensation     | 2,802                           | 3,790       |
| Temporary differences        | 10,238                          | 8,510       |
|                              | 54,678                          | 51,220      |
| Less: valuation allowance    | (53,614)                        | (50,002)    |
| Net deferred tax assets      | 1,064                           | 1,218       |
| Deferred tax liabilities:    |                                 |             |
| Intangible assets            | (1,064)                         | (1,218)     |
| Net deferred taxes           | \$                              | \$          |

The Company has recorded a full valuation allowance against its net deferred tax assets because, based on the weight of available evidence, the Company believes it is more likely than not that the deferred tax assets will not be

realized. At December 31, 2005, the Company has federal and state net operating loss carryforwards of approximately \$82.8 million and \$75.3 million, respectively, which begin to expire in 2009 and 2006, respectively. The Company has federal and state credit carryforwards of approximately \$3.3 million and \$1.6 million which begin to expire in 2009 and 2013, respectively. The Company also has foreign net operating loss carryforwards of \$14.9 million. The carryforwards expire through 2024 and are subject to review and possible adjustment by the Internal Revenue Service. Ownership changes, as defined in the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income.

F-21

---

Table of Contents**ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

Of the \$53.6 million valuation allowance, \$2.8 million relates to nonqualified stock option deductions, the benefit of which will be credited to additional paid in capital if and when realized.

In December 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position No. SFAS-109-2 ( SFAS 109-2 ), Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004. The American Jobs Creation Act of 2004 ( the Act ) was passed in October 2004. The Act contains certain tax incentives including a deduction for income from qualified production activities and an 85% dividend received deduction for certain dividends from controlled foreign corporations. These incentives are subject to a number of limitations. None of these incentives are expected to have a significant impact on our income tax liability.

At December 31, the Company's valuation allowance consisted of the following (in thousands):

| Description | Balance at<br>Beginning of<br>Period | Additions | Deductions | Balance at<br>End of Period |
|-------------|--------------------------------------|-----------|------------|-----------------------------|
| 2005        | \$50,002                             | 3,612     |            | \$53,614                    |
| 2004        | \$42,234                             | 7,768     |            | \$50,002                    |
| 2003        | \$28,966                             | 13,268    |            | \$42,234                    |

**8. Long-Term Debt Obligations**

The Company had the following long-term debt obligations outstanding as of December 31, 2005 and 2004 (in thousands):

|  | December 31, |          |
|--|--------------|----------|
|  | 2005         | 2004     |
| Debt facility loans                          | \$ 1,480     | \$ 3,135 |
| Notes payable to related party               |              | 15,422   |
| Capital lease obligations                    | 147          | 179      |
| Total long-term debt                         | 1,627        | 18,736   |
| Less: current portion                        | (1,543)      | (17,164) |
| Total long-term debt, net of current portion | \$ 84        | \$ 1,572 |

***Debt facility loans***

In October 2003, the Company entered into a \$5,000,000 loan agreement with GE Capital Corporation. Borrowings under this agreement bear interest at 6.9 percent per annum and are collateralized by the property and equipment of the Company. Monthly payments of interest and principal are due through October 2006. Approximately \$1,485,000 was outstanding under this loan as of December 31, 2005. In October 2003, the Company was required to make a \$1,750,000 cash deposit with the lender as additional collateral for this loan. As of December 31, 2005 and 2004, the net book value of the fixed assets which are collateralized under this agreement was \$1,485,000 and \$3,159,000, respectively.

During 2005, \$413,632 of the deposit was returned based on the repayment schedule of the loan agreement. As of December 31, 2005, the remaining deposit was \$943,000 and is included with other current assets in the

accompanying consolidated balance sheet.

The Company also issued a warrant to GE Capital Corporation, in connection with the above financing, for the purchase of 18,750 shares of Series J preferred stock with an exercise price of \$8 per share with a life of ten years. The Company valued the warrant under a Black-Scholes model deriving a fair market value of approximately \$57,000. This amount was recorded as a deferred financing cost and is being amortized over the

F-22

---

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

term of the note. Warrant amortization was approximately \$18,000 and \$29,000 for the periods ended December 31, 2005 and December 31, 2004, respectively.

In connection with this debt facility, the Company entered into a negative pledge agreement with GE Capital Corp. that, among other things, precludes the Company from rolling, transferring, assigning, mortgaging, leasing, granting a security interest in or encumbering any of its intellectual property. The negative pledge agreement, however, does not preclude the Company from granting a license or sublicense in the ordinary course of business. There are no financial covenants associated with this new agreement.

