VIACELL INC Form 10-K March 16, 2007

# 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, 2006
- o 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)

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

04-3244816

245 First Street, Cambridge, Massachusetts **02142** (*Zip code*)

(Address of principal executive offices)

(Registrant s telephone number, including area code) (617) 914-3400

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

Name of Exchange On Which Registered:

Common Stock, \$0.01 par value

The Nasdaq Stock Market LLC

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

(Title of class)

None

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

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

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 b No o

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):

Large accelerated filer o Accelerated filer b Non-accelerated filer o

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 o No b

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 \$156,937,890.

As of March 9, 2007, the Registrant had 38,714,960 shares of Common Stock, \$0.01 par value, issued and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2007 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

#### ViaCell, Inc.

# Annual Report on Form 10-K For the Fiscal Year Ended December 31, 2006

#### 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<sup>®</sup> and ViaCord<sup>®</sup> are registered trademarks of ViaCell, Inc. ViaCyte<sup>sm</sup> is a service mark of ViaCell, Inc. Cell Sentinel<sup>tm</sup> is a trademark of Pall Corporation. Motherhood Maternity<sup>®</sup>, A Pea in the Pod<sup>®</sup>, Mimi Maternity<sup>®</sup>, and Destination Maternity<sup>tm</sup> are trademarks of Mothers Work, 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 research and development programs, and our views as to the possible outcome of pending litigation related to our intellectual property portfolio and other disputes. 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 in Part I, Item 1A Risk Factors beginning at page 17. 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.

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#### PART I

#### ITEM 1. DESCRIPTION OF BUSINESS

#### Overview

ViaCell is a biotechnology company dedicated to enabling the widespread application of human cells as medicine. We have a reproductive health business that generated revenues of \$54.1 million in 2006 from sales of ViaCord, a service offering through which expectant families can preserve their baby sumbilical cord blood for possible future medical use. Stem cells from umbilical cord blood are a treatment option today for over 40 diseases, including certain blood cancers and genetic diseases. We are also working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte<sup>sm</sup>, our product candidate being studied for its potential to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs. Our other research and development efforts are focused on investigating the potential for new therapeutic uses of umbilical cord blood-derived and adult stem cells and on technology for expanding populations of these cells. We are concentrating these efforts in the areas of cancer, cardiac disease and diabetes.

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

#### **Our ViaCell Reproductive Health Business**

Our ViaCell Reproductive Health business is responsible for marketing and sales of our ViaCord service offering for the collection, testing, processing and storage of umbilical cord blood stem cells, and for development of ViaCyte, our product candidate for the cryopreservation of human unfertilized eggs for future *in vitro* fertilization use. We also continue to evaluate opportunities to license, acquire or collaborate on other products or product candidates in the areas of women shealth that would leverage our existing sales and marketing infrastructure.

#### ViaCord Collection, Testing, Processing and Storage of Umbilical Cord Blood Stem Cells

#### **Background**

Umbilical cord blood is an important source of blood-forming stem cells, also known as hematopoietic stem cells. Physicians are increasingly using stem cells derived from umbilical cord blood as an alternative to bone marrow and peripheral blood transplants when a patient s existing bone marrow is diseased or has been impacted by a genetic disorder, or is damaged by high-dose chemotherapy. In this type of treatment, blood from the umbilical cord containing hematopoietic stem cells is infused into the patient s circulatory system from which the cells find their way to the bone cavity. Once established in the bone, if the transplant is successful, the cells begin to grow or engraft and produce new cells of the blood and immune system. 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. Scientists are also continuing to investigate other potential therapeutic uses of umbilical cord blood-derived stem cells. Data supports the potential of these stem cells to differentiate into cells found in various tissue and organs, including the liver, cartilage, brain and heart.

Umbilical cord blood stem cells for transplant can be sourced from a patient s own umbilical cord blood that has been collected at birth and stored or through a match with a sibling or family member or a match with donor umbilical cord blood from an unrelated person, depending in each case on availability and the particular medical condition being treated. Studies have shown that umbilical cord blood stem cell 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 graft-versus-host-disease (GVHD), a serious potential side effect following transplantation, than transplants from an unrelated donor.

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### ViaCord Service Offering

Through our ViaCord service 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. Over the past several years, the number of families choosing to preserve their baby s umbilical cord blood has grown significantly. We currently store over 110,000 cord blood units for customers. In 2006, we generated revenues of \$54.1 million from our ViaCord service offering compared to \$43.8 million in 2005.

As part of our ViaCord service 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 sumbilical cord blood at birth and packaging the unit for transportation to our laboratory. These materials include the Cell Sentinel<sup>tm</sup> collection bag, the only FDA-approved cord blood collection bag suitable for use in a sterile field. The kit also provides the materials necessary for collecting a maternal blood sample for later testing.

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

*Processing.* At our laboratory in Hebron, Kentucky, we process the cord blood using a process designed to maximize the number of stem cells preserved. We take a customized approach to processing with the ability to use the first FDA-cleared fully automated processing system or a semi-automated system depending in part on the cord blood collection volume.

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

We continually work to differentiate our ViaCord service offering. We collaborated with Pall Corporation on the development and design of the Cell Sentinel bag which became part of the ViaCord collection kit in the second quarter of 2006. In January 2007, we began to integrate automation technology into our processing system at our laboratory in Hebron, Kentucky. The automation technology we use is the SEPAX Cord Blood Processing System from Biosafe SA, a functionally closed and sterile processing system that efficiently harvests stem cells from cord blood in a large-scale processing environment. SEPAX is the first FDA-cleared cord blood processing system. Biosafe received FDA clearance for SEPAX in January 2007 and European CE mark approval in 2001. We also collaborate with leading hospitals and universities in the area of cord blood banking and transplantation. In May 2006, we entered into an agreement with Children's Hospital Oakland Research Institute, or CHORI, to combine our directed transplant programs for sibling donor cord blood. The CHORI/ViaCord sibling transplant program, or Sibling Connection, offers umbilical cord blood preservation services to expectant parents who have a child with a disease currently treatable with cord blood stem cells and who meet the other requirements of the program.

#### Sales and Marketing

Our Reproductive Health sales and marketing organization consists of sales and marketing professionals supporting our ViaCord service offering. We substantially completed an expansion of our field sales organization in the second quarter of 2006. We now have sales representatives in territories covering most of the high birthing areas in the United States. Our sales representatives in the field educate obstetricians, child birth educators, labor and delivery room

nurses, and hospitals on the benefits of cord blood preservation. Our internal sales and customer service staff directs its efforts at educating expectant families and guiding families who choose to preserve their child sumbilical cord blood through the collection, processing and storage process. We educate expectant families through many media, including targeted advertising, direct mail and web-based marketing activities.

From time to time, we augment our internal marketing efforts with external relationships. In August 2006, we entered into a data license and marketing services agreement with Mothers Work, Inc., the world s largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as

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Motherhood Maternity®, A Pea in the Pod®, Mimi Maternity®, and Destination Maternitytm. Under the terms of our agreement, Mothers Work has granted us an exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. Under the terms of our agreement, we will pay Mothers Work \$5,000,000 per year over the three-year term of the agreement which began on January 1, 2007 and, unless earlier terminated, ends on December 31, 2009. Under certain circumstances, we will also be obligated, at the beginning of 2009, to issue Mothers Work a warrant to purchase 100,000 shares of our common stock (see Note 10 to our consolidated financial statements). The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work s commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. While there is no assurance that the third party will not challenge the arbitrator s ruling, we believe that reversal of the ruling is unlikely and that the termination rights under our agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us. We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the low likelihood that we might have to pay damages or legal fees given the arbitrator s ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of December 31, 2006.

# **ViaCyte**

We are working to leverage our Reproductive Health business by developing a proprietary media intended for the cryopreservation of human unfertilized 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 are seeking *in vitro* fertilization, 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 30s and 40s. 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, also known as IVF, 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 chloride 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 product candidate would complement our ViaCord service offering 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

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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. In June 2006, the FDA gave us conditional approval of our Investigational Device Exemption, or IDE, to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. The FDA has approved the design and size of the trial. We expect to initiate the pivotal clinical trial in March 2007. The primary objective of the study is to determine the efficacy of the ViaCyte media for the cryopreservation and thawing of human oocytes. The open-label study will also evaluate safety. The eligible patient population for the study is women seeking IVF, diagnosed with male factor infertility. The primary endpoint of the study is 50 live births. Participants in the study will undergo traditional IVF. After the eggs are retrieved, the oocytes will be cryopreserved using the ViaCyte media, and stored in liquid nitrogen. The oocytes will then be thawed and subsequently inseminated.

Embryos will be transferred to the subject suterus using a non-surgical procedure. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. In February 2007, we entered into an agreement with Invitrogen, Inc. to manufacture the ViaCyte media to be used in the clinical trial.

# **Our Cellular Therapy Technology and Product Candidates**

ViaCell is dedicated to enabling the widespread application of human cells as medicine. We direct our research and development efforts in this area to investigating the potential therapeutic uses of umbilical cord blood-derived and adult stem cells and on technology for the expansion of the populations of these cells. Our primary focus is in the areas of cancer, cardiac disease and diabetes.

## **Background**

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.

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. 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.

# Our Programs in Cellular Therapies

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,

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cartilage, brain and heart of transplanted animals. We are currently studying the potential for these cells to be used 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 a heart attack 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 into 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 pre-clinical 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. In June 2006, we entered into a research collaboration agreement with the Stem Cell Internal Venture of Centocor Research and Development, Inc., or SCIV Centocor, a wholly-owned subsidiary of Johnson & Johnson, Inc., to evaluate USSCs as a potential treatment for cardiac disease. The collaboration is also supported by the Biologics Delivery Systems Group of Cordis Corporation, also a wholly-owned subsidiary of Johnson & Johnson, Inc., and is focused on dosing, delivery, and targeting of USSCs using Cordis NOGA XP delivery system in pre-clinical models. We expect to generate sufficient data in 2007 from the pre-clinical development work to determine whether we will file an investigational new drug application, or IND, with the FDA.

# Hematopoietic Stem Cells

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 from bone marrow, 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 have few, if any, therapeutic options.

Despite the proven clinical utility of hematopoietic stem cell therapy and the potential of stem cell therapy to treat other types of diseases, significant challenges exist on the path toward widespread application, including the challenges of harvesting sufficient quantities of stem cells. The number of stem cells collected from any particular

tissue source is typically low compared to the quantity required for therapeutic benefit. For example, most cord blood units collected do not alone contain sufficient stem cells to treat an adult patient. The likelihood and speed of successful stem cell engraftment are impacted by the number of stem cells transplanted. Through our research and development efforts, we are exploring ways to expand the number of stem cells derived from umbilical cord blood and to improve clinical outcome in transplant therapy.

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In February 2007, we announced the results of a Phase 1 clinical trial of one of our product candidates in this area, CB001. CB001 is comprised of stem cells isolated from umbilical cord blood and expanded using ViaCell s proprietary Selective Amplification technology. The Phase 1 clinical trial was primarily designed to evaluate safety in patients with advanced hematologic cancers in need of a hematopoietic stem cell transplant and who were unable to find a suitable bone marrow donor. Patients participating in the study received CB001 plus a standard cord blood unit following full myeloablative therapy. Patients were followed for 100 days post-transplant. Ten patients received treatment in the study. The study achieved its primary endpoint with no evidence of infusion toxicity related to CB001. Engraftment, based on neutrophil reconstitution, was demonstrated in nine of ten patients. In the patients who achieved neutrophil recovery, the median time to engraftment was 24 days. This compares to published clinical trial data showing a median time to engraftment of 23 days when two umbilical cord blood grafts are transplanted. Platelet recovery was demonstrated in seven of ten patients. The time to platelet recovery based on cumulative incidence was 54 days compared to published clinical trial data showing 97 days reported for dual cord transplants. Three of ten patients were positive for the presence of CB001 cells at day 7; however, there was no chimerism contribution from CB001 between days 21-28. Chimerism, the presence of donor cells, is, by day 21-28, an indication of the potential ability of a transplant source to reconstitute a patient. Four of ten of patients experienced Grade III/IV acute GVHD, a common side effect in transplant medicine. This rate is within the range of rates reported in the literature to date for cord blood transplantation. Eight of ten patients were alive at day 100 post transplant. Given these results and the shift in the treatment paradigm in transplant medicine from single cord to dual cord transplants, we made the decision not to advance CB001 in future clinical trials.

We continue to work on other approaches to expand the populations of stem cells from umbilical cord blood for potential use in hematopoietic stem cell therapy, including the use of USSCs as a platform for cell expansion.

#### 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 the 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 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, or MGH.

#### Other Areas of Interest

We expect to supplement our internal research and development efforts through the acquisition or licensing from third parties of product candidates or 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.

# **Research and Development Expenses**

Our research and development expenses were \$14.0 million, \$13.7 million and \$16.0 million for the years ended December 31, 2006, 2005 and 2004, respectively.

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### Collaborations, Licenses and Strategic Relationships

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

# Stem Cell Internal Venture of Centocor Research & Development, Inc.

In June 2006, we entered into a research collaboration agreement with SCIV Centocor to evaluate USSCs as a potential treatment for cardiac disease. The collaboration is also supported by the Biologics Delivery Systems Group of Cordis Corporation, and is focused on dosing, delivery, and targeting of USSCs using Cordis NOGA XP delivery system. Under the terms of the agreement, we received an initial up-front payment of \$350,000. SCIV Centocor is responsible for its own costs under the collaboration and pays 50% of the research costs that we incur under the collaboration, consistent with the agreed upon budget. In addition, the agreement provides SCIV Centocor with the first right to negotiate a collaboration with us on the clinical development and commercialization of a cardiac product offering based on our proprietary cord blood stem cells. Either party may terminate the agreement following an uncured material breach by the other. In addition, SCIV Centocor has the right to terminate the agreement at the end of each new phase of the joint research program.

# Johns Hopkins University

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 20 years. The agreement may be terminated by us at any time without cause with a specified amount of notice.

# Genzyme Corporation

In December 2004, we entered into a research agreement with Genzyme under which Genzyme conducts specified research using pancreatic 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 expires in June 2007, and may be terminated earlier 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.

## Tyho Galileo Research Laboratory

In September 2004, we entered into a license agreement with Tyho Galileo Research Laboratory, or Galileo, under which we received exclusive rights to intellectual property covering proprietary media for use in the field of oocyte cryopreservation. Our agreement with Galileo includes 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 licensed U.S. patent expires in 2017 if not extended.

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### Amgen Inc.

In December 2003, we entered into a license and collaboration agreement with Amgen Inc. under which we received a 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 the agreement, we can purchase current Good Manufacturing Practices, or 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. 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 the 2003 license and collaboration agreement, Amgen made a \$20 million investment in ViaCell. As part of our agreement with Amgen, 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 vested warrant to purchase 560,000 shares of our common stock at \$12.00 per share issued as consideration for a previous license agreement that was superseded by the 2003 license and collaboration agreement. In connection with the expansion of the collaboration agreement in 2005, 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.

## Massachusetts General Hospital

In March 2002, we entered into a license agreement with MGH under which we received exclusive, worldwide rights to develop and commercialize products based on patents and patent applications 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, if successfully developed.

#### **Intellectual Property**

The protection of our intellectual property is a strategic part of our business. We have exclusively licensed from Galileo a U.S. patent 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. We have exclusively licensed from MGH a U.S. patent broadly covering 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 U.S. patent applications directed to compositions and methods of using USSCs to treat a broad class of diseases. We have three issued U.S. patents directed at methods of manufacturing target populations of cells for use as cellular medicines. These patents broadly cover the use of

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selective elements to select a target population of cells. These patents expire in 2015 if not extended. Furthermore, we own or have licensed a number of patent applications pending in the U.S. and in other countries.

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 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 product candidates. 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 service 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 product candidates. 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 results of operation 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

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, a subsidiary of Cord Blood America, Inc., LifeBankUSA, a division of Celgene Cellular Therapeutics, a wholly-owned subsidiary of Celgene Corporation, 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 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 financing for a national system of public cord blood banks in the U.S. to encourage cord blood donations from an ethnically diverse population. In addition, many states are evaluating the feasibility of establishing cord blood repositories for transplantation purposes. An increase in the

number and diversity of publicly-available cord blood units from public banks would correspondingly increase the probability of finding suitably matched cells for a family member, which may result in a decrease in demand for private cord blood banking.

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

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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, including Extend Fertility, though none has taken its product through the rigors of the FDA approval process. We are aware of approximately twenty IVF centers already offering oocyte cryopreservation, which may make it more difficult for ViaCyte, if successfully developed, to achieve a significant market share. We expect to initiate a clinical trial of ViaCyte in March 2007. If we 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.

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, Inc., Cellerant Therapeutics, Inc., Celgene Corporation, Cytori Therapeutics, Inc., Gamida-Cell, Ltd., Genzyme Corporation, Bioheart, Inc. and Osiris Therapeutics, Inc. 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. In addition, public cord blood banks may, as a result of the Stem Cell Therapeutic Act, be able to better compete with our potential cell therapy products. 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.

Other than ViaCyte, our product candidates are at an early stage of development. We are aware of products manufactured or under development by competitors that are used, or being studied for use, in the prevention or treatment of diseases and health conditions which we have targeted for product development. For example, several companies are developing stem cell therapies for the treatment of cardiac disease. Other companies have 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.

#### **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 pre-clinical 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. The regulatory approval process can take many years and requires the expenditure of substantial resources.

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### 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:

pre-clinical 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 pre-clinical 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 involves 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, manufacturing facilities must be inspected and found to be 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 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, is required for Class III devices, those devices which are 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) clearance. The PMA pathway is much more costly, lengthy and uncertain than the 510(k) clearance pathway. A PMA applicant must provide extensive pre-clinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing,

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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 its Quality System Regulations, or QSRs. QSRs impose specific testing, control, documentation and other quality assurance procedures on manufacturers.

We expect to seek 510(k) clearance for our ViaCyte oocyte cryopreservation product candidate if the results of the clinical trial are favorable. 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 pre-clinical 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 provide.

## Regulations Relating To ViaCord

FDA Regulations. We have registered ViaCord with the FDA as a cord blood preservation service and are subject to FDA inspection. In addition, the FDA is good tissue practice regulations, or GTPs, establish a comprehensive regulatory program for human cellular and tissue-based products and rules for donor eligibility. We believe that we comply with applicable GTPs. 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 or could impose other regulatory requirements applicable to the collection and storage of cord blood. For example, in January 2007, FDA published a draft guidance document for comment that would require public cord blood banks to file BLAs. While the draft guidance does not currently apply to us, the FDA could decide to impose these requirement or others on our business. 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 us to cease distribution of the collection kits and obtain 510(k) clearance or PMA prior to further distribution of the kits.

*State Regulations*. We provide cord blood preservation services in all 50 states. Several states require that cord blood services be licensed, permitted or registered. We believe that we are currently licensed, permitted or registered to operate in all states where we are required to be licensed, permitted or registered. 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.

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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 we do not engage in certain electronic transactions related to reimbursement for health care and because blood and tissue procurement and banking activities are exempt, we are 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 us only as permitted by HIPAA (for example, with written patient authorizations which comply with certain detailed requirements). Although we are 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 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 other local, state and federal laws and regulations, including telemarketing laws and other laws related to the marketing of healthcare products as well as laws and regulations related 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. The laws related to use and disposal of hazardous or potentially hazardous substances 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 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, 2006, we had 254 full-time employees, of which 246 are based in the United States and 8 are based in Singapore. All of our employees are at-will employees, other than Marc Beer, Anne Marie Cook, Jim Corbett, Stephen Dance, Morey Kraus and Mary Thistle, 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.

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#### ITEM 1A. RISK FACTORS

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to events and potential results related to our research and development programs, and our views as to the possible outcome of pending litigation related to our intellectual property portfolio and other disputes. 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 Risk Factors section. 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 may not achieve our goal of becoming cash flow positive, and may never become profitable.

We have generated operating losses since our inception. As of December 31, 2006, we had cumulative net losses of approximately \$194.5 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately \$115.6 million since our inception. We expect that our research and development expenses will continue to increase over the next several years as a result of increased costs and expenses associated with our ViaCyte clinical trial and possible future clinical trials of other product candidates, if pre-clinical data supports moving forward. Future research and development expenses may also include costs associated with product candidates that we might license or acquire, and, if our programs are successful, costs and expenses associated with submissions for regulatory approvals and the expansion of clinical and commercial scale manufacturing facilities. However, the amount of these increases is difficult to predict, and will depend on a number of factors, such as results of our clinical programs, the design of future clinical trials, the results of our efforts to acquire or license new technologies, and decisions made with respect to advancement of our clinical programs. Furthermore, we may make additional sales and marketing investments in our Reproductive Health business, if deemed advisable to expand the market for our ViaCord service offering. Our ability to become cash flow positive and to achieve profitability, and the timing of such events, will depend on many factors, including some or all of the following:

our ability to increase sales of our ViaCord service offering particularly in the face of significant competition;

continued acceptance in the marketplace for private cord blood banking;

the impact of any unexpected issues or failures related to the collection, processing, or storage of umbilical cord blood by us or others in the industry;

the impact of any potential adverse outcome in the patent infringement lawsuit brought against us by PharmaStem, including legal expenses, and the material impact on our business if PharmaStem were able to obtain an injunction;

the level of our expenses, including as a result of difficulties or delays related to our research and development programs, and any unexpected expenses; and

the overall net impact on revenues and expenses of new licensing deals, collaborations or other strategic efforts.

We cannot assure you that we will ever become cash flow positive or profitable. Other factors that may affect our ability to become cash flow positive and profitable are described in more detail elsewhere in this Risk Factors section.

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

Revenues from sales of ViaCord have grown significantly over the past several years, from \$7.1 million in 2001, to \$20.1 million, \$30.9 million, \$36.8 million, \$43.8 million and \$54.1 million in 2002, 2003, 2004, 2005 and 2006, respectively. We believe that this revenue growth is a result of our increased marketing efforts and from

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increased awareness by the public generally of the concept of umbilical cord blood preservation. We may not be able in the future, however, to sustain this growth rate or the current level of ViaCord s revenues. The principal factors that may adversely affect our revenues include competition from other private cord blood banks, any decline in the market or market acceptance for cord blood banking, the impact or recommendations as to public banking over private banking from physician groups, such as the recent policy statement issued by the American Academy of Pediatricians, the risks associated with litigation, in particular, the pending PharmaStem litigation, the risk of operational issues, the risks of not being able to maintain relationships with key third party marketing partners, 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 section. If we are unable to sustain our revenues, we may need to reduce our research and 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 service offering, or may have to incur significant expenses.

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the U.S. District Court for the District of Delaware, alleging infringement of U.S. 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., which is now a subsidiary of Cord Blood America 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 revenues 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 prove infringement. Consequently, we have not recorded a liability as of December 31, 2006. 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 was held at the U.S. Court of Appeals for the Federal Circuit on April 4, 2006. A final ruling has not been issued in the appeal.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the U.S. 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. 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.

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 described below.

In late 2006, the U.S. PTO issued final decisions in the existing 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. The U.S. PTO had ordered a second re-examination of the 427 patent in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO issued notice of its intent to allow the

remaining claims of all of the patents.

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against us. If we are found to infringe during the course of either case, including if the court of appeals were to overturn the district court s non-infringement ruling, we could also

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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 could 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.

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

## A third party could try to challenge the arbitrator s decision related to our agreement with Mothers Work.

We have an agreement with Mothers Work related to the marketing of our ViaCord service offering. The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work s commitment to us. A third party has claimed that it has rights under an agreement with Mothers Work that supersede Mothers Work s commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. There is no assurance that the third party will not challenge the arbitrator s ruling, although we believe that reversal of the ruling is unlikely. If the third party were to be successful in efforts to overturn the arbitrator s decision, the termination rights under our agreement with Mothers Work could be triggered. In addition, as a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us. We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the low likelihood that we might have to pay damages or legal fees given the arbitrator s ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of December 31, 2006.

# The Government of Singapore may seek to recover grant funds received by us if we do not agree to extend the term of the current grant.

We record revenues from a grant agreement with the Economic Development Board (EDB) of the Government of Singapore related to our research facility in Singapore. Government grants are routinely subject to review. We are in discussions with the EDB regarding conclusion of our current grant, which expires in May 2007. In the course of these discussions, the EDB has taken the position that a prior period increase in the EDB s cost reimbursement percentage constituted an advance on future grant funding. We, however, believe that the increase constituted a mutually agreed upon increase in the reimbursement percentage for the period, after which the reimbursement rate was to revert to the rate prior to such increase. The amount received by us under the increased reimbursement percentage was approximately \$1.0 million. The EDB has asked for repayment of the disputed amount. In connection with this dispute, the EDB is now also asserting that we have not fulfilled a commitment to employ a specified number of people in Singapore that was an original condition of the grant. Under the terms of the grant, a breach by us of a condition of the grant could result in the EDB pursuing repayment of some or all of the amounts disbursed to us. We believe that the EDB has waived this commitment, and that, as a result, we have satisfied all requirements under the

grant. If we do not agree to repay the disputed amount, the EDB may seek to recover grant funds previously paid and/or withhold payment of existing or future grant claims that are as yet unpaid. We believe we have met our performance obligations and would be successful in our defense of any such claims. We are attempting to resolve this dispute with the EDB and have proposed the possibility of amending the grant to reduce its term and cumulative funding. Accordingly, we have recorded negative revenues of approximately \$0.2 million in

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the quarter ended December 31, 2006 as estimated settlement costs. As of December 31, 2006, we had received grant payments from EDB totaling approximately \$1.9 million and had recognized cumulative grant revenues of approximately \$1.7 million as of December 31, 2006.

### If we are not able to successfully develop and commercialize new products, our future prospects may be limited.

Very few companies have been successful in their 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 their approval or commercial use.

Our cellular therapy product candidates are in the early stages of development. Drug development in general involves a high degree of risk. As we obtain results and safety information from pre-clinical or clinical trials of our product candidates, we may elect to discontinue development or delay additional pre-clinical studies or clinical trials in order to focus our resources on more promising product candidates. For example, we recently made the decision not to advance CB001, one of our product candidates in the area of hematopoietic stem cell therapy, in future clinical trials. 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 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 U.S., we will need to submit clinical data concerning our products and receive regulatory approval from the appropriate governmental agencies. Standards for approval outside the U.S. 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.

In June 2006, the FDA gave us conditional approval of our Investigational Device Exemption, or IDE, to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. We expect to initiate the pivotal clinical trial in March 2007. We are currently planning to conduct a single, pivotal clinical trial to study the safety and efficacy of ViaCyte. 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 prior 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. There is no assurance that we will be able to show that our ViaCyte cryopreservation product candidate is safe and effective for its intended use. While methods for preserving sperm and embryos are well-established and have been utilized for *in vitro* fertilization procedures, methods for cryopreserving oocytes have not been widely

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employed due to difficulties encountered in freezing this cell. We may not be able to generate the number of live births needed to show that our product candidate is effective. We may also encounter unexpected safety issues. Even if the results of the 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 pre-market approval, or PMA, and additional trials, which would involve additional time and expense. Even if we are successful in our efforts to develop and gain approval for ViaCyte, the FDA could ask for post-approval safety monitoring which would entail additional expense. The FDA could also restrict the label for the product to limited patient populations which could limit its commercial potential.

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

As of December 31, 2006, we had approximately \$51.2 million in cash, cash equivalents and short-term investments. In order to develop and bring new products to market, we must commit substantial resources to costly and time-consuming research and development, pre-clinical 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 service offering;

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 and other disputes;

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

the costs of increasing or expanding our ViaCord sales and marketing efforts;

the costs of research and development work focused on developing clinical and commercial scale processes for manufacturing cellular products and, if we advance our products, the costs of building and operating our manufacturing facilities, both 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 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,

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reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business.

### 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 U.S. patents and international patents. We also own or have exclusive licenses to pending applications in the U.S. and 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 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 technologies. For example, our patent applications covering Unrestricted Somatic Stem Cells, or USSCs, claim these cells and/or their use in the treatment of many diseases. It is possible, however, 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 our 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. 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. Others may independently develop substantially equivalent proprietary information 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 U.S.

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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 U.S., 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.

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 U.S., 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 specific 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, 2006, we have incurred total legal expenses of approximately \$7.4 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.

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

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on their own or in collaboration with others or commercialize or market competitive products 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, potential products or existing products may be substantially delayed or adversely impacted.

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

Cord blood preservation. The FDA has adopted good tissue practice regulations, or GTPs, that establish a comprehensive regulatory program for human cellular and tissue-based products. Our ViaCord service offering is subject to GTPs. We have registered with the FDA as an umbilical cord blood preservation service and we are subject to FDA inspection. We believe that we comply with GTPs, 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. Unlike our business of private cord blood banking for related use, the collection, processing and storage of umbilical cord blood stem cells intended to be used in a recipient unrelated to the donor is regulated as biological products. In January 2007, the FDA published draft guidance document for comment that would require public cord blood banks to file BLAs. While the draft guidance does not currently apply to us, the FDA could decide to impose these requirements or others on our business. Moreover, the cost of compliance with government regulations may adversely affect our revenues and profitability. If the FDA were to require companies that bank umbilical cord blood for related use to comply with the recommendations set forth in the guidance, we would need to change certain of our processes. The costs of such changes or the cost of compliance with any other new requirements that may be imposed in the future could adversely affect our revenues and profitability. Regulation of our cord blood preservation services in foreign jurisdictions is still evolving.