***Notes Payable to Related Party***

A portion of the consideration paid by the Company in its acquisition of Kourion consisted of promissory notes in an aggregate principal amount of \$14.0 million. The notes were held by several funds that are also stockholders of the Company and that are affiliated with MPM Asset Management LLC, the manager of which served on the Company's board of directors. The notes bore interest at a rate of 8% per annum, compounded annually, and had a maturity date of September 30, 2007. The Company recorded \$1,422,000 in accrued interest related to this note for the period ended December 31, 2004. The notes were subject to mandatory prepayment upon the earlier of an initial public offering of the Company's common stock or a sale of the Company. The total outstanding principal and unpaid accrued interest on the notes as of December 31, 2004 was \$15,422,000. On January 26, 2005, following the completion of its initial public offering, the Company paid off the related party note of \$15,509,760, which included all outstanding principal and interest owed at that date.

***Capital Lease Obligations***

The Company leases scientific equipment under lease agreements that qualify for capitalized treatment under SFAS No. 13, *Accounting for Leases*.

At December 31, 2005, payments of principal and interest on existing debt were due as follows (in thousands):

|                          |          |
|--------------------------|----------|
| Year Ending December 31, |          |
| 2006                     | \$ 1,594 |
| 2007                     | 56       |
| 2008                     | 30       |
| Total payment            | 1,680    |
| Less: interest           | (53)     |
| Total debt               | 1,627    |
| Less: current portion    | (1,543)  |
| Total long-term debt     | \$ 84    |

**9. Commitments and Contingencies*****Contingent Purchase Price***

The fair value of the net assets acquired from Kourion exceeded the total consideration paid by ViaCell, resulting in negative goodwill of approximately \$8.2 million. Because the acquisition involved contingent consideration, the Company was required to recognize additional purchase consideration equal to the lesser of the negative goodwill of \$8.2 million or the maximum amount of contingent consideration of \$16.2 million. Accordingly, contingent purchase price totaling \$8.2 million has been included in the Company's consolidated

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

balance sheet as a non-current liability (Note 3).

***Leases***

The Company conducts its operations in leased facilities under noncancelable operating leases expiring through 2014.

Future minimum rental payments under the operating leases are approximately as follows (in thousands):

| Year Ending December 31, |           |
|--------------------------|-----------|
| 2006                     | \$ 1,994  |
| 2007                     | 1,896     |
| 2008                     | 1,744     |
| 2009                     | 1,704     |
| 2010                     | 1,730     |
| Thereafter               | 6,564     |
| Total lease payments     | \$ 15,632 |

Rent expense was approximately \$1,812,000, \$2,212,000, and \$1,797,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

In connection with the above commitments, the Company has issued letters of credit totaling approximately \$1,844,000 as collateral against these leases. These letters of credit are collateralized by certificates of deposit that are classified as restricted cash on the accompanying consolidated balance sheets.

In 2005 and 2004 the Company received approximately \$2.4 million and \$1.0 million, respectively, as a tenant improvement allowance to offset the fixed asset costs incurred to build out the Company's office and lab facility. The tenant improvement allowance is amortized as a reduction to rent expense over the life of the lease.

In February 2006, the Company leased an additional 7,600 square feet of office space in its Cambridge facility for a term of approximately 8.5 years to run concurrently with its existing operating leases for office space in its Cambridge facility. The total lease commitment for this additional office space is approximately \$1.9 million. As this lease was effective subsequent to December 31, 2005, it is not included in the future minimum rental payments schedule above.

***Agreements***

In January 2005, the Company entered into development and supply agreements with Miltenyi Biotec GmbH. The development agreement provides for the development by Miltenyi of a cGMP cell separation kit for ViaCell consisting of various antibodies conjugated with magnetic particles to be used in ViaCell's proprietary Selective Amplification process for the development and commercialization of certain of ViaCell's proprietary cellular therapy product candidates. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the cell separation kit, including making various filings with the FDA. The Company is obligated to pay up to \$950,000. As of December 31, 2005, the Company had paid \$700,000 relating to the development of the product, and is recognizing expense as the work is performed over the development period. The remaining payment of \$250,000 relates to a milestone to be paid upon filing the master files for the cell separation kits with the FDA. For the year ended December 31, 2005, the Company recognized \$950,000 of expense related to this

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

development agreement. The agreement terminates on the earlier of the expiration of both parties' obligations under the development agreement or January 24, 2007.

The supply agreement provides for the exclusive supply of the cell separation kits by Miltenyi to ViaCell. The initial term of the supply agreement is for seven years. The Company has agreed to purchase at least \$1.3 million of cell separation kits within the first year after the process development program has been completed. The Company also has certain minimum annual purchase requirements starting in fiscal 2007 which will apply if its investigational product for hematopoietic stem cell transplantation, CB001, continues in clinical trials or is commercialized.

The Company has entered into an agreement with the Economic Development Board of the Government of Singapore under which the Government of Singapore has agreed to give the Company a grant of up to \$4,000,000 to fund stem cell research and development programs conducted in Singapore. Under this agreement, the Government of Singapore reimburses the Company for a portion of research and development expenses incurred for work done in Singapore. The Company funded approximately \$1,333,000, \$1,045,000, and \$968,000 of research and development in Singapore during the twelve months ended December 31, 2005, 2004, and 2003, respectively, and recorded grant revenue of approximately \$732,000, \$287,000, and \$252,000 during the twelve months ended December 31, 2005, 2004, and 2003, respectively.

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, typically with business partners, licensors and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the party's activities. Certain indemnification provisions survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date, the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2005.

***Litigation***

In 2002, PharmaStem Therapeutics, Inc. filed suit against the Company and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 ( '681) and No. 5,192,553 ( '553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. The Company believes that it does not infringe these patents and that the patents are invalid.

In 2003, a jury ruled against the Company and the other defendants, Cbr Systems Inc, CorCell, Inc. and Cryo-Cell International Inc, who represent a majority of the family cord blood preservation industry finding that the patents were valid and enforceable, and that the defendants infringed the patents. A judgment was entered against the Company for approximately \$2.9 million, based on 6.125% royalties on the Company's revenue from the processing and storage of umbilical cord blood since April 2000. In 2004, the District Court judge in the case overturned the jury's verdict stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge's decision. The Company has appealed the jury's finding as to validity of the patents. A hearing on the appeal is scheduled for April 4, 2006.

In July 2004, PharmaStem filed a second complaint against the Company. The second complaint was filed in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patents No. 6,461,645 ( '645) and 6,569,427 ( '427), which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. The Company believes that the patents in this new action are invalid and that the Company does not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachu-

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

settles litigation. That motion is currently stayed. The Company believes the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, the Company filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, the Company's request was granted. The cases have been consolidated in Delaware.

The U.S. PTO has ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and 427 patents at issue in the second case based on prior art. A second re-examination of the 427 patent was ordered in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010. Final decisions on the re-examinations have not yet been issued.

On October 6, 2005, the Delaware court granted the Company's motion to stay all discovery in the second lawsuit pending decisions from the Federal Circuit on PharmaStem's appeal of the District Court's ruling of non-infringement in the original case and from the U.S. PTO on the patent re-examinations.

In either of the pending cases, if the Company is ultimately found to infringe, the Company could have a significant damages award entered against us. If the Company is found to infringe or at any other time during the course of either case, including possibly if the court of appeals were to overturn the district court's non-infringement ruling, the Company could also face an injunction which could prohibit the Company from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant the Company a license or to do so on economically reasonable terms, and previously informed the Company that it would not do after October 15, 2004. While the Company does not believe this outcome is likely, in the event of an injunction, if the Company is not able to obtain a license under the disputed patents on economically reasonable terms or at all and the Company cannot operate under an equitable doctrine known as intervening rights, the Company will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products. The Company may enter into settlement negotiations with PharmaStem regarding the litigation. The Company cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all.

On May 13, 2004, the Company received a First Amended Complaint filed in the Superior Court of the State of California by Kenneth D. Worth, by and for the People of the State of California, and naming as defendants a number of private cord blood banks, including the Company. The complaint alleges that the defendants have made fraudulent claims in connection with the marketing of their cord blood banking services and seeks restitution for those affected by such marketing, injunctive relief precluding the defendants from continuing to abusively and fraudulently market their services and requiring them to provide certain information and refunds to their customers, unspecified punitive and exemplary damages and attorney's fees and costs. Subsequently, the Company received a Notice of Ex Parte Application for Leave to Intervene filed on behalf of the Cord Blood Foundation by the same individual and seeking similar relief. On October 7, 2004, the Court orally granted a motion to strike the complaint under the California anti-SLAPP statute and dismissed the complaint as to all defendants without leave to amend. Judgment has been entered, dismissing the complaint, and plaintiff has filed a notice of appeal and a brief for the appeal and a petition for a writ of mandate. The petition has been dismissed and the appeal is proceeding. The plaintiff has settled the litigation with all defendants other than the Company. The Company is not yet able to conclude as to the likelihood that plaintiff's claims would be upheld if the judgment of dismissal were reversed on appeal, nor can the Company estimate the possible financial consequences should plaintiff prevail. However, the Company believes this suit to be without merit and intend to continue to vigorously defend itself.

On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against the Company in the United States District Court for the Northern District of California alleging false and misleading advertising by the Company in violation of the federal Lanham Act and various California



**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. On April 13, 2005, the Company answered the complaint, denying Cbr's allegations, and filed counterclaims alleging false and misleading advertising by Cbr. On October 27, 2005, the Company entered into an agreement to settle the pending litigation with Cbr. Under terms of the agreement the companies agreed to dismiss all outstanding legal claims. There were no financial payments to be made by either party under the settlement agreement.

The Company has undertaken a review of its various job classifications for legal compliance under state and federal employment laws. Based on that review, the Company has identified certain job classifications that may be subject to possible challenge and for which there is a reasonable possibility that the Company could incur a liability, although the Company also believes that the present classifications can be supported and defended. It is not possible based on the current available information to reasonably estimate the scope of any potential liability.