We provide cord blood banking services in all 50 states. Several states currently require that cord blood services be licensed, permitted or registered. We believe that we are currently licensed, permitted or registered to operate in all states requiring us to be licensed, permitted or registered. 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. In June 2006, the FDA gave us conditional approval of an IDE to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. We are currently planning to conduct a single, pivotal clinical trial to study the safety and efficacy of ViaCyte. We expect to initiate the pivotal clinical trial in March 2007. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. There is no assurance that we will be able to complete the clinical trial or that we will be able to show that our ViaCyte cryopreservation product candidate is safe and effective for its intended use. If we submit a new 510(k) and the FDA does not find the information adequate to support 510(k) clearance, the FDA could require us to obtain PMA to market ViaCyte. This requirement could substantially lengthen our planned developmental timeline and increase the costs of developing and commercializing ViaCyte. We may not receive either 510(k) clearance or PMA for ViaCyte. 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. We may not be able to generate sufficient data to receive approval to market ViaCyte in the U.S. or any other jurisdictions.

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 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-

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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 costs 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 to successfully commercialize our ViaCord service offering, for certain components of our product candidates and to manufacture and supply our ViaCyte product candidate. The loss of such suppliers or our inability to establish such relationships may inhibit our ability to commercialize ViaCord, delay development or limit our ability to manufacture our stem cell therapy products or our ViaCyte product candidate.

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 current good manufacturing practices, or cGMP. To meet this requirement, we will need to maintain supply agreements with third parties 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. 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 pre-clinical 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 advance the development of our pre-clinical stem cell product candidates.

We are utilizing Invitrogen, Inc. to manufacture, supply and package our ViaCyte product candidate for our clinical trial. We are dependent on Invitrogen and our relationships with component and testing service providers to satisfy all regulatory requirements and produce sufficient amounts of cGMP-quality product on commercially reasonable terms for the trial. Invitrogen has the ability to terminate its obligation to manufacture clinical supplies of ViaCyte under certain conditions including if it is unable for reasons outside of its control to consistently meet specifications or there is a change in specifications it cannot meet or due to an uncured material breach of the agreement by us. If ViaCyte is successfully developed, we will need to establish similar relationships for our commercial supply. In the event that we are unable to maintain a suitable contract manufacturer that is willing to produce such products on commercially reasonable terms or the contract manufacturer terminates or breaches its relationship with us or we encounter unexpected manufacturing hurdles or delays, we may not be able to complete our clinical trial or, if successfully developed, to commercialize our ViaCyte product candidate.

We also source a substantial portion of the components of our ViaCord collection kits and processing and testing services from a concentrated group of third party contractors. The production of the collection kits and the processing and testing of cord blood units require successful coordination among us and multiple third party providers. Our inability to coordinate these efforts or any other problems with the operations of our third party contractors could increase our costs, cause us to lose revenue or market share, and damage our reputation. Some of the components of the ViaCord collection kits, including the Cell Sentinel bag, are produced by single source providers. For other components, we make every effort to qualify new vendors and to develop contingency plans so that our ViaCord business is not impacted by short-term issues associated with single source providers. Our business could be

materially impacted by long-term or chronic issues associated with single source providers or other vendors.

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If our cord blood processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business, programs and prospects could 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 preservation services.

We expect to manufacture all of our stem cell product candidates in our Cambridge manufacturing facility for the next several years. If the Cambridge 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 \$22.2 million against damage to our property and equipment, and an additional \$18.8 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., a subsidiary of Cord Blood America Inc., and LifeBank USA, a division of Celgene Cellular Therapeutics, a wholly-owned subsidiary of Celgene Corporation. 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 other public cord blood banks around the world. Public cord blood banks provide families with the option of donating their cord blood for public use at no cost. The Stem Cell Therapeutic Act provides financing for a national system of public cord blood banks in the U.S. to encourage cord blood donations from an ethnically diverse population. In addition, many states are evaluating the feasibility of establishing cord blood repositories for transplantation purposes. An increase in the number and diversity of publicly-available cord blood units from public banks would increase the probability of finding suitably matched cells for a family member, which may result in a decrease in the demand for private cord blood banking. If the science of human leukocyte antigens, or 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, Inc., Cellerant Therapeutics, Inc., Celgene Corporation, Cytori Therapeutics, Inc., Gamida-Cell Ltd., Genzyme Corporation, Bioheart, Inc., and Osiris Therapeutics, Inc. 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. In addition, public cord blood banks may, as a result of the Stem Cell Therapeutic Act, be able to better compete with our potential cell therapy products. 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.

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In oocyte cryopreservation, if our ViaCyte product candidate is successfully developed and approved, we expect to compete with IVF centers 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 are already performing oocyte cryopreservation on a limited basis and Extend Fertility is offering related services, which may make it more difficult ViaCyte, if successfully developed and approved, to 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. 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. 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 service offering. This is due in significant part to the nature of the service we provide. For instance, as part of our ViaCord service offering, we are assuming custodial care of a child sumbilical cord blood stem cells 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 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. Loss or damage to the units would be loss or damage to the customer s property. 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, and if we are found liable, whether 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 clinical and commercial activities, we will need to increase our insurance coverage if and when we begin commercializing additional 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.

# Our success is dependent upon recruiting and retaining qualified management and other personnel.

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, has significant and unique expertise in stem cell expansion and related technologies. We maintain key man life insurance on the lives of

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Mr. Beer and Mr. Kraus. Additionally, we have several other employees with scientific or other skills that we consider important to the successful commercialization of our products and 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.

Our reporting obligations as a public company, as 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 Global Market, place significant 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.

Our business could be disrupted or harmed and we could be subject to liability if we are unable to operate our information systems effectively, successfully implement new technologies and protect the confidentiality of our or our customers data.

The efficient operation of our business is dependent on our information systems, including our ability to operate them effectively and to successfully implement new technologies, systems, controls and adequate disaster recovery systems. In addition, we must protect the confidentiality of our and our customers—data, including credit card information. The failure of our information systems to perform as designed or our failure to implement and operate them effectively could disrupt our business, harm our reputation and/or subject us to liability, any of which could impact our financial condition and results of operations.

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, Inc. 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. 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.

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The successful commercialization of products may depend on patients and physicians obtaining reimbursement for products 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 U.S. and, potentially, outside the U.S. In the U.S., 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 patients and physicians 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 U.S. 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. If our potential cell therapy products are not reimbursed by 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.

Although we are aware of a small fraction of ViaCord customers receiving reimbursement, we believe our ViaCord service offering, like other private cord blood banking, is not generally subject to reimbursement. We do not currently believe that our ViaCyte product candidate will be subject to reimbursement. In cases of preserving eggs for fertility preservation for cancer patients, it is unknown at this time if it will be covered.

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 the Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we ourselves are not directly regulated by HIPAA, 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.

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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 U.S., 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.

### 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.

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### ITEM 2. PROPERTIES

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 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. We completed the transfer of our manufacturing operations from our former Worcester, Massachusetts facility to the Cambridge manufacturing facility in late 2006. We expect that the Cambridge manufacturing facility will be able to produce cells for Phase 1, 2 and 3 trials of our current cell therapy product candidates, and potentially initial commercialization of our first approved product if we receive any marketing approvals. The lease on the Cambridge facility expires in 2014.

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 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.

### ITEM 3. LEGAL PROCEEDINGS

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the U.S. 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., which was recently acquired by Cord Blood America 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 prove infringement, consequently we have not recorded a liability as of September 30, 2006. 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 was held at the U.S. Court of Appeals for the Federal Circuit, on April 4, 2006 and a final ruling has not been issued.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the U.S. 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/or 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.

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 described below.

In late 2006, the U.S. PTO issued final decisions in the existing 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. The U.S. PTO had ordered a second re-examination of the 427 patent in order to determine

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whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO issued notice of its intent to allow the remaining claims of all of the patents.

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against us. If we are found to infringe or at any time during the course of either case, including 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 could 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.

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 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.

### **PART II**

# ITEM 5. MARKET FOR THE REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### **Market for Common Equity**

Our common stock has been traded on the NASDAQ Global Market, or 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 9, 2007, as reported by NASDAQ, was \$5.01.

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

	Price per Share				
For the Year Ended December 31, 2006	High	Low			
First Quarter	\$ 6.28	\$ 4.79			
Second Quarter	5.95	3.90			
Third Quarter	4.54	3.56			
Fourth Quarter	5.84	4.10			

For the Year Ended December 31, 2005		Price pe High	r Share Low
First Quarter (from January 21, 2005) Second Quarter Third Quarter		\$ 14.60 11.39 11.51	\$ 6.75 5.42 4.97
Fourth Quarter		6.37	4.66
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The following table sets forth information concerning our equity compensation plan as of December 31, 2006.

	<b>Equity Compensation Plan Information</b>					
			<b>Number of Securities</b>			
			Remaining Available for			
	<b>Number of Securities</b>					
	to be	Weighted Averag	ge Future Issuance Under			
	<b>Issued Upon Exercise</b>		<b>Equity Compensation</b>			
	of	Exercise Price o	f Plan			
		Outstanding				
	<b>Outstanding Options,</b>	Options,	(Excluding Securities			
		Warrants and	Referenced in Column			
Plan Category	Warrants and Rights	Rights	(a))			
	(a)					
Equity compensation plan						
approved by security holders	3,991,327	\$ 3.	02 1,829,118			

### **Holders**

As of February 28, 2007, there were 94 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

None.

### **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 and normal investing activities, 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.

# **Issuer Purchase of Equity Securities**

None.

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### 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, 2006. 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,								
		2006		2005		2004	2	2003(1)	2002
		(	(In th	ousands, ex	cept	share and p	oer s	hare data)	
Consolidated Statement of Operations Data: Total revenues	\$	54,426	\$	44,443	\$	38,274	\$	31,880	\$ 20,375
Operating expenses: Cost of processing and storage revenues:(2)		10.252		0.200		<b>7.20</b> 6		7.140	5.005
Direct costs		10,253		8,298		7,396		7,148	5,897
Royalty (recovery) expense						(3,258)		3,258	
Total cost of processing and									
storage revenues		10,253		8,298		4,138		10,406	5,897
Research and development		13,984		13,653		16,030		14,299	13,918
Sales and marketing		37,154		24,909		19,497		21,373	17,248
General and administrative		18,525		13,835		15,551		16,960	14,205
In-process technology(3)								23,925	5,889
Restructuring		(1,070)		305		3,188			
Total operating expenses		78,846		61,000		58,404		86,963	57,157
Loss from operations		(24,420)		(16,557)		(20,130)		(55,083)	(36,782)
Interest income (expense), net		3,090		1,880		(967)		(385)	744
Net loss before cumulative effect of change in accounting principle Cumulative effect of change in accounting principle	\$	(21,330)	\$	(14,677)	\$	(21,097)	\$	(55,468)	\$ (36,038)
Net loss attributable to common stockholders	\$	(21,047)	\$	(15,663)	\$	(34,168)	\$	(64,884)	\$ (44,182)
	\$	(0.56)	\$	(0.44)	\$	(12.62)	\$	(24.63)	\$ (17.60)
	-	` /		` /		` /	•	,	` /

Net loss per common share, basic and diluted before cumulative effect of change in accounting principle Cumulative effect of change in accounting principle

0.01

Net loss per common share,

basic and diluted \$ (0.55) \$ (0.44) \$ (12.62) \$ (24.63) \$ (17.60) Weighted average shares used in

computing net loss per common

share, basic and diluted 38,377,238 35,777,308 2,707,219 2,634,096 2,510,632

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	2006	2005	As of December 2004 (In thousands)	2003	2002	
Consolidated Balance Sheet Data:						
Cash and cash equivalents	\$ 18,039	\$ 33,138	\$ 6,746	\$ 39,008	\$ 15,239	
Investments	33,206	27,406	21,839	7,824	13,949	
Working capital	48,004	60,946	14,437	22,857	25,407	
Total assets	82,282	94,230	61,091	78,161	56,119	
Long-term debt obligations, including						
current portion	82	1,627	18,736	19,238	5,173	
Redeemable convertible preferred stock			175,173	162,141	110,912	
Total stockholders equity (deficit)	38,317	56,010	(160,957)	(130,151)	(70,487)	

- (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 year ended December 31, 2002 represented the fair value of warrants related to technology licensed from Amgen of \$5.9 million.

# 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 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 Part I Item 1A (Risk Factors) of this report.

### Overview

ViaCell is a biotechnology company dedicated to enabling the widespread application of human cells as medicine. We have a reproductive health business that generated revenues of \$54.1 million in 2006 from sales of ViaCord, a service offering through which expectant families can preserve their baby s umbilical cord blood for possible future medical use. Stem cells from umbilical cord blood are a treatment option today for over 40 diseases, including certain blood

cancers and genetic diseases. We are also working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte<sup>sm</sup>, our product candidate being studied for its potential to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs. Our other research and development efforts are focused on investigating the potential for new therapeutic uses of umbilical cord blood-derived and adult stem cells and on technology for expanding populations of these cells. We are concentrating these efforts in the areas of cancer, cardiac disease and diabetes.

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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 U.S., and the majority of our long-lived assets are located in the U.S.

#### Revenues

Our current revenues are derived primarily from fees charged to families for the processing and storage of a child s umbilical cord blood stem cells collected at birth. These fees consist of an initial fee for collection, processing and freezing of the umbilical cord blood stem cells and an annual storage fee. The annual storage fee provides a growing annuity of future revenue as the number of stored umbilical cord stem cells increases. Our revenues are recorded net of discounts and rebates that we offer our customers from time to time under certain circumstances. 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 long-term future revenues from our umbilical cord blood preservation 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 pay 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 as of December 31, 2006.

We are in ongoing litigation with PharmaStem Therapeutics, Inc. over PharmaStem s claims that our cord blood preservation business infringes certain claims 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 separate 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 service offering, we recorded revenues in the periods presented from a grant agreement with the Economic Development Board (EDB) of the Government of Singapore. We maintain a research facility in Singapore. We are in discussions with the EDB regarding conclusion of our current grant, which expires in May 2007. In the course of these discussions, the EDB has taken the position that a prior period increase in the EDB s cost reimbursement percentage constituted an advance on future grant funding. We, however, believe that the increase constituted a mutually agreed upon increase in the reimbursement percentage for the period, after which the reimbursement rate was to revert to the rate prior to such increase. The amount received by us under the increased reimbursement percentage was approximately \$1.0 million. The EDB has asked for repayment of the disputed amount. In connection with this dispute the EDB is now also asserting that we have not fulfilled a commitment to employ a specified number of people in Singapore that was an original condition of the grant. Under the terms of the grant, a breach by us of a condition of the grant could result in the EDB pursuing repayment of some or all of the amounts disbursed to us. We believe that the EDB has previously waived this commitment, and that, as a result, we have satisfied all requirements under the grant. If we do not agree to repay the disputed amount, the EDB may seek to recover grant funds previously paid and/or withhold payment of existing or future grant claims that are as yet unpaid. We believe we have met our performance obligations and would be successful in our defense of any such claims. We are attempting to resolve this dispute with the EDB and have proposed the possibility of amending the grant to reduce its term and cumulative funding. Accordingly, we have recorded negative revenues of approximately \$0.2 million during the quarter ended December 31, 2006 as estimated settlement costs. As of December 31, 2006, we had received grant payments from EDB totaling approximately \$1.9 million and had recognized cumulative grant revenues of

approximately \$1.7 million.