***Physician Indemnification Program***

During September 2004, the Company launched an indemnification program offering protection to physicians from patent litigation actions taken against them by PharmaStem Therapeutics, Inc. Under this program, the Company agrees to pay reasonable defense costs resulting from such litigation, providing that the physicians allow ViaCell to manage their defense. In addition, the Company agrees to indemnify the physicians against all potential financial liability resulting from such litigation, and pay additional remuneration of \$100,000, should PharmaStem prevail in any patent infringement action against the physician. In order to qualify for this indemnification the physicians are required to comply with certain requirements, including returning a signed acknowledgement form regarding the particulars of the indemnification program. The Company has recorded a reserve of \$51,000 associated with this program as of December 31, 2005 and 2004. The reserve is equal to the estimated fair value of the indemnifications in place at December 31, 2005 and 2004, in accordance with FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). The Company has determined the reserve through a probability model based on assumptions related to the likelihood of legal ramifications, and the extent of those ramifications, applicable under this program for the potential professional fees, damages, and remunerations related to the agreements executed as of December 31, 2005 and 2004. The Company may record additional reserves as more physicians enroll in this program.

***ViaCord Guarantee Program***

Beginning in November 2002, the Company began providing its customers a product guarantee under which the Company agreed to pay \$25,000 to defray the costs associated with the original collection and storage of the cord blood, and procurement of an alternative stem cell source, if medically indicated, in the event that the customer's cord blood (unit) is used in a stem cell transplant and fails to engraft. The Company has never experienced any claims under the guarantee program nor has it incurred costs related to these guarantees. However, the Company does not maintain insurance to cover these potential liabilities and, therefore, maintains reserves to cover these potential liabilities. The Company accounts for the guarantee as a warranty obligation and, accordingly, recognizes the obligation in accordance with the provisions of SFAS No. 5, *Accounting for Contingencies*. The reserve balance is determined by the Company based on the \$25,000 maximum payment multiplied by the number of units covered by the guarantee multiplied by the expected transplant rate multiplied by the expected engraftment failure rate.

F-27

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

The following table summarizes the activities in the ViaCord Guarantee Program reserve for the years ended December 31, 2005, and 2004 (table in thousands):

|   | <b>For the<br/>Years Ended<br/>December 31,</b> |             |
|---|---|-------------|
|   | <b>2005</b>                                     | <b>2004</b> |
| Balance at the beginning of the period              | \$ 73   | \$ 43       |
| Accrual for additional units sold during the period | 19  | 30          |
| Balance at the end of the period                    | \$ 92   | \$ 73       |

**10. Redeemable Convertible Preferred Stock, Preferred Stock, and Common Stock**

The Company's redeemable convertible preferred stock is accreted to redemption value through the redemption date and consists of the following as of December 31, 2005 and 2004, respectively (table in thousands):

|                                   |            |
|-----------------------------------|------------|
| Balance, December 31, 2004        | \$ 175,173 |
| Accretion                         | 986        |
| Conversion to Common Stock at IPO | (176,159)  |
| Balance, December 31, 2005        | \$         |

In 2005 the Company incurred an additional \$986,000 in accretion associated with the outstanding redeemable convertible preferred stock through January 26, 2005 aggregating to a total of approximately \$176 million. All preferred stock immediately converted to common stock upon the completion of the Company's initial public offering.

The Company's convertible preferred stock consisted of the following as of December 31, 2005 and 2004, respectively:

|                                   | <b>Series A</b> | <b>Series B</b> | <b>Total</b> |
|-----------------------------------|-----------------|-----------------|--------------|
| Balance, December 31, 2004        | \$ 1,000        | \$ 829          | \$ 1,829     |
| Conversion to Common Stock at IPO | (1,000)         | (829)           | (1,829)      |
| Balance, December 31, 2005        | \$              | \$              | \$           |

The Company's Board of Directors authorized 30,825,000 shares of \$0.01 par value preferred stock.

On June 1, 1999, the Company issued 1,983,334 shares of its Series E convertible preferred stock at \$3.00 per share for total gross proceeds to the Company of approximately \$5,950,000. In connection with the sale, the Company issued warrants to investors to purchase up to 100,000 shares of the Company's common stock at an exercise price of \$1.50 per share.

In connection with the April 2000 merger with ViaCord, the Company authorized and issued 2,666,666 shares of \$0.01 par value Series F convertible preferred stock. Upon closing, the Company also issued 3,666,667 shares of

\$0.01 par value Series G convertible preferred stock at \$3.00 per share to three venture capital investors in exchange for a total of \$11,000,000.

On November 10, 2000, the Company issued 7,577,334 shares of Series H convertible preferred stock at \$6.38 per share and received proceeds of approximately \$48,200,000, net of \$120,000 of financing costs.

On October 25, 2001, the Company issued 1,875,000 shares of Series I convertible preferred stock for gross proceeds of approximately \$15,000,000, excluding \$79,000 of issuance costs. In addition, the Company

F-28

---

**Table of Contents**

**ViaCell, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

may sell and issue an additional 375,000 shares of Series I stock for \$8 per share pursuant to an option agreement dated October 25, 2001.

In January 2002, the Company issued 187,500 shares of Series I preferred stock for an aggregate price of \$1,500,000 upon the exercise of an option. In connection with this exercise, the option holder and the Company mutually agreed to terminate the remaining portion of the option.

In connection with the September 2003 acquisition of Kourion, the Company issued 549,854 shares of \$0.01 par Series I convertible preferred stock. The Company determined the fair value of the Series I preferred stock to be \$8.00 per share. The Company also issued 241,481 shares to an escrow account. These shares will be released either upon a change in control of the company or an underwritten initial public offering of its common stock at a price per share of at least \$9.70 resulting in net proceeds of at least \$50 million. If neither event occurs prior to September 30, 2006, the escrow shares will revert back to the Company.

In September 2003 and October 2003, the Company issued 2,190,000 of its Series J convertible preferred stock for total gross proceeds to the Company of \$17,520,000. The Company incurred approximately \$505,000 of issuance costs related to the Series J offering. The fair value of the Company's Series J convertible preferred stock was determined to be \$8.57 per share. A right to contingent warrants was granted to all purchasers of Series J preferred stock. Upon the earlier to occur of an initial public offering that is not a Qualified Public Offering (an initial public offering at a minimum price of \$9.70 per share in which net proceeds equal or exceed \$50 million) or the three year anniversary of the Initial Closing (September 30, 2006), the Company will issue warrants to the holders of Series J preferred stock for the purchase of Common Stock equal to the number of shares owned of Series J (2,190,000 shares). The initial warrant purchase price will be \$5.00. The warrant price and number of shares purchasable will be adjustable from time to time based on specific criteria to prevent dilution. The right to the contingent warrants had a fair value of approximately \$1,620,000 at the time of grant. The fair value was estimated using a binomial valuation model. The Company recorded the Series J convertible preferred stock and the contingent warrants, at their relative fair values of \$15,622,000 and \$1,390,000, respectively. In January 2005, the Company completed its initial public offering. Since this offering was not a Qualified Public Offering the Company issued the warrants to the holders of Series J preferred stock in February 2005.

In December 2003, in connection with the license and collaboration agreement described in Note 9, the Company issued 2,500,000 warrants of its Series K convertible preferred stock to Amgen at \$8.00 per share for total gross proceeds to the Company of \$20,000,000 and incurred issuance costs of approximately \$127,000. The Company recorded this preferred stock at its determined fair value of \$8.69 per share. The excess of the fair value of the Series I preferred stock over the gross proceeds of \$1,725,000 was allocated to the technology license and was charged to expense as in-process technology.

In connection with the shares of Series K convertible preferred stock issued to Amgen and the current PharmaStem litigation, the Company has a side agreement under which Amgen has a one-time option to require the Company to redeem up to 1,250,000 of its Series K shares at a price of \$8.00 per share. This option is triggered upon the occurrence of the earliest of June 23, 2007, a settlement or final judgment against the Company for a total amount exceeding \$30 million (including the initial judgment amount as well as certain royalties, if any, that the Company becomes obligated to pay PharmaStem), or an injunction enjoining the Company's cord blood preservation operations that has not been stayed or vacated. This option expires upon the earliest of the second anniversary of the triggering event, a settlement or final judgment against the Company for a total amount less than or equal to \$30 million (provided that an injunction is not currently in effect at the time), or a public offering of the Company's common stock in which all outstanding shares of convertible preferred stock of the Company automatically convert into common stock. All preferred stock immediately converted to common stock upon the completion of the Company's initial public offering.

**Table of Contents**

**ViaCell, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**

***Common and Preferred Stock***

As of December 31, 2005, the Company has authorized 100,000,000 and 5,000,000 shares of common and preferred stock, respectively, each with a \$0.01 par value. Each holder of a share of common stock is entitled to one vote for each share held at all meetings of stockholders.

**11. Warrants**

In August 2005, the Company amended its existing license and collaboration agreement with Amgen to include a nonexclusive license to patent rights covering an additional Amgen growth factor. In connection with this amendment, the Company issued Amgen a warrant to purchase 200,000 shares of the Company's common stock at an exercise price of \$7.85 per share. The warrant will vest upon the successful treatment of a human in a Phase II clinical trial utilizing the specific growth factor that is the subject of the amendment. The term of the warrant is seven years from the effective date of the amendment. The warrant will be recognized as in-process research and development expense when and if it vests, based on the fair value at that time.

In December 2003, the Company entered into a license and collaboration agreement under which Amgen, Inc. made a \$20 million investment in the Company's preferred stock. As part of this agreement, the Company may offer Amgen the right to make an additional investment of up to \$15 million in connection with a future strategic transaction by the Company that would further the Company's collaboration with Amgen. Amgen also holds a warrant to purchase 560,000 shares of the Company's common stock at \$12.00 per share as consideration for a previous license agreement that was superseded by this license and collaboration agreement.