# **Operating Expenses**

Cost of processing and storage revenues reflects the cost of transporting, testing, processing and storing umbilical cord blood stem cells at our processing facility in Hebron, Kentucky. Our cost of processing and storage revenues includes expenses incurred by third party vendors relating to the transportation of cord blood stem cells to

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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.

In 2003, we recorded a royalty expense of \$3.3 million following an unfavorable jury verdict in the PharmaStem litigation. In 2004, the District Court overturned the jury verdict. Based on the court 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. In July 2004, PharmaStem filed a separate lawsuit claiming that we infringed additional patents. Pending a decision on the appeal and further action by the court in this 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 our litigation with PharmaStem could result in us being required to pay damages to PharmaStem 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 to PharmaStem, or what those amounts might be.

Our research and development expenses consist primarily of costs associated with development of our stem cell product candidates, including our recently completed Phase 1 clinical trial of our expanded umbilical cord blood product candidate, CB001, and development of 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 those involved in pre-clinical studies, consulting expenses, and lab supplies. The major outside expenses relating to our CB001 clinical trial included 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 included site costs and the cost of the cord blood. We recently announced that, based on the results of the Phase 1 study, we have decided not to advance CB001 in further clinical trials.

We expect that our research and development expenses will continue to increase over the next several years as a result of increased costs and expenses associated with our ViaCyte clinical trial and possible future clinical trials of other product candidates, if pre-clinical data supports moving forward. Future research and development expenses may also include costs associated with product candidates that we might license or acquire, and, if our programs are successful, costs and expenses associated with submissions for regulatory approvals and the expansion of clinical and commercial scale manufacturing facilities. 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, other than ViaCyte, are currently in early stages. Based on these assessments, we consider options for each program, 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 reproductive health business and, specifically, our ViaCord service offering. The majority of these costs relate to our sales force and support personnel, marketing expenses and telecommunications expense related to our call center. We also incur external costs associated with advertising, direct mail, promotional and other marketing services. However, we may, from time to time, implement additional

promotions and other marketing programs that may increase sales and marketing expenses, and augment our internal marketing efforts with external relationships such as the data license and marketing services agreement we entered into with Mothers Work, Inc. in August 2006. For a description of the agreement with Mothers Work, including the risks related thereto, see Commitments and Contingencies Other Arrangements .

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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.

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, as described in Results of Operations Restructuring.

In August 2006, we amended our German facility office lease to change the termination date from May 31, 2008 to December 31, 2006. In addition, we sold fixed assets at the facility that had been written off in the December 2004 restructuring for approximately \$0.6 million. The sale of fixed assets, combined with the amendment of the lease, is reflected as a change in our December 2004 restructuring estimates of approximately \$1.1 million for the year ended December 31, 2006.

During the year ended December 31, 2006, we finalized discussions with German grant authorities regarding repayment of part of certain grants made to our German subsidiary in 2003 and 2004 and remitted approximately \$0.5 million to satisfy all potential claim reimbursements. We also paid approximately \$0.1 million in professional fees incurred in connection with the negotiations with the German grant authorities and fees associated with the August 2006 lease amendment and sale of fixed assets.

As of December 31, 2006, we had received approximately \$3.6 million in cumulative grant proceeds from the German grant authorities and remitted back approximately \$0.5 million as noted above.

### **Results of Operations**

Years Ended December 31, 2006, 2005 and 2004 (amounts in millions, year over year changes based on rounded amounts in millions)

	2006	2005	2004	\$ Chang 2005 to 2006		20	Change 004 to 2005	% Change 2004 to 2005
Processing revenues Storage revenues	\$ 43.5 10.6		\$ 31.7 5.1	\$ 7. 2.		\$	4.4 2.6	14% 51%
Total processing and storage revenues Grant and contract revenues	54.1 0.3		36.8 1.5	10.			7.0 (0.9)	19% (60)%
Total revenues	\$ 54.4	\$ 44.4	\$ 38.3	\$ 10.	.0 23%	\$	6.1	16%

The increases in processing revenues of \$7.4 million, or 20%, from 2005 to 2006 and \$4.4 million, or 14%, from 2004 to 2005 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 increases in storage revenues of \$2.9 million, or 38%, from 2005 to 2006 and \$2.6 million, or 51%, from 2004 to 2005 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 \$0.3 million, or 50%, from 2005 to 2006 was related to a decrease in grant revenues from the EDB of Singapore and the creation of a reserve to cover potential grant settlement costs. The reserve reflects our recent dispute with the EDB regarding conclusion of the grant. 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 United States of \$0.2 million. These decreases were partially offset by an increase in grant revenues from the EDB of \$0.4 million.

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	2006	2005	2004	\$ Chang 2005 to 2006		\$ Chan 2004 t 2005	to 2004 to
Cost of processing and storage revenues: Direct costs Royalty recovery	\$ 10.3	\$ 8.3	\$ 7.4 (3.3)	\$ 2	2.0 24%	·	0.9 12% 3.3 100%
Total cost of processing and storage revenues	\$ 10.3	\$ 8.3	\$ 4.1	\$ 2	2.0 24%	\$	4.2 102%

The increase in direct costs of \$2.0 million, or 24%, from 2005 to 2006 and the increase in direct costs of \$0.9 million, or 12%, from 2004 to 2005 were due primarily to higher variable expenses related to the increased numbers of umbilical cords processed and stored. These variable expenses relate to transportation of the cord blood, materials for related collection and testing and additional costs associated with the processing and storage of the umbilical cord blood.

The royalty recovery of \$(3.3) million in 2004 was due to the reversal of the accrual of \$3.3 million, recorded in 2003, that we took to cover our cumulative royalty expense from August 2000 through December 31, 2003 following the jury verdict of infringement in the PharmaStem lawsuit in October 2003. The jury verdict of infringement was overturned by the District Court judge in the second half of 2004 and we subsequently recorded a credit to royalty expense of \$3.3 million 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.

	2006	2005	2004	\$ Change 2005 to 2006	% Change 2005 to 2006	\$ Change 2004 to 2005	% Change 2004 to 2005
Research and development	\$ 14.0	\$ 13.7	\$ 16.0	\$ 0.3	2%	\$ (2.3)	(14)%

During the years ended December 31, 2006 and 2005, our research and development expenses primarily consisted of costs related to the CB001 trial and ongoing costs of pre-clinical testing of our therapeutic product candidates, as well as expenses related to ViaCyte, our product candidate being studied for its potential to broaden reproductive options for women through the cryopreservation of oocytes. In February 2007, we announced our decision not to advance development of CB001 and expect to reduce our hematopoietic program-related costs in 2007. The increase in costs associated with research and development of \$0.3 million, or 2%, from 2005 to 2006 was primarily due to an increase in outside services related to clinical and pre-clinical testing of our therapeutic product candidates.

The decrease in our research and development expenses of \$2.3 million, or 14%, 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.

					<b>%</b>				
	•006	-00-	•004	\$ Change 2005 to	2005 to	20	Change 004 to	Change 2004 to	
	2006	2005	2004	2006	2006	2	2005	2005	
Sales and marketing	\$ 37.2	\$ 24.9	\$ 19.5	\$ 12.	3 49%	\$	5.4	28%	

The increase in sales and marketing expenses of \$12.3 million, or 49%, from 2005 to 2006 was due to the significant expansion of our inside sales and field sales teams, as well as increased spending on marketing programs. 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.

	2006	2005	2004	\$ Change 2005 to 2006	% Change 2005 to 2006	\$ Change 2004 to 2005	% Change 2004 to 2005
General and administrative	\$ 18.5	\$ 13.8	\$ 15.6 3	\$ 4.7 39	34%	\$ (1.8)	(12)%

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The increase in general and administrative expenses of \$4.7 million, or 34%, from 2005 to 2006 was primarily due to increased accounting fees and outside service fees of approximately \$1.5 million associated with compliance with the Sarbanes-Oxley Act of 2002, increased employee-related expenses of approximately \$1.4 million, increased expenses related to our ViaCord service offering of approximately \$1.4 million, as well as increased stock-based compensation expense associated with the adoption of Statement of Financial Accounting Standards No. 123R Share-Based Payment (SFAS 123R) of approximately \$0.4 million. The decrease in general and administrative expenses of \$1.8 million, or 12%, from 2004 to 2005 was primarily due to a decrease in employee-related costs of \$0.9 million resulting from our restructuring in September 2004 as well as a decrease in consulting costs of \$0.6 million, a decrease in litigation expenses of \$0.7 million relating to the PharmaStem lawsuit and a decrease in stock-based compensation expense of \$0.5 million, 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.

					%			<b>%</b>
	2006	2005	2004	\$ Change 2005 to 2006	Change 2005 to 2006	20	Change 004 to 2005	Change 2004 to 2005
Restructuring	\$ (1.1)	\$ 0.3	\$ 3.2	\$ 1.4	(467)%	\$	(2.9)	(91)%

The income related to restructuring expense of \$1.1 million for the year ended December 31, 2006 reflects changes to the original estimate of our restructuring accrual, recorded in 2004, due to the August 2006 sale of fixed assets and lease amendment. During 2006, we recorded a reduction to restructuring expense of approximately \$0.6 million related to our agreement to sell certain property, plant and equipment previously written off in the December 2004 restructuring. We also accelerated the recognition of \$0.4 million of prepaid rent received from our German sub-lessee for the period of January 2007 through May 2008 as a result of the August 2006 amendment of our German facility lease which changed the lease termination date from May 31, 2008 to December 31, 2006. In 2006, we also settled with the German grant authorities and remitted approximately \$0.5 million to satisfy all potential claim reimbursements, all of which was previously accrued.

Restructuring expense of \$0.3 million for the year ended December 31, 2005 was related to changes in estimates of the grant refunds due to the German grant authorities.

In September 2004, we restructured our operations to reduce operating expenses and concentrate our resources on certain key products and product candidates. As a result, we recorded a \$1.7 million restructuring charge in 2004 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 second restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility-related 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.

Following is the activity in our restructuring accrual (in thousands):

Balance, December 31, 2004	\$ 907
Adjustments	255
Payments	(530)

Balance, December 31, 2005 Adjustments Payments		632 (34) (598)
Balance, December 31, 2006		\$
	40	
	40	

	2	2006	2	2005	2	2004	20	hange 05 to 006	% Change 2005 to 2006	20	hange 04 to 005	% Change 2004 to 2005
Interest income Interest expense	\$	3.2 (0.1)	\$	2.2 (0.3)	\$	0.5 (1.5)	\$	1.0 0.2	45% (67)%	\$	1.7 1.2	340% (80)%
Total interest income (expense), net	\$	3.1	\$	1.9	\$	(1.0)	\$	1.2	63%	\$	2.9	290%

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 \$1.0 million, or 45%, from 2005 to 2006 primarily related to higher interest rates during 2006.

The increase in interest income of \$1.7 million, or 340%, from 2004 to 2005 primarily related to increased average investment balances resulting from a higher cash balance available for investment following our initial public offering in January 2005, or IPO, as well as higher interest rates.

The decrease in interest expense of \$0.2 million, or 67%, from 2005 to 2006 was primarily related to lower outstanding debt obligations. The decrease in interest expense of \$1.2 million, or 80%, from 2004 to 2005 relates primarily to lower outstanding debt obligations, as well as the reduction of interest on the related party notes payable, which were paid in full following the closing of our IPO in January 2005.

### **Liquidity and Capital Resources**

From inception through December 31, 2006, we have raised \$192.5 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 payable of \$14.0 million, and accrued interest thereon of \$1.5 million. As of December 31, 2006, we had approximately \$51.2 million in cash, cash equivalents and investments.

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

	Years E	Ended Decei	mber 31,	\$ Change 2005 to	\$ Change 2004 to 2005	
	2006	2005	2004	2006		
Net cash used in operating activities	\$ (8.4)	\$ (1.4)	\$ (15.1)	\$ (7.0)	\$ 13.7	
Net cash used in investing activities	(6.7)	(9.5)	(15.6)	2.8	6.1	
Net cash provided by (used in) financing						
activities	(0.1)	37.6	(1.3)	(37.7)	38.9	
Cash and cash equivalents, end of period	\$ 18.0	\$ 33.1	\$ 6.7	\$ (15.1)	\$ 26.4	

Net cash used in operating activities was \$8.4 million for the year ended December 31, 2006, an increase of 500% from the \$1.4 million used in 2005. Net cash used in operating activities decreased 91% in 2005 compared to the

### \$15.1 million used in 2004.

For the year ended December 31, 2006, the \$8.4 million cash used in operating activities was primarily due to our net loss of \$21.0 million and a net decrease in deferred rent of \$1.0 million due to amortization against rent expense of rent credits received from our landlord, reduced by non-cash expenses of \$6.0 million, a net increase in deferred revenue of \$6.3 million related to sales of long-term pre-paid storage contracts, and a net decrease in working capital (accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses) of \$1.3 million.

Net cash used in investing activities for the year ended December 31, 2006 was \$6.7 million, a decrease of 29% from the \$9.5 million used in 2005. Net cash used in investing activities decreased 39% in 2005 compared to the \$15.6 million used in 2004. For the year ended December 31, 2006, \$50.6 million of U.S. Government and high-rated corporate securities matured and \$56.4 million was invested in similar securities. We also invested approximately \$1.8 million in property and equipment during 2006 and received proceeds of approximately \$0.6 million related to our agreement to sell certain property and equipment previously written off in the December 2004 restructuring.

our agreement to sell certain property and equipment previously written off in the December 2004 restructuring.

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Net cash used in financing activities in 2006 was \$0.1 million, net cash provided by financing activities amounted to \$37.6 million in 2005 and net cash used in financing activities amounted to \$1.3 million in 2004. For the year ended December 31, 2006, the net cash used in financing activities was related to repayment of debt obligations of \$1.5 million, offset by proceeds from the return of a security deposit related to our debt obligations of \$0.9 million and proceeds of \$0.5 million from the exercise of stock options.

We anticipate that our current cash, cash equivalents and investments will be sufficient to fund our operations and meet our anticipated liquidity needs 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 and meet our liquidity needs is a forward-looking statement that involves risks and uncertainties. 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, 2006 (in millions and does not include our accounts payable and accrued expenses):

Contractual Obligations	Total	T	Less Than e Year	T	one to Three Years	F	ur to Five ears	H	fter Five ears
Operating lease obligations	\$ 15.0	\$	1.8	\$	3.8	\$	4.0	\$	5.4
Capital lease obligations	0.1		0.1						
Purchase obligations(1)	20.0		6.5		11.1		1.1		1.3
Contingent purchase price(2)	8.2		2.2						6.0
Total contractual obligations	\$ 43.3	\$	10.6	\$	14.9	\$	5.1	\$	12.7

- (1) Of the \$20.0 million payable under purchase obligations, \$2.2 million relates to cancelable agreements.
- (2) See Note 8 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, provided that the physician allows 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 of \$51,000 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, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, (FIN 45). We further re-evaluated this reserve at December 31, 2006 and 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.

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Other than outstanding warrants exercisable for up to 1,443,333 shares of our common stock at December 31, 2006, we have no off balance sheet arrangements , as defined by Item 303(a)(4) of the SEC s Regulation S-K. Please see note 10 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 a lender. Borrowings under this agreement bore interest at 6.9% percent per annum and were collateralized by our property and equipment. The loan balance was fully repaid in October 2006. Upon repayment of the loan, the \$0.9 million deposit held by the lender was refunded to us.

# Lease Obligations

We entered into a new operating lease commitment in December 2003 to consolidate our headquarters and U.S. laboratory facilities in one location in Cambridge, Massachusetts. Rent expense on the office portion of the original lease commenced in April 2004 and the rent on the laboratory facilities commenced in November 2004, 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. In February 2006, we amended this lease agreement to add an additional 7,600 feet of office space. 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 had 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. In November 2005, the sub-lessee verbally gave notice of its intent not to extend the sublease past December 31, 2006. The sublessee had prepaid rent through December 2006. In August 2006, we amended our lease agreement to terminate the lease on December 31, 2006 and sold the clean room and laboratory equipment for approximately \$0.6 million in cash.

In February 2002, we entered into a lease commitment for our research facility in Singapore. This lease has a five-year term that terminates in May 2007 with an annual rent of approximately \$0.1 million per year.

### Acquisition of Kourion Therapeutics

There are potential future payments totaling up to \$9.0 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, as potential additional consideration in our acquisition of Kourion Therapeutics, we issued 241,481 additional shares of Series I convertible preferred stock (which automatically converted into common stock upon completion of our IPO) to an escrow account and reserved 289,256 shares of Series I convertible preferred stock for possible issuance in the future. We have made a determination that the underlying conditions for issuance of the escrow

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shares and the reserved shares are no longer capable of being met. As a result, as of September 30, 2006, the escrow shares were deemed cancelled and the reserved shares will not be issued.

### License Agreement

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. The agreement provides for 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

# Mothers Work Data and Marketing Services

In August 2006, we entered into a data license and marketing services agreement with Mothers Work, Inc., the world s largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as Motherhood Maternity®, A Pea in the Pod®, Mimi Maternity®, and Destination Maternitytm. Under the terms of our agreement, Mothers Work has granted us an exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. Under the terms of our agreement, we will pay Mothers Work \$5,000,000 per year over the three-year term of the agreement which began on January 1, 2007 and, unless earlier terminated, ends on December 31, 2009. Under certain circumstances, we will also be obligated, at the beginning of 2009, to issue Mothers Work a warrant to purchase 100,000 shares of our common stock (See Note 10 to our consolidated financial statements). A third party is claiming that it has rights under an agreement with Mothers Work that supersede Mothers Work s commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. While there is no assurance that the third party will not challenge the arbitrator s ruling, we believe that reversal of this ruling is unlikely and that the termination rights under our agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us. We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the low likelihood that we might have to pay damages or legal fees given the arbitrator s ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of December 31, 2006.

# SCIV Centocor Research Collaboration

In June 2006, we entered into a research collaboration agreement with the Stem Cell Internal Venture of Centocor Research and Development, Inc., or SCIV Centocor, to evaluate our proprietary cord blood-derived multi-potent stem cells in pre-clinical testing as a potential treatment for cardiac disease. The collaboration is also supported by the Biologics Delivery Systems Group of Cordis Corporation, and will focus on dosing, delivery and targeting of our expanded proprietary cord blood stem cells using Cordis NOGA XP delivery system. Under the terms of the agreement, we received an initial up-front payment of \$350,000 which we recorded as a liability and are amortizing as a reduction of research and development expense, as work is performed. SCIV Centocor will be responsible for its own costs under the collaboration and will pay 50% of the research costs that we incur under the collaboration, consistent with the agreed upon budget. In addition, the agreement provides SCIV with the first right to negotiate a collaboration with us on the clinical development and commercialization of a cardiac product offering based on our

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### Amgen Collaboration

In December 2003, we entered into a license and collaboration agreement with Amgen under which we received a 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 current Good Manufacturing Practices, or 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.

### Miltenyi

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 was 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 were obligated to pay Miltenyi up to \$1.0 million for development work. As of December 31, 2006, we had paid the entire \$1.0 million relating to the development of the product.

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. In 2006, we purchased approximately \$1.3 million of cell separation kits to be used in our research. We have a firm order to purchase an additional \$0.3 million of kits in 2007. Since we have decided not to progress CB001 into further clinical trials, we do not expect that we will have any additional commitments beyond our current firm order.

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 future. We may require additional funds for conducting clinical trials and for pre-clinical 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, 2006, we had federal and state net operating loss carryforwards of approximately \$87.8 million and \$93.3 million, respectively. These carryforwards begin expiring in 2009 and 2006, respectively. We also had federal and state credit carryforwards of approximately \$3.4 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. We also have foreign net operating loss carryforwards of \$14.8 million. The carryforwards expire through 2024 and are subject to review and possible adjustment by the local tax authorities. 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

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offset future taxable income. Of the \$61.0 million valuation allowance, \$1.0 million relates to nonqualified stock option deductions, the benefit of which will be credited to additional paid in capital if and when realized.

### **Legal Proceedings**

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the U.S. District Court for the District of Delaware, alleging infringement of U.S. 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., a subsidiary of Cord Blood America 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 prove infringement, consequently we have not recorded a liability as of September 30, 2006. 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 took place at the U.S. Court of Appeals for the Federal Circuit on April 4, 2006 and a final ruling has not been issued.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the U.S. 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/or that we do not infringe them. 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.

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 described below.

In late 2006, the U.S. PTO issued final decisions in the existing 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. The U.S. PTO had ordered a second re-examination of the 427 patent in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO issued notice of its intent to allow the remaining claims of all of the patents.

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against us. If we are found to infringe during the course of either case, including 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 could 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.

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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 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, or GAAP. 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 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 stock-based compensation;

accounting for accounts receivable;

accounting for research and development expenses; and

accounting for the Mothers Work indemnification agreement.

*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 Revenue Recognition in Financial Statements , (SAB 101) as amended by SAB 104, *Revenue Recognition, corrected copy* , and Emerging Issues Task Force (EITF) Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 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. 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. We have concluded that the collection, testing and freezing service has stand alone value to the customer. The fair value of our processing service cannot be determined but we have objective evidence of the fair value of the undelivered storage. The fair value of the storage is equal to the annual storage fee charged to customers on a stand-alone basis. We charge an initial fee which covers collection, testing, freezing, and, typically, one year of storage. We defer the fair value of the revenue related to the future storage of the unit and recognize the remainder of the revenue for processing under the residual method.

Accounting for Stock-Based Compensation. We have one stock-based employee compensation plan. On January 1, 2006, we adopted SFAS 123R using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation expense is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. Stock-based employee compensation expense was \$3.1 million for the year ended December 31, 2006. Previously, we had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee stock options at their intrinsic value in the consolidated financial statements.

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We utilize the Black Scholes option pricing model to calculate the fair value of stock options granted under SFAS 123(R). We are required to make significant estimates to note all required inputs to the Black Scholes model including expected volatility and expected term which are discussed separately. Changes in the subjective input assumptions can materially affect the fair value estimate of stock-based compensation expense. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. For stock options granted during the year ended December 31, 2006, we used a weighted-average expected stock-price volatility of 65%. Higher estimated volatility increases the fair value of a stock option, and therefore increases the expense to be recognized per stock option. We also determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the year ended December 31, 2006, we used a weighted-average expected option life assumption of 4.57 years. Longer expected term assumptions increase the fair value of the stock option, and therefore increase the expense to be recognized per stock option.

We recognized the full impact of our stock-based employee compensation plan in the consolidated statement of income for year ended December 31, 2006 under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets. Upon adoption of SFAS 123R, using the modified prospective method, we recognized a benefit of \$0.3 million during the year ended December 31, 2006 as a cumulative effect of a change in accounting principle resulting from the requirement to estimate forfeitures of our stock option grants at the date of grant instead of recognizing them as incurred. The estimated forfeiture rate was applied to the previously recorded stock-based compensation expense of our unvested stock options in determining the cumulative effect of a change in accounting principle.

Accounting for accounts receivable. Accounts receivable consists of amounts primarily due from customers that have used the ViaCord service offering. 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 research and development expenses. Our research and development expenses consist primarily of costs associated with development of our stem cell product candidates, including the recently completed Phase 1 clinical trial of our expanded umbilical cord blood product candidate, CB001, and development of ViaCyte, our oocyte cryopreservation product candidate. 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. 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 these potential increases 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.

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Accounting for the Mothers Work indemnification agreement. In August 2006, we entered into a data license and marketing services agreement with Mothers Work, Inc., the world s largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as Motherhood Maternity®, A Pea in the Pod®, Mimi Maternity<sup>®</sup>, and Destination Maternity<sup>tm</sup>. Under the terms of our agreement, Mothers Work has granted us an exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work s commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. While there is no assurance that the third party will not challenge the arbitrator s ruling, we believe that reversal of the ruling is unlikely and that the termination rights under our agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us. We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. FASB Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (FIN 45) requires us to record a liability based on the estimated fair value of the indemnification provided. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the amount of damages and legal fees that could be payable, and the low likelihood that they might have to be paid given the arbitrator s ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of December 31, 2006. Our assumptions involve judgments by management and are subject to change based on on-going developments or binding results of the arbitration proceedings that could result in materially different results than our current estimate.

# **Recent Accounting Pronouncements**

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 will be effective for the first fiscal year that begins after November 15,2007. We have not yet completed our evaluation of the impact of adoption of SFAS 159 on our financial position or results of operations.

In September 2006, FASB issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements (SFAS No. 157) which defines fair value under GAAP, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. Where applicable, SFAS No. 157 simplifies and codifies related guidance within GAAP and does not require any new fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We do not expect the adoption of SFAS No. 157 to have a significant immediate effect on our financial position or results of operations.

In June 2006, FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109 (FIN 48), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 will be effective for fiscal years beginning after December 15, 2006. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We do

not expect the adoption of FIN 48 to have a significant immediate effect on our financial position or results of operations.

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# 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 U.S. 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 the 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 U.S. government and its agencies, investment grade corporate and money market instruments. These investments are denominated in U.S. 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

### Disclosure Controls and Procedures and Internal Control over Financial Reporting

# **Controls and Procedures**

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our

disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act), as of December 31, 2006. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of that period, our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (b) such information 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. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives,

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and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

# Changes in Internal Control over Financial Reporting

We evaluate the effectiveness of our internal control over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in all annual reports. We have not made any changes in our internal control over financial reporting during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Management s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, a company s principal executive and principal financial officers and effected by a company s board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2006. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2006, our internal control over financial reporting is effective based on those criteria. Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page F-2 of this Annual Report on Form 10-K.

# ITEM 9B. OTHER INFORMATION

None.

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### **PART III**

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required with respect to directors is incorporated herein by reference to the information contained in the definitive proxy statement for our 2007 Annual Meeting of Stockholders, or the Proxy Statement. The information with respect to our audit committee and the 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 Corporate 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 Corporate Code of Business Conduct and Ethics is available in the Governance section of the Investor Information section of our website at www.viacellinc.com. We intend to disclose any amendments to, or waivers from, our Corporate Code of Business Conduct and Ethics on our website. Stockholders may request a free copy of the Corporate 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**

Set forth below is information regarding our executive officers and key employees as of March 8, 2007.

Name	Age	Positions
<b>Executive Officers:</b>		
Marc D. Beer	42	President, Chief Executive Officer and Director
Anne Marie Cook	45	General Counsel, Senior Vice President, Business and
		Corporate Development
Stephen G. Dance	55	Senior Vice President, Finance and Chief Financial
		Officer
Jim Corbett	44	President, ViaCell Reproductive Health
Morey Kraus	48	Vice President and Chief Technology Officer
Mary T. Thistle	47	Senior Vice President, Business Development, ViaCell
		Reproductive Health

### **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).

Anne Marie Cook. Ms. Cook has served as General Counsel, Senior Vice President, Business and Corporate Development, 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, she was in private practice at Testa, Hurwitz & Thibeault, 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.

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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.

Jim Corbett. Mr. Corbett has served as our President, ViaCell Reproductive Health since April 2006. Prior to joining ViaCell, Mr. Corbett co-founded CADx Systems, a company focused on the oncology market, where he held the position Executive Vice President and Director with responsibility for worldwide sales and marketing, technical support and business development. Following the 2004 acquisition of CADx by iCAD, Inc., Mr. Corbett served as Chief Commercial Officer of the combined company. Prior to founding CADx Systems, Mr. Corbett held a variety of sales and marketing positions at Abbott Laboratories, Inc., including Worldwide Marketing Manager for Abbott Diagnostics Immunoassay Systems and Region Manager of Abbott Diagnostics. Mr. Corbett received a B.Sc. from the University of Massachusetts, Amherst.

Morey Kraus. Mr. Kraus is the co-founder of ViaCell. Mr. Kraus 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.

Mary T. Thistle. Ms. Thistle has served as our Senior Vice President, Business Development, ViaCell Reproductive Health since April 2006. Prior to her current position, she served as our Senior Vice President and General Manager of ViaCell Reproductive Health from October 2004 to April 2006, Vice President, ViaCord Operations from March 2002 to October 2004, and Vice President, Financial and Corporate Planning and Treasurer, from October 2000 to March 2002. 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. 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, Amherst.

### ITEM 11. EXECUTIVE COMPENSATION

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

# 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, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the Proxy Statement under the heading Related Person Transactions and Director Independence.

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# ITEM 14. PRINCIPAL ACCOUNTANT 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.

	Page Number in	
	This Form 10-K	
Report of Independent Registered Public Accounting Firm	F-1	
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

Exhibit No.	Description of Document
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(5)	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.
4.4(9)	Warrant issued to Amgen Inc. on August 29, 2005.
10.1(4)	Amended and Restated 1998 Equity Incentive Plan.**
10.2(7)	Form of Non-statutory Stock Option Certificate.**
10.3(7)	Form of Incentive Stock Option Certificate.**
10.4(1)	Letter agreement dated September 12, 2003 between ViaCell and Jan van Heek.**

- 10.5(1) Letter agreement dated November 4, 2003 between ViaCell and Vaughn M. Kailian.\*\*
- 10.6(6) Letter agreement dated December 15, 2002 between ViaCell and Paul Hastings.\*\*
- 10.7(1) Stock Purchase Agreement dated September 30, 2003 by and among ViaCell, Kourion Therapeutics AG and the shareholders of Kourion Therapeutics.
- 10.8(2) Amendment to Stock Purchase Agreement dated October 25, 2004 by and among ViaCell, Kourion Therapeutics AG and the shareholders of Kourion Therapeutics.
- 10.9 (1) Non-Exclusive License Agreement dated January 1, 2003 between ViaCell and SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Glaxo Group Limited.
- 10.10 (1) Collaboration Agreement dated December 23, 2003 between ViaCell and Amgen Inc.