In September and October 2003, the Company issued 2,190,000 shares of its Series J convertible preferred stock for total gross proceeds to the Company of \$17,520,000. A right to contingent warrants was granted to all purchasers of Series J preferred stock (the "Series J investors"). Under that right, upon the earlier to occur of an initial public offering that is not a Qualified Public Offering (an initial public offering at a minimum price of \$9.70 per share in which net proceeds equal or exceed \$50 million) or September 30, 2006, the Company would be required to issue warrants to the Series J investors for the purchase of Common Stock equal to the number of shares of Series J owned (for a total of 2,190,000 shares). The initial warrant purchase price would be \$5.00. The right to the contingent warrants had a fair value of approximately \$1,620,000 at the time of grant. The fair value was estimated using a binomial valuation model. The Company recorded the Series J convertible preferred stock and the contingent warrants, at their relative fair values of \$15,622,000 and \$1,390,000, respectively. In January 2005, the Company completed its initial public offering. Since the offering was not a Qualified Public Offering, the Company issued warrants to purchase a total of 2,190,000 shares of Common Stock to the Series J investors in February 2005. During the year ended December 31, 2005, certain Series J investors fully exercised their warrants using a "net exercise" feature that resulted in the issuance of 82,447 shares of the Company's Common Stock in consideration of canceling the remaining portion of the warrants covering 138,803 shares. In January 2006, certain Series J investors fully exercised their warrants using a "net exercise" feature that resulted in the issuance of 207,116 shares of the Company's Common Stock in consideration of canceling the remaining portion of the warrants covering 1,574,134 shares. The Company also canceled additional warrants to convert into 187,500 shares of the Company's Common Stock.

In November 1997, in connection with the issuance of Series D preferred stock, the Company issued warrants to certain stockholders ("Series D investors") to purchase 750,000 shares of the Company's common stock at a price per share of \$1.50. These warrants vested 100 percent on the date of grant and are exercisable through November 12, 2007. The value ascribed to these warrants was not material. During the year ended December 31, 2005, certain Series D investors fully exercised their warrants using a "net exercise" feature that resulted in the issuance of 142,800 shares of our common stock in consideration of canceling the remaining portion of the warrants covering 23,867 shares.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

In May 1999, in connection with the issuance of Series E preferred stock, the Company issued a warrant to a shareholder to purchase 100,000 shares of the Company's common stock at a price per share of \$1.50. The warrant vested 100 percent on the date of grant and is exercisable through May 21, 2009. The value ascribed to this warrant was not material.

**12. Stock Option Plan**

The ViaCell, Inc. Amended and Restated 1998 Equity Incentive Plan (the Plan), which was adopted on February 12, 1998, provides for the granting of incentive and nonqualified stock options to purchase an aggregate of 4,000,000 shares of common stock to employees, consultants and directors of the Company. The Board of Directors increased the number of shares of common stock available for issuance under the Plan from 5,000,000 to 6,000,000 in 2003, to 7,200,000 in 2004. The number of shares of common stock available for issuance under the Plan as of December 31, 2005 was 7,200,000. Incentive stock options may only be granted to employees of the Company. The exercise price of each option is determined by the Board of Directors. The exercise price of each incentive stock option, however, may not be less than the fair market value of the stock on the date of grant, as determined by the Board of Directors.

Options granted under the Plan vest over a period of four years and expire ten years from the grant date. At December 31, 2005, there were 2,081,504 shares available for future grant under the Plan. Information with respect to option activity is as follows (in thousands, except share data):

|                                | <b>Number<br/>of<br/>Options<br/>Authorized</b> | <b>Number of<br/>Options<br/>Outstanding</b> | <b>Exercise<br/>Price</b> | <b>Aggregate<br/>Exercise<br/>Price</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> |
|--------------------------------|---|--|---------------------------|---|--|
| Outstanding, December 31, 2002 | 5,000,000                                       | 4,375,752                                    | \$0.10-5.00               | \$ 7,627                                | \$ 1.74  |
| Authorized                     | 1,000,000                                       |  |                           |   |  |
| Granted                        |   | 713,436                                      | 5.00                      | 3,567                                   | 5.00   |
| Exercised                      |   | (101,280)                                    | 0.15-5.00                 | (54)                                    | 0.53   |
| Canceled                       |   | (282,572)                                    | 0.30-5.00                 | (1,096)                                 | 3.88   |
| Outstanding, December 31, 2003 | 6,000,000                                       | 4,705,336                                    | 0.10-5.00                 | 10,044                                  | 2.13   |
| Authorized                     | 1,200,000                                       |  |                           |   |  |
| Granted                        |   | 903,500                                      | 5.00                      | 4,518                                   | 5.00   |
| Exercised                      |   | (89,915)                                     | 0.30-5.00                 | (109)                                   | 1.21   |
| Canceled                       |   | (1,063,383)                                  | 0.30-5.00                 | (4,308)                                 | 4.03   |
| Outstanding, December 31, 2004 | 7,200,000                                       | 4,455,538                                    | 0.30-5.00                 | 10,145                                  | 2.28   |
| Authorized                     |   |  |                           |   |  |
| Granted                        |   | 420,200                                      | 5.31-11.10                | 3,065                                   | 7.30   |
| Exercised                      |   | (689,164)                                    | 0.30-5.00                 | (1,170)                                 | 1.70   |
| Canceled                       |   | (255,880)                                    | 0.75-11.10                | (1,164)                                 | 4.55   |
| Outstanding, December 31, 2005 | 7,200,000                                       | 3,930,694                                    | \$0.30-11.10              | \$ 10,876                               | \$ 2.77  |
| Exercisable, December 31, 2003 |   | 1,806,628                                    | \$ 0.30-5.00              | \$ 1,784,266                            | \$ 0.99  |