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Exhibit No.	<b>Description of Document</b>
10.11 (1)	License Agreement dated March 15, 2002 between ViaCell Endocrine Science, Inc. and the
	General Hospital Corporation, d/b/a Massachusetts General Hospital.
10.12 (1)	License Agreement dated August 1, 2002 between ViaCell and Massachusetts Institute of Technology.
10.13(1)	Lease Agreement dated April 12, 2002 between ViaCell and Dugan Financing LLC.
10.14(1)	Lease Agreement dated December 22, 2003 between ViaCell and MA-Riverview/245 First Street, LLC.
10.15(10)	First Amendment dated February 14, 2006 to Lease Agreement between ViaCell and MA-Riverview/245 First Street, LLC.
10.16(1)	Letter Agreement dated March 11, 2004 between ViaCell and Stephen Dance.**
10.17 (2)	License Agreement dated September 1, 2004 between Tyho Galileo Research Laboratory, LLC and ViaCell.
10.18 (3)	Research Agreement dated December 13, 2004 between Genzyme Corporation and ViaCell.
10.19 (8)	Development Agreement dated January 24, 2005 between ViaCell and Miltenyi Biotec GmbH.
10.20 (8)	Supply Agreement dated January 24, 2005 between ViaCell and Miltenyi Biotec GmbH.
10.21 (9)	Amendment No. 1 to Collaboration Agreement dated August 29, 2005 between ViaCell and Amgen Inc.
10.22(9)	Warrant Purchase Agreement dated August 29, 2005 between ViaCell and Amgen Inc.
10.23 (9)	Exclusive License Agreement dated August 29, 2005 among Johns Hopkins University, Zheijiang University and ViaCell.
10.24(4)	2004 Employee Stock Purchase Plan.**
10.25(11)	Amended and restated employment agreement dated March 12, 2007 between ViaCell and Marc D. Beer.**
10.26(11)	Amended and restated letter agreement dated March 12, 2007 between ViaCell and Anne Marie Cook.**
10.27(11)	Amended and restated letter agreement dated March 12, 2007 between ViaCell and Jim Corbett.**
10.28(11)	Amended and restated employment agreement dated March 12, 2007 between ViaCell and Morey Kraus.**
10.29(11)	Amended and restated letter agreement dated March 12, 2007 between ViaCell and Mary Thistle.**
21.1	Subsidiaries of ViaCell.
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. 3 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on October 26, 2004.
- (3) 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.

- (4) 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.
- (5) Incorporated by reference to the Company s registration statement on Form S-1 (No. 333-81650) filed with the SEC on January 30, 2002.

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- (6) Incorporated by reference to the Company s Amendment No. 1 to the registration statement on Form S-1 (No. 333-81650) filed with the SEC on March 25, 2002.
- (7) Incorporated by reference to the Company s annual report on Form 10-K (No. 000-51110) filed with the SEC on March 31, 2005.
- (8) Incorporated by reference to the Company s quarterly report on Form 10-Q (No. 000-51110) filed with the SEC on May 13, 2005.
- (9) Incorporated by reference to the Company s quarterly report on Form 10-Q (No. 000-51110) filed with the SEC on November 14, 2005.
- (10) Incorporated by reference to the Company s annual report on Form 10-K (No. 000-51110) filed with the SEC on March 31, 2006.
- (11) Incorporated by reference to the Company s current report on Form 8-K (No. 000-51110) filed with the SEC on March 13, 2007.

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.

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# **SIGNATURES**

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

ViaCell, Inc.

By /s/ Marc D. Beer

Marc D. Beer

Chief Executive Officer

Date: March 16, 2007

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, 2007.

Signature	Title	Date
/s/ Marc D. Beer	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2007
Marc D. Beer	(Timespar Executive Officer)	
/s/ Stephen G. Dance	Chief Financial Officer	March 16, 2007
Stephen G. Dance	(Principal Financial Officer and Principal Accounting Officer)	
/s/ Barbara Bierer	Director	March 16, 2007
Barbara Bierer		
/s/ Paul Blake	Director	March 16, 2007
Paul Blake		
/s/ Paul Hastings	Director	March 16, 2007
Paul Hastings		
/s/ Vaughn M. Kailian	Director	March 16, 2007
Vaughn M. Kailian		
/s/ Denise Pollard-Knight	Director	March 16, 2007
Denise Pollard-Knight		

/s/ James Sigler	Director	March 16, 2007
James Sigler		
/s/ James Tullis	Director	March 16, 2007
James Tullis		
/s/ Jan van Heek	Director	March 16, 2007
Jan van Heek		
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# **Report of Independent Registered Public Accounting Firm**

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

We have completed an integrated audit of ViaCell, Inc. s 2006 consolidated financial statements and of its internal control over financial reporting as of December 31, 2006 and audits of its 2005 and 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

#### **Consolidated financial statements**

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of ViaCell, Inc. and its subsidiaries at December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 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 of financial statements 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

# Internal control over financial reporting

Also, in our opinion, management s assessment, included in Management s Annual Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control* Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal* Integrated Framework issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable

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assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP Boston, Massachusetts March 16, 2007

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# ViaCell, Inc.

# **Consolidated Balance Sheets**

	(Iı	As of Dec 2006 n thousand and per s	s exce	2005 ept share
ASSETS				
Current assets:				
Cash and cash equivalents	\$	18,039	\$	33,138
Short-term investments		33,206		27,406
Accounts receivable, less allowances of \$1,787 and \$1,068 in 2006 and 2005,		12 (16		12.726
respectively  Proposid expanses and other current assets		12,616 2,008		13,736 2,679
Prepaid expenses and other current assets Restricted cash		2,008		162
Restricted casir				102
Total current assets		65,869		77,121
Property and equipment, net		8,376		8,702
Goodwill		3,621		3,621
Intangible assets, net		2,621		2,823
Restricted cash		1,795		1,932
Other assets				31
Total assets	\$	82,282	\$	94,230
LIABILITIES AND STOCKHOLDERS EQUIT	Y			
Current liabilities:				
Current portion of long-term debt obligations	\$	55	\$	1,543
Accounts payable		960		1,141
Accrued expenses		9,550		7,706
Deferred revenue		7,300		5,785
Total current liabilities		17,865		16,175
Deferred revenue		14,666		9,930
Deferred rent		3,252		3,876
Contingent purchase price		8,155		8,155
Long-term debt obligations, net of current portion		27		84
Total liabilities		43,965		38,220
Commitments and contingencies (Note 8)				
Stockholders equity:				
Preferred stock, \$0.01 par value; authorized 5,000,000 shares in 2006 and 2005				

Common stock, \$0.01 par value; authorized 100,000,000 shares in 2006 and 2005,		
respectively; issued and outstanding 38,525,036 and 38,117,725 shares in 2006 and		
2005, respectively	385	381
Additional paid-in capital	232,215	229,955
Deferred compensation		(1,087)
Accumulated deficit	(194,490)	(173,443)
Accumulated other comprehensive income	207	204
Total stockholders equity	38,317	56,010
Total liabilities and stockholders equity	\$ 82,282	\$ 94,230

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

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ViaCell, Inc.

# **Consolidated Statements of Operations**

	(Ir	2006	ed December 2005 t share and p	2004 are data)
Processing and storage revenues Grant and contract revenues	\$	54,136 290	\$ 43,775 668	\$ 36,805 1,469
Total revenues		54,426	44,443	38,274
Operating expenses: Cost of processing and storage revenues: Direct costs		10,253	8,298	7,396
Royalty recovery		10,233	0,270	(3,258)
Total cost of processing and storage revenues Research and development Sales and marketing General and administrative		10,253 13,984 37,154 18,525	8,298 13,653 24,909 13,835	4,138 16,030 19,497 15,551
Restructuring		(1,070)	305	3,188
Total operating expenses		78,846	61,000	58,404
Loss from operations Interest income (expense):		(24,420)	(16,557)	(20,130)
Interest income Interest expense		3,141 (51)	2,216 (336)	530 (1,497)
Total interest income (expense), net		3,090	1,880	(967)
Loss before cumulative effect of change in accounting principle Cumulative effect of change in accounting principle		(21,330) 283	(14,677)	(21,097)
Net loss Accretion on redeemable convertible preferred stock		(21,047)	(14,677) (986)	(21,097) (13,071)
Net loss attributable to common stockholders	\$	(21,047)	\$ (15,663)	\$ (34,168)
Net loss per share: Basic and diluted net loss per common share before cumulative				
effect of change in accounting principle Cumulative effect of change in accounting principle	\$	(0.56) 0.01	\$ (0.44)	\$ (12.62)

Basic and diluted net loss per common share \$ (0.55) \$ (0.44) \$ (12.62) Weighted average shares used in basic and diluted net loss per share computation \$ 38,377,238 \$ 35,777,308 \$ 2,707,219

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

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# ViaCell, Inc.

# **Consolidated Statements of Comprehensive Loss**

	Years Ended December 31,							
		2006	(In	2005 thousands)		2004		
Net loss Foreign currency translation adjustment	\$	(21,047)	\$	(14,677) (105)	\$	(21,097) (175)		
Comprehensive loss	\$	(21,044)	\$	(14,782)	\$	(21,272)		

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

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Accumulated

	Preferred S	Stock Par	Common S	Stock Par			Accumulat@d	Other omprehensi		
	Shares	Value	Shares	Value (In tho	Capital ( usands except	Compensation t share data)	n Deficit	Income	Equity (Defici	
nce, December 31,	182,857	\$ 2	2,659,854	\$ 27	\$ 1,437	\$ (3,422)	\$ (128,679)	\$ 484	\$ (130,1	
k option exercises etion on redeemable	, ,	r —	89,915	1	107			,	1	
ertible preferred stock employee stock-based					(4,081)		(8,990)		(13,0	
pensation			14,192		415				4	
rred compensation					2,882	(2,882)				
eiture of stock options ification of stock					(413)	413				
ons					774				7	
ortization of deferred					/1 101\	2.261			2.2	
pensation					(1,121)	3,361	(21.007)		2,2	
loss slation adjustment							(21,097)	(175)	(21,0	
nce, December 31,	100 057	¢ 2	2.762.061	¢ 20	¢	¢ (2.520)	¢ (150.766)	¢ 200	¢ (160.0	
k option exercises	182,857	\$ 2	2,763,961 685,157	\$ 28 7	\$ 1,157	\$ (2,530)	\$ (158,766)	\$ 309	\$ (160,9 1,1	
al public offering			8,625,000	86	56,062				56,1	
al public offering costs etion on redeemable			5,5 <b>25,</b> 550	23	(2,899)				(2,8	
ertible preferred stock version of redeemable					(986)				(9	
ertible preferred stock										
es A and B) version of redeemable	(182,857)	(2)	182,857	2						
ertible preferred stock										
es C through K) unce of common stock exercise of warrants,			25,628,075	256	175,903				176,1	
cacioise of warrants,			229,818	2	(2)					
employee stock-based			- ,		(-)					
pensation			2,857		20					
rred compensation, net					700	1,443			2,1	

oss slation adjustment							(14,677)	(105)	(14,6 (1
nce, December 31,									
	\$ 0	38,117,725	\$ 38	81	\$ 229,955	\$ (1,087)	\$ (173,443)	\$ 204	\$ 56,0
k option exercises unce of common stock exercise of warrants,		198,938		2	539				5
· 		208,373		2	(2)				,
ersal of deferred		,							1
pensation k-based compensation					(1,087) 2,810	1,087			2,8
loss					,		(21,047)		(21,0
slation adjustment								3	
nce, December 31,									
<b>5</b>	\$	38,525,036	\$ 38	85	\$ 232,215	\$	\$ (194,490)	\$ 207	\$ 38,3

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

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ViaCell, Inc.

# **Consolidated Statements of Cash Flows**

	Year 2006	s Ended Decemb 2005 (In thousands)	er 31, 2004
Cash flows from operating activities:			
Net loss	\$ (21,047)	\$ (14,677)	\$ (21,097)
Adjustments to reconcile net loss to net cash used in operating activities:	2 2 4 4	2.110	0.577
Depreciation and amortization	2,244	2,110	2,577
Stock-based compensation	3,095	2,163	3,429
Cumulative effect of change in accounting principle	(283)		249
Reserve for bad debt	1,502	515	248
Non-cash interest expense on related party notes	(520)	88	1,142
(Gain) loss on disposal of property and equipment	(528) 60		2,155 1,004
Tenant improvement allowance Changes in assets and liabilities, excluding the effect of acquisition:	00	2,437	1,004
Accounts receivable	(367)	(3,276)	(3,376)
Prepaid expenses and other current assets	(192)		(615)
Accounts payable	(208)	·	(2,192)
Accrued expenses	2,050	51	(2,1)(2) $(2,513)$
Deferred revenue	6,251	5,527	4,092
Deferred rent	(1,005)	873	31
Deterior for	(1,002)	0,3	31
Net cash used in operating activities	(8,428)	(1,434)	(15,115)
Cash flows from investing activities:			
Purchases of property and equipment	(1,791)	(3,923)	(2,393)
Proceeds from sale of property and equipment	603		
Proceeds from maturities and sales of investments	50,645	36,532	22,682
Purchases of investments	(56,444)	(42,099)	(36,697)
Restricted cash	317		732
Security deposit		7	85
Net cash used in investing activities	(6,670)	(9,483)	(15,591)
Cash flows from financing activities:			
Proceeds from exercise of stock options	541	1,164	108
Net proceeds from sale of common stock in initial public offering, net of			
offering costs		53,249	
Proceeds from return of security deposits on debt obligations	943	414	403
Repayments on credit facilities	(1,485)	(1,674)	(1,562)
Repayments of notes payable to related party, including accrued interest		(15,510)	
Payments on capital lease principal	(65)	(86)	(267)

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Net cash (used in) provided by financing activities Effect of change in exchange rates on cash	(66) 65	37,557 (248)	(1,318) (238)
Net (decrease) increase in cash and cash equivalents	(15,099)	26,392	(32,262)
Cash and cash equivalents, beginning of period	33,138	6,746	39,008
Cash and cash equivalents, end of period	\$ 18,039	\$ 33,138	\$ 6,746
Supplemental disclosures of cash flow information and non cash transactions:			
Interest paid	\$ 53	\$ 273	\$ 325
Income taxes paid	71	153	73
Accretion of redeemable convertible preferred stock		986	13,071
Equipment purchased under capital lease, net of disposals		56	140

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

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#### ViaCell, Inc.