Edgar Filing: VIACELL INC - Form 10-K

|                                |           |              |              |         |
|--------------------------------|-----------|--------------|--------------|---------|
| Exercisable, December 31, 2004 | 2,228,710 | \$ 0.30-5.00 | \$ 3,161,845 | \$ 1.42 |
| Exercisable, December 31, 2005 | 2,080,738 | \$0.30-11.10 | \$ 4,090,384 | \$ 1.97 |

F-31

---

**Table of Contents**

**ViaCell, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**

| Options Outstanding at December 31, 2005 |                  |   | Options Exercisable at December 31, 2005 |                  |                                 |
|--|------------------|---|--|------------------|---------------------------------|
| Exercise Price                           | Number of Shares | Weighted Average Remaining Contractual Life | Exercise Price                           | Number of Shares | Weighted Average Exercise Price |
| \$ 0.30                                  | 1,396,843        | 4.56  | \$ 0.30                                  | 1,096,843        | \$ 0.30                         |
| 0.75                                     | 45,450           | 5.08  | 0.75                                     | 45,450           | 0.75                            |
| 0.95                                     | 130,987          | 5.49  | 0.95                                     | 130,987          | 0.95                            |
| 2.00                                     | 731,425          | 6.02  | 2.00                                     | 197,650          | 2.00                            |
| 4.00                                     | 51,775           | 6.23  | 4.00                                     | 43,174           | 4.00                            |
| 5.00                                     | 1,233,619        | 7.62  | 5.00                                     | 502,876          | 5.00                            |
| 5.31                                     | 138,781          | 9.72  | 5.31                                     | 8,694            | 5.31                            |
| 5.62                                     | 18,000           | 9.93  | 5.62                                     | 249              | 5.62                            |
| 7.25                                     | 25,000           | 9.32  | 7.25                                     | 4,687            | 7.25                            |
| 8.17                                     | 102,064          | 9.44  | 8.17                                     | 39,398           | 8.17                            |
| 9.00                                     | 7,500            | 9.11  | 9.00                                     |                  | 9.00                            |
| 10.89                                    | 40,000           | 9.53  | 10.89                                    | 10,000           | 10.89                           |
| 11.10                                    | 9,250            | 9.53  | 11.10                                    | 730              | 11.10                           |
|  | 3,930,694        |   | \$ 2.77                                  | 2,080,738        | \$ 1.97                         |

The weighted average fair value of options granted in 2005, 2004 and 2003 was \$6.26, \$7.23 and \$6.18, respectively.

In September 2004 the Company recorded stock-based compensation expense of approximately \$774,000 related to the modification of existing grants to severed employees to allow them an additional 90 days to exercise their vested options following termination due to restructuring (Note 14). The impact of the option modification was partially offset by the cancellation of 244,726 unvested options in connection with the restructuring and the reversal of the accelerated amortization expense related to the actual vested shares at the date of termination amounting to \$532,000.

In July 2005 the Company's Board of Directors approved an increase, from 90 days to three years, in the amount of time allowed for non-employee directors to exercise vested options following the termination of their service to the Company. As a result, the Company recognized additional stock-based compensation expense of approximately \$763,000 in the year ended December 31, 2005. An additional \$241,000 will be recognized in years 2006 through 2008 based on respective vesting schedules associated with each modified option grant.

### 13. Employee Benefit Plan

The Company maintains a qualified 401(k) retirement savings plan (the "401(k) Plan") covering all employees. Under the 401(k) Plan, the participants may elect to defer a portion of their compensation, subject to certain limitations. Company matching contributions may be made at the discretion of the Board of Directors. There have been no discretionary contributions made by the Company to the 401(k) Plan to date.



**14. Restructuring**

In September 2004, the Company restructured its operations to reduce operating expenses and concentrate its resources on four key products and product candidates, and related business initiatives. These products and product candidates consist of the Company's ViaCord service, and its ViaCyte, CB001 and cardiac research and development programs. As a result, the Company recorded a \$1.7 million restructuring

F-32

---

Table of Contents**ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)**

charge in the third quarter of 2004 related to employee severance, contract termination costs and the write-down of excess equipment. The majority of the contract termination costs related to a \$175,000 payment to terminate its agreement with Gamete Technologies.