#### **Notes to Consolidated Financial Statements**

# 1. Organization and Nature of Business

ViaCell, Inc. (the Company or ViaCell ) is a biotechnology company dedicated to enabling the widespread application of human cells as medicine. The Company has a reproductive health business that generated revenues of \$54.1 million in 2006 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 in this area by developing ViaCyte<sup>sm</sup>, its product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs. The Company s other research and development efforts are focused on investigating new potential therapeutic uses of umbilical cord-derived and adult stem cells and on technology for expanding populations of these cells.

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

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 outstanding immediately prior to the initial public offering converted into 25,810,932 shares of common stock. On January 26, 2005, the Company paid in full a 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.

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## 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.

		De	ecem	ber 31, 20	06	<b>December 31, 2005</b>						
	Am	ortized			Unr	ealized	Aı	nortized			Unr	ealized
				Fair						Fair		
	(	Cost		Value	G	Sain		Cost		Value	I	LOSS
Cash and cash equivalents												
(money market accounts)	\$	14,492	\$	14,492	\$		\$	29,807	\$	29,807	\$	
Government securities		1,144		1,144				1,432		1,432		
Cash		2,403		2,403				1,899		1,899		
Total cash and cash equivalents		18,039		18,039				33,138		33,138		
Short-term investments: Commercial paper		33,206		33,216		10		27,406		27,362		(44)
Total cash, cash equivalents and short term investments	\$	51,245	\$	51,255	\$	10	\$	60,544	\$	60,500	\$	(44)

In connection with Company s commitments under various agreements (Note 8) and one of the Company s operating bank accounts, the Company issued letters of credit totaling \$2.6 million collateralized by certificates of deposit of which \$1.8 million are classified as restricted cash on the accompanying consolidated balance sheet.

### 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 for the processing fees.

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 undelivered items that have a right of return.

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#### ViaCell, Inc.

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

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.

Revenue recognized from the collection, testing and freezing of cord blood units was approximately \$43.5 million, \$36.1 million, and \$31.7 million for the years ended December 31, 2006, 2005 and 2004, respectively.

Revenue from storage fees is recognized over the contractual period on a straight-line basis and amounted to approximately \$10.6 million, \$7.7 million, and \$5.1 million for the years ended December 31, 2006, 2005 and 2004, respectively.

Deferred revenue of \$22.0 million and \$15.7 million at December 31, 2006 and 2005, respectively, consists primarily of the unearned portions of annual storage fees and deposits paid by customers prior to completion of the Company s processing service. Deferred revenue at December 31, 2006 and 2005 also includes approximately \$0 and \$0.7 million, respectively, of unearned revenue related to the Company s grant from the Economic Development Board of Singapore.

The Company recognizes shipping costs billed to customers as revenues and records the corresponding amount incurred 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 \$0.5 million, \$0.1 million, and \$0.3 million for the years ended December 31, 2006, 2005 and 2004, respectively. The rebates have been recorded as a reduction of processing revenues for the years ended December 31, 2006, 2005 and 2004.

Revenues from short-term research contracts are recognized over the contract period as services are provided. Revenues from research contracts amounted to \$0, \$0, and \$0.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.

The Company recognized approximately \$0.3 million, \$0.7 million, and \$1.3 million in grant revenues in the years ended December 31, 2006, 2005, and 2004, 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 their 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.

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## ViaCell, Inc.

# Notes to Consolidated Financial Statements (Continued)

## 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 reversal of a royalty accrual in 2004. In 2003, the Company recorded a royalty expense of \$3.3 million following an unfavorable jury verdict in the ongoing litigation with PharmaStem in October 2003. In 2004, the District Court overturned the jury verdict. Based on the judge s ruling, the Company reversed the entire royalty accrual in 2004 and has not recorded any royalties since such date. PharmaStem has appealed the District Court s ruling. PharmaStem has also filed a new lawsuit claiming that the Company infringes additional patents (Note 8). Pending a decision on the appeal and further action by the court on the new litigation, the Company does not intend to record a royalty expense in future periods, since the Company believes PharmaStem s claims are without merit.

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

## **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 \$3.7 million, \$3.1 million, and \$2.5 million for the years ended December 31, 2006, 2005 and 2004, 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.

#### Foreign Currency Translation

The financial statements of the Company's German subsidiary, Kourion Therapeutics AG (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 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 U.S. 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 website development

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## ViaCell, Inc.

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

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:

Asset Classification	Useful Life
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

**Estimated** 

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 the statement of 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, and equipment loans. 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; 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 and 20 years for trademarks.

# 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 an asset is sold; and

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## ViaCell, Inc.

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

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 long-lived assets to its results of 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, 2006 and 2005, 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, 2006 and 2005, 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.

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):

		Balance at Beginning of Period			Bal	lance at
	`			Write-Offs	End of Period	
December 31, 2006	\$	1,068	1,502	(783)	\$	1,787
December 31, 2005	\$	1,197	515	(644)	\$	1,068
December 31, 2004	\$	1,044	248	(95)	\$	1,197

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. The Company has registered ViaCord with the FDA as a cord blood preservation service and is subject to inspection by the FDA.

# **Stock-Based Compensation**

The ViaCell, Inc. Amended and Restated 1998 Equity Incentive Plan (the Plan ) provides for the grant of incentive and nonqualified stock options and other equity-based compensation to employees, consultants and directors of the Company. The number of shares of common stock authorized for issuance under the Plan as of December 31, 2006 was 7,200,000. Incentive stock options may only be granted to employees of the Company. The exercise price of each stock 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. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R Share-Based Payment (SFAS 123R) using the modified prospective method, which results in the provisions of SFAS 123R

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## ViaCell, Inc.

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

only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provision of SFAS 123R, stock-based compensation expense related to stock options awarded by the Company is measured using the Black-Scholes option pricing model at the grant date based on the value of the award and is recognized as expense on a straight-line basis over the requisite service period. Previously, the Company had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretation, which resulted in the accounting for employee stock options at their intrinsic value in the consolidated financial statements. The Company recognized the full impact under SFAS 123R of the Company s equity-based plan as stock-based compensation expense in its consolidated statements of operations for the year ended December 31, 2006 as no amounts qualified for capitalization. Stock-based compensation included in the Company s statements of operations is as follows (in thousands):

	Years Ended December 31,						
	2	2006	2	005	2	2004	
Cost of processing and storage revenues	\$	67	\$	20	\$	32	
Research and development		446		294		896	
Sales and marketing		282		207		175	
General and administrative		2,300		1,642		2,083	
Restructuring						243	
Total stock-based compensation expense	\$	3,095	\$ :	2,163	\$	3,429	

The Company had previously adopted the provisions of SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, through disclosure only. The following table illustrates the effect on net loss and net loss per share for the years ended December 31, 2005 and 2004 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee awards (in thousands):

	Years Ended				
	December 31 2005		Dec	cember 31 2004	
Net loss attributable to common stockholders as reported Add: employee stock-based compensation expense included in reported net loss Deduct: total employee stock-based compensation expense determined under fair	\$	(15,663) 2,143	\$	(34,168) 3,014	
value based method for all awards		(4,630)		(5,175)	
Pro forma net loss attributable to common stockholders	\$	(18,150)	\$	(36,329)	
Basic and diluted net loss per common share as reported	\$	(0.44)	\$	(12.62)	

Pro forma basic and diluted net loss per common share

\$ (0.51) \$ (13.42)

The Company s expected stock-price volatility assumption in its Black-Scholes option-pricing model for SFAS 123(R) is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. The Company determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns.

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# ViaCell, Inc.

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

The fair market value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	December 31,					
	2006	2005	2004			
Risk-free interest rate	4.66%	3.92%	2.86%			
Expected life	4.57 years	5 years	5 years			
Expected volatility	65%	100%	100%			
Dividend yield	0%	0%	0%			

As of December 31, 2006, there remained approximately \$3.1 million of compensation costs related to non-vested stock options to be recognized as expense over a weighted-average period of approximately 1.7 years. Presented below is the Company s stock option activity for the year ended December 31, 2006:

	Number of Options	Number of Options	Exercise	•	ggregate xercise	A	eighted verage kercise
<b>Amounts in Thousands Except Share Data</b>	Authorized	Outstanding	Price		Price	]	Price
Outstanding, December 31, 2005 Granted Exercised Canceled and forfeited	7,200,000	3,930,694 613,525 (199,018) (353,874)	\$ 0.30-11.10 4.00- 5.21 0.30- 5.21 0.30-11.10	\$	10,876 3,035 (541) (1,319)	\$	2.77 4.95 2.72 3.73
Outstanding, December 31, 2006	7,200,000	3,991,327	\$ 0.30-11.10	\$	12,051	\$	3.02
Exercisable, December 31, 2006		2,333,832	\$ 0.30-11.10	\$	5,960	\$	2.55

Options Outstanding a	t December 31, 2006 Weighted Average Remaining	Ор	tions Exercisal	ble at December 31, 2006
Number of Shares	Contractual Life		ercise Price	Number of Shares
1,252,543	3.36	\$	0.30	952,543
32.200	4.36		0.75	32,200

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96,986	4.38	0.95	96,986
718,625	4.97	2.00	361,375
30,775	7.41	4.00	16,709
65,375	9.55	4.04	5,092
23,650	9.95	4.50	1,250
981,210	6.85	5.00	586,362
259,812	9.38	5.03	92,834
210,870	9.17	5.21	41,026
135,452	8.72	5.31	42,808
9,562	8.93	5.62	2,655
25,000	8.32	7.25	10,937
93,533	8.01	8.17	66,308
7,000	8.36	9.00	1,750
40,000	8.78	10.89	20,000
8,734	8.53	11.10	2,997
3,991,327			2,333,832

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## ViaCell, Inc.

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

The aggregate intrinsic value of outstanding and exercisable options as of December 31, 2006 and 2005 was \$8.1 million and \$5.7 million, respectively. The intrinsic value of options exercised during the years ended December 31, 2006, 2005 and 2004 was \$0.5 million, \$4.5 million and \$0.3 million, respectively.

Options granted under the Plan generally vest over a period of four years and expire ten years from the grant date. At December 31, 2006, there were 1,829,118 shares available for future grant under the Plan.

The weighted average fair value of options granted in 2006, 2005 and 2004 was \$2.79, \$5.55 and \$3.77, respectively.

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.

# **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.

The following table presents total long-lived tangible assets by geographic areas as of December 31, 2006 and 2005, respectively (in thousands):

	December 31, 2006		
Long-lived assets, net United States Singapore	\$ 8,183 193	\$	8,430 272
Total long-lived tangible assets, net	\$ 8,376	\$	8,702

The following table presents revenues by geographic areas (in thousands):

		Years Ended				
United States Germany	De	December 31, 2006		nber 31, 2005		
	\$	54,136	\$	43,812 (101)		

Singapore		290	732		
Total Revenues	\$	54.426	\$ 44.443		

# 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 common 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 common 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

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## ViaCell, Inc.

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

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):

	Years Ended December 31,					
		2006		2005		2004
Basic and diluted net loss per share						
Net loss attributable to common stockholders	\$	(21,047)	\$	(15,663)	\$	(34,168)
Weighted average number of common shares outstanding		38,377		35,777		2,707
Basic and diluted net loss per share	\$	(0.55)	\$	(0.44)	\$	(12.62)

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

	Years	Years Ended December 31,		
	2006	2005	2004	
Options	3,787,146	3,746,395	4,222,211	
Warrants	1,558,541	3,349,455	1,428,750	
Convertible preferred stock		1,433,941	25,810,932	

#### Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 will be effective for the first fiscal year that begins after November 15,2007. The Company has not yet completed its evaluation of the impact of adoption of SFAS 159 on its financial position or results of operations.

In September 2006, FASB issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements (SFAS No. 157) which defines fair value under GAAP, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. Where applicable, SFAS No. 157 simplifies and codifies related guidance within GAAP and does not require any new fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company does not expect the adoption of SFAS No. 157 to have a significant immediate effect on its financial position or results of operations.

In June 2006, FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109 (FIN 48), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 will be effective for fiscal years beginning after December 15, 2006. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company does not expect the adoption of FIN 48 to have a significant immediate effect on its financial position or results of operations.

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## ViaCell, Inc.

## Notes to Consolidated Financial Statements (Continued)

## 3. Property and Equipment

Property and equipment consisted of (in thousands):

	Decer	December 31,	
	2006	2005	
Software	\$ 3,389	\$ 3,098	
Laboratory equipment	5,996	5,230	
Office and computer equipment	3,021	2,611	
Leasehold improvements	5,310	5,267	
Furniture and fixtures	907	767	
Construction in progress	46	8	
Property and equipment, gross	18,669	16,981	
Less: accumulated depreciation and amortization	(10,293)	(8,279)	
Property and equipment, net	\$ 8,376	\$ 8,702	

At December 31, 2006 and 2005, the net book value of property and equipment serving as collateral under loan agreements amounted to \$0, and \$1.5 million, respectively.

Equipment held under capital leases totaled \$0.5 million at both December 31, 2006 and 2005, and accumulated depreciation related to this leased equipment totaled approximately \$0.4 million and \$0.3 million, at December 31, 2006 and 2005, respectively.

Depreciation and amortization expense on property and equipment totaled approximately \$2.0 million, \$1.9 million, and \$2.4 million in the years ended December 31, 2006, 2005 and 2004, respectively.

# 4. Intangible 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 when the Company adopted SFAS No. 142.

Amortization of intangible assets was approximately \$0.2 million, \$0.2 million, and \$0.3 million for the years ended December 31, 2006, 2005 and 2004, respectively.

At December 31, 2006 and 2005, the Company s goodwill and intangible assets consisted of the following (in thousands):

	December 31,		
	2006		2005
Goodwill	\$ 3,621	\$	3,621
Intangible assets:			
Trademark	\$ 4,400	\$	4,400
Employment agreements	288		288
Intangible assets, gross	4,688		4,688
Less: accumulated amortization	(2,067)		(1,865)
Intangible assets, net	\$ 2,621	\$	2,823

The Company expects amortization of these intangible assets to be approximately \$0.2 million annually through 2019, at which point they will be fully amortized.

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### ViaCell, Inc.