In December 2004, the Company restructured its German operations and sublet its laboratory facility in Germany to a third party effective January 1, 2005. As a result, the Company recorded an additional restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility-related costs of \$1.1 million and a contract termination fee of \$0.1 million. The majority of the facility related costs consisted of the write off of the leasehold improvements and fixed assets in the Company's German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future sublease payments received from the sublessee. At December 31, 2004, restructuring costs of \$1.2 million had been paid, the net book value of fixed assets was written down by \$0.9 million and the accrued liability relating to the restructurings was \$0.9 million.

The Company is finalizing discussions with the German grant authorities regarding repayment of part of certain grants made to our German subsidiary in 2003 and 2004. The Company was notified that approximately \$500,000 in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. As a result, the Company reserved an additional \$410,000 during the year ended December 31, 2005 for its estimated liability under this grant. The additional reserves resulted in reversals of grant revenue of approximately \$105,000 for the year ended December 31, 2005. In addition, the Company reclassified approximately \$200,000 of accrued restructuring reserves to reduce outstanding grants receivable. In February 2006 the Company was notified by the State of North-Rhine-Westfalia, Germany that it plans on performing an audit of the State's economic grants granted throughout its territory, including the grant to Kourion. It is possible that the grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany, however the Company considers this possibility to be remote. As of December 31, 2005 the Company had received approximately \$3.6 million in cumulative grant proceeds from the German grant authorities.

The Company's activity in the restructuring accrual for the years ended December 31, 2005 and December 31, 2004 consisted of the following:

|                          | <b>Balance as<br/>of<br/>December 31,<br/>2004</b> | <b>Additions</b> | <b>Writedowns</b> | <b>Adjustments</b> | <b>Payments</b> | <b>Balance as<br/>of<br/>December 31,<br/>2005</b> |
|--------------------------|--|------------------|-------------------|--------------------|-----------------|--|
| Severance related        | \$ 421   | \$               | \$                | \$                 | \$ (421)        | \$   |
| Contractual terminations | 5  |                  |                   |                    | (5)             |  |
| Facility related         | 481  |                  |                   | 255                | (104)           | 632  |
|                          | \$ 907   | \$               | \$                | \$ 255             | \$ (530)        | \$ 632   |

|                          | <b>Balance as<br/>of<br/>December 31,<br/>2003</b> | <b>Additions</b> | <b>Writedowns</b> | <b>Adjustments</b> | <b>Payments</b> | <b>Balance as<br/>of<br/>December 31,<br/>2004</b> |
|--------------------------|--|------------------|-------------------|--------------------|-----------------|--|
| Severance related        | \$   | \$ 1,316         | \$                | \$                 | \$ (895)        | \$ 421   |
| Contractual terminations |  | 296              |                   |                    | (291)           | 5  |

|                  |       |          |          |            |        |
|------------------|-------|----------|----------|------------|--------|
| Facility related | 1,334 | (853)    |          |            | 481    |
|                  | \$    | \$ 2,946 | \$ (853) | \$ (1,186) | \$ 907 |

F-33

---

Table of Contents

**ViaCell, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**

**15. Unaudited Quarterly Financial Information****Selected Quarterly Consolidated Financial Data:**

|  | <b>First<br/>Quarter</b> | <b>Second<br/>Quarter</b> | <b>Third<br/>Quarter</b> | <b>Fourth<br/>Quarter</b> |
|--|--------------------------|---------------------------|--------------------------|---------------------------|
| <b>(In thousands, except per share data)</b> |                          |                           |                          |                           |
| <b>Year ended December 31, 2005</b>          |                          |                           |                          |                           |
| Total revenues                               | \$ 10,140                | \$ 11,383                 | \$ 11,690                | \$ 11,230                 |
| Loss from operations                         | \$ (4,196)               | \$ (3,515)                | \$ (3,976)               | \$ (4,870)                |
| Net loss attributable to common stockholders | \$ (5,023)               | \$ (3,095)                | \$ (3,558)               | \$ (3,987)                |
| Net loss per share (basic and diluted)       | \$ (0.17)                | \$ (0.08)                 | \$ (0.09)                | \$ (0.10)                 |
| <b>Year ended December 31, 2004</b>          |                          |                           |                          |                           |
| Total revenues                               | \$ 9,019                 | \$ 9,676                  | \$ 9,938                 | \$ 9,641                  |
| Loss from operations                         | \$ (7,197)               | \$ (2,088)                | \$ (5,919)               | \$ (4,926)                |
| Net loss attributable to common stockholders | \$ (10,761)              | \$ (5,650)                | \$ (9,454)               | \$ (8,303)                |
| Net loss per share (basic and diluted)       | \$ (4.03)                | \$ (2.10)                 | \$ (3.49)                | \$ (3.00)                 |

F-34