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

### 5. Accrued Expenses

At December 31, 2006 and 2005, accrued expenses consisted of the following (in thousands):

	December 31,		
	2006	2005	
Payroll and payroll related	\$ 1,904	\$ 1,541	
Management incentive	1,047	881	
Professional fees	1,829	1,206	
Accrued marketing	2,079	1,260	
Accrued restructuring (Note 12)		632	
Deferred rent, current	345	619	
Accrued taxes	459	537	
Other	1,887	1,030	
Accrued expenses	\$ 9,550	\$ 7,706	

### 6. Income Taxes

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

	2006	2005	2004
Domestic Foreign	\$ (21,398 351	, , , ,	\$ (16,019) (5,078)
Total Loss Before Income Taxes	\$ (21,047)	7) \$ (14,677)	\$ (21,097)

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

	Years Ended December 31,				
	2006	2005 2		2006 2005	
US Statutory rate	34.00%	34.00%	34.00%		
State taxes, net	(0.12)%	(0.66)%	3.70%		
Foreign rate differential	(0.77)%	0.02%	1.80%		
Benefit of tax credits	1.47%	4.37%	2.60%		

Change in valuation allowance	(31.22)%	(34.41)%	(36.80)%
Stock-based compensation	(1.78)%	(1.41)%	(5.10)%
Other	(1.78)%	(1.03)%	(0.20)%
Change in local tax rate	0.00%	(1.89)%	0.00%
Effective tax rate	(0.20)%	(1.01)%	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

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#### ViaCell, Inc.

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

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 (in thousands):

	2	006		ember 31, 2005		2004
Deferred tax assets: Operating loss carryforwards	\$ 4	41,506	\$	37,323	\$	35,436
Tax credit carryforwards	Ψ	4,470	Ψ	4,315	Ψ	3,484
Stock-based compensation		1,727		2,802		3,790
Temporary differences		14,403		10,238		8,510
	(	62,106		54,678		51,220
Less: valuation allowance	((	61,045)		(53,614)		(50,002)
Net deferred tax assets Deferred tax liabilities:		1,061		1,064		1,218
Intangible assets		(1,061)		(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, 2006, the Company has federal and state net operating loss carryforwards of approximately \$87.8 million and \$93.3 million, respectively, which begin to expire in 2009 and 2006, respectively. The Company has federal and state credit carryforwards of approximately \$3.4 million and \$1.6 million, respectively which begin to expire in 2009 and 2013, respectively. The Company also has foreign net operating loss carryforwards of \$14.8 million. The carryforwards expire through 2024 and are subject to review and possible adjustment by the local tax authorities. 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.

Of the \$61.0 million valuation allowance, \$1.0 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, 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 the Company s income tax liability.

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

		lance at inning of			nlance at End of
Description	I	Period	Additions	Deductions	Period
2006	\$	53,614	7,431		\$ 61,045
2005	\$	50,002	3,612		\$ 53,614
2004	\$	42,234	7,768		\$ 50,002
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#### ViaCell, Inc.

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

#### 7. Long-Term Debt Obligations

The Company had the following long-term debt obligations outstanding as of December 31, 2006 and 2005 (in thousands):

	<b>Dece</b> 2006	mber 31, 2005	
Debt facility loans Capital lease obligations	\$ 82	\$ 1,480 147	
Total long-term debt Less: current portion	82 (55)	1,627 (1,543)	
Total long-term debt, net of current portion	\$ 27	\$ 84	

#### Debt facility loans

In October 2003, the Company entered into a \$5.0 million loan agreement with a lender. Monthly payments of interest and principal were due through October 2006. Borrowings under this agreement bore interest at 6.9 percent per annum and were collateralized by certain property and equipment of the Company. The Company repaid the balance of this loan in October 2006 and the lender returned the Company security deposit of approximately \$0.9 million.

#### 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, 2006, payments of principal and interest on existing debt were due as follows (in thousands):

Year Ending December 31,	
2007	\$ 56
2008	28
2009	
Total payments	84
Less: interest	(2)
Total debt	82
Less: current portion	(55)

Total long-term debt \$ 27

#### 8. Commitments and Contingencies

#### Contingent Purchase Price

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.

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

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#### ViaCell, Inc.

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

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 balance sheet at December 31, 2006 and 2005 as a non-current liability. The total potential 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 Company made a determination that the underlying conditions for issuance of the escrow shares and the reserved shares are no longer capable of being met. As a result, as of December 31, 2006, the escrow shares were deemed cancelled and the reserved shares will not be issued.

A milestone representing \$2.2 million of the \$8.2 million of contingent purchase price outstanding as of December 31, 2006 will expire on June 30, 2007. The Company considers the likelihood of this milestone being achieved by June 30, 2007 to be unlikely.

#### 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	\$ 1,873
2007	1,853
2008	1,924
2009	1,936
2010	2,005
Thereafter	5,448
Total lease payments	\$ 15,039

Rent expense was approximately \$1.8 million, \$1.8 million, and \$2.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.

In connection with the above commitments, the Company has issued letters of credit totaling approximately \$1.5 million 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 2006 and 2005, the Company received approximately \$0.1 million and \$2.4 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 and laboratory space in its Cambridge facility. The total lease commitment for this additional office space is approximately \$1.9 million.

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#### ViaCell, Inc.

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

### Agreements

In August 2006, the Company entered into a data license and marketing services agreement with Mothers Work, Inc., the world s largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as Motherhood Maternity<sup>®</sup>, A Pea in the Pod<sup>®</sup>, Mimi Maternity<sup>®</sup>, and Destination Maternity<sup>tm</sup>. Under the terms of the agreement, Mothers Work has granted the Company an exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. Under the terms of the agreement, the Company will pay Mothers Work \$5,000,000 per year over the three-year term of the agreement which began on January 1, 2007 and, unless earlier terminated, ends on December 31, 2009. Under certain circumstances, the Company will also be obligated, at the beginning of 2009, to issue Mothers Work a warrant to purchase 100,000 shares of the Company s common stock (see Note 10). The warrant would be exercisable for a one year period beginning on January 1, 2010. The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work s commitment to us. The dispute between Mothers Work and the third party is the subject of an ongoing arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. While there is no assurance that the third party will not challenge this ruling, the Company believes that reversal of this ruling is unlikely and that the termination rights under its agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, the Company agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with the Company. The Company also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. The Company s potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on the Company s assessment of the low likelihood that it might have to pay damages or legal fees given the arbitrator s ruling, the Company concluded the fair value of its indemnification obligation is not material and has not recorded a liability as of December 31, 2006.

In June 2006, the Company entered into a research collaboration agreement with the Stem Cell Internal Venture (SCIV) of Centocor Research and Development, Inc. to evaluate ViaCell s proprietary cord blood-derived multi-potent stem cells in pre-clinical testing as a potential treatment for cardiac disease. The collaboration is also supported by the Biologics Delivery Systems Group of Cordis Corporation, and will focus on dosing, delivery and targeting of ViaCell s expanded proprietary cord blood stem cells using Cordis NOGA XP delivery system. Under the terms of the agreement, ViaCell received an initial up-front payment of \$350,000 which it recorded as a liability and is amortizing as a reduction of research and development expense, as work is performed. SCIV will be responsible for its own costs under the collaboration and will pay 50% of the research costs that ViaCell incurs under the collaboration, consistent with the agreed upon budget. As of December 31, 2006, SCIV has reimbursed the Company approximately \$85,000 of these costs. In addition, the agreement provides SCIV with the first right to negotiate a collaboration with ViaCell on the clinical development and commercialization of a cardiac product offering based on ViaCell s proprietary cord blood stem cells.

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 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 was 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 was obligated to pay up to \$1.0 million to Miltenyi under the agreement. As of December 31, 2006, the Company had paid the entire \$1.0 million related to this development agreement.

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#### ViaCell, Inc.

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

The supply agreement with Miltenyi provides for the exclusive supply of the cell separation kits by Miltenyi to ViaCell. The initial term of the supply agreement is seven years. The Company purchased \$1.3 million of cell separation kits in 2006. The Company has a firm order to purchase an additional \$0.3 million of kits in 2007. Since the Company has decided not to progress CB001 into further clinical trials, the Company does not expect to have any additional commitments beyond its current firm order.

The Company has entered into an agreement with the Economic Development Board (EDB) of the Government of Singapore under which the Government of Singapore has agreed to give the Company a grant of up to \$5,900,000 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 \$1.1 million, \$1.3 million, and \$1.0 million of research and development in Singapore during the years ended December 31, 2006, 2005 and 2004, respectively, and recorded grant revenue of approximately \$0.3 million, \$0.7 million, and \$0.3 million during the years ended December 31, 2006, 2005 and 2004, respectively. The Company is in discussions with the EDB regarding conclusion of its current grant, which expires in May 2007. In the course of these discussions, the EDB has taken the position that a prior period increase in the EDB s cost reimbursement percentage constituted an advance on future grant funding. The Company, however, believes that the increase constituted a mutually agreed upon increase in the reimbursement percentage for the period, after which the reimbursement rate was to revert to the rate prior to such increase. The amount received by the Company under the increased reimbursement percentage was approximately \$1.0 million. The EDB has asked for repayment of the disputed amount. In connection with this dispute, the EDB is now also asserting that the Company has not fulfilled a commitment to employ a specified number of people in Singapore that was an original condition of the grant. Under the terms of the grant, a breach by the Company of a condition of the grant could result in the EDB pursuing repayment of some or all of the amounts disbursed to it. The Company believes that the EDB has previously waived this commitment, and that, as a result, the Company has satisfied all requirements under the grant. If the Company does not agree to repay the disputed amount, the EDB may seek to recover grant funds previously paid and/or withhold payment of existing or future grant claims that are as yet unpaid. The Company believes it has met its performance obligations and would be successful in its defense of any such claims. The Company is attempting to resolve this dispute with the EDB and has proposed the possibility of amending the grant to reduce its term and cumulative funding. The Company has recorded a reduction of grant revenues of approximately \$0.2 million during the fourth quarter of 2006 to reflect the estimated potential settlement costs. As of December 31, 2006, the Company had received grant payments from EDB totaling approximately \$1.9 million and had recognized cumulative grant revenues of approximately \$1.7 million.

The Company enters into indemnification provisions under its agreements with other companies and individuals performing services for the Company 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. The Company has approximately \$51,000 recorded for these agreements as of December 31, 2006 and December 31, 2005.

#### Litigation

In 2002, PharmaStem Therapeutics, Inc. filed suit against the Company and several other defendants in the U.S. District Court for the District of Delaware, alleging infringement of U.S. 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.

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#### ViaCell, Inc.

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

In 2003, a jury ruled against the Company and the other defendants, Cbr Systems Inc, CorCell, Inc., a subsidiary of Cord Blood of America, 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 stem cells since April 2000. In 2004, the District Court judge in the case overturned the jury s verdict stating that PharmaStem had failed to prove infringement, consequently the Company has not recorded a liability as of September 30, 2006. 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 took place at the U.S. Court of Appeals for the Federal Circuit, on April 4, 2006 and a final ruling has not been issued.

In July 2004, PharmaStem filed a second complaint against the Company. The second complaint was filed in the U.S. 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/or that the Company does not infringe them. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts 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.

In late 2006, the U.S. Patent and Trademark Office (PTO) issued final decisions in the existing 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. The U.S. PTO has ordered a second re-examination of the 427 patent in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO reversed its prior actions and issued notice of its intent to allow the remaining claims of all of the patents.

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 described below.

In either of the pending cases, if the Company is ultimately found to infringe valid claims of the PharmaStem patents, the Company could have a significant damages award entered against it. If the Company is found to infringe at any time during the course of either case, including 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 so 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 could 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.

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,

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#### ViaCell, Inc.

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

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, 2006 and 2005 equal to the estimated fair value of the indemnifications, 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, 2006 and 2005. 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.

The following table summarizes the activities in the ViaCord Guarantee Program reserve for the years ended December 31, 2006, and 2005 (in thousands):

For the Years Ended December 31, 2006 2005

Balance at the beginning of the period

92 \$ 73

Accrual for additional units sold during the period

19

Balance at the end of the period

\$ 100 \$ 92

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#### 9. Common and Preferred Stock

As of December 31, 2006 and 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.

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#### ViaCell, Inc.

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

#### 10. Warrants

Under certain circumstances, the Company will be obligated, at the beginning of 2009, to issue Mothers Work a warrant to purchase 100,000 shares of the Company s common stock with an exercise price of \$6.29, which represents a 30% premium to the average closing price of the Company s common stock over the ten trading days immediately preceding January 1, 2007. The warrant would be exercisable for a one year period beginning on January 1, 2010. The fair market value of the warrant will be remeasured at each reporting period and recognized over the three year term of the agreement.

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 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.

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 vested 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 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 other Series J investors 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 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 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 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. In February 2007, another Series D investor exercised its warrant using a net exercise feature that resulted in the issuance of 187,437 shares of the Company s Common Stock in consideration of canceling the remaining portion of the warrants covering 62,563 shares.

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#### ViaCell, Inc.

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

In 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.

#### 11. 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. There have been no discretionary contributions made by the Company to the 401(k) Plan to date.

#### 12. Restructuring

In December 2004, the Company restructured its German operations and sub-leased its German facility to a third party. As a result the Company recorded a restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility-related 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 its 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 August 2006, the Company amended its German facility office lease to change the termination date from May 31, 2008 to December 31, 2006. In addition, the Company sold fixed assets at the facility that had been written off in the December 2004 restructuring for approximately \$0.6 million. The sale of fixed assets, combined with the amendment of the lease, is reflected as a change in the Company s December 2004 restructuring estimates of approximately \$1.1 million for the year ended December 31, 2006.

During the year ended December 31, 2006, the Company finalized discussions with German grant authorities regarding repayment of part of certain grants made to the Company's German subsidiary in 2003 and 2004 and remitted approximately \$0.5 million to satisfy all potential claim reimbursements. The Company also paid approximately \$0.1 million in professional fees incurred in connection with the negotiations with the German grant authorities and fees associated with the August 2006 lease amendment and sale of fixed assets.

As of December 31, 2006, the Company had received approximately \$3.6 million in cumulative grant proceeds from the German grant authorities and remitted back approximately \$0.5 million as noted above.

Following is the Company s activity in the restructuring accrual (in thousands):

Balance, December 31, 2004	\$ 907
Adjustments	255
Payments	(530)
Balance, December 31, 2005	632
Adjustments	(34)

Payments (598)

Balance, December 31, 2006 \$

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ViaCell, Inc.

# Notes to Consolidated Financial Statements (Continued)

# 13. Unaudited Quarterly Financial Information

# **Selected Quarterly Consolidated Financial Data:**

	First Quarter (In th	Second Quarter lousands, exce	Third Quarter pt per share d	Fourth Quarter ata)
Year ended December 31, 2006 Total revenues	\$ 12,081	\$ 13,539	\$ 14,667	\$ 14,139
Loss from operations	\$ (6,092)	\$ (7,665)	\$ (5,281)	\$ (5,382)
Net loss attributable to common stockholders	\$ (5,111)	\$ (6,879)	\$ (4,462)	\$ (4,595)
Net loss per common share (basic and diluted)	\$ (0.13)	\$ (0.18)	\$ (0.12)	\$ (0.12)
Year ended December 31, 2005 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 common share (basic and diluted)	\$ (0.17)	\$ (0.08)	\$ (0.09)	\$ (0.10)

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