VIACELL INC
Form 10-K
March 31, 2005

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

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

For the fiscal year ended December 31, 2004

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	**04-3244816**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
245 First Street, Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	*(Zip Code)*

(617) 914-3400
(Registrant s telephone number, including area code)
Securities registered under Section 12(b) of the Exchange Act:
None
Securities registered under Section 12(g) of the Exchange Act:
Common Stock, $0.001 par value
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 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 þ 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 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. þ

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Act of 1933. Yes o No þ

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2004: not applicable because trading of the registrant s Common Stock on the Nasdaq National Market did not commence until January 20, 2005.

The number of shares of the registrant s Common Stock outstanding as of March 28, 2005 was 37,750,701.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the Registrant s Annual Meeting of Shareholders to be held on June 9, 2005 are incorporated herein by reference into Part III of this report.

ViaCell, Inc.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2004
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PART I

Unless the context requires otherwise, references in this report to we, our, us and ViaCell refer to ViaCell, Inc. its subsidiaries.

Preliminary Note Regarding Forward-Looking Statements

The information set forth in this report in Item 1 Description of Business and in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and is subject to the safe harbor created by that section. Such statements may include, but are not limited to, projections of revenues, income or loss, capital expenditures, plans for product development and cooperative arrangements, future operations, financing needs or plans of the Company, as well as assumptions relating to the foregoing. The words believe, expect, will, anticipate, estimate, target, project, plan, and similar expressions identify forward-looking statements, w speak only as of the date the statement was made. Certain factors that realistically could cause actual results to differ materially from those projected in the forward-looking statements are set forth in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Risk Factors That May Affect Results.

ITEM 1. *DESCRIPTION OF BUSINESS*

Overview

We are a biotechnology company dedicated to enabling the widespread application of human cells as medicine. We were incorporated in the State of Delaware on September 2, 1994.

To date, the widespread application of human cells as medicine has not been proven to be possible. We are in an early stage of development for our cellular therapeutic candidates, and we are developing a pipeline of proprietary product candidates intended to address cancer, cardiac diseases, diabetes and infertility. If and when we have successfully developed our product candidates, we intend to manufacture, market and sell these products ourselves or through commercial partners. Cellular therapy already has a significant role in the treatment of human disease. For example, according to the International Bone Marrow Transplant Registry, over 45,000 bone marrow and other hematopoietic (blood) stem cell transplant procedures were performed worldwide in 2002. Although it has not been proven in clinical trials that cellular therapy will be an effective treatment for diseases other than those currently addressed by hematopoietic stem cell transplants, cellular therapies are generally believed to have far-reaching potential beyond these current applications, with the possibility of treating and curing many serious diseases. However, the potential of cellular therapy has been largely unrealized due, in part, to the fact that current sources of stem cells are difficult to harvest and compatible donors are often not found.

We have assembled an organization with research, cell sourcing, clinical development and manufacturing, cell processing and marketing capabilities, which together with strategic partnerships and our proprietary technologies, if proven to be effective, we believe could enable us to overcome current limitations on the development of cellular therapeutics. We have proprietary technologies, including our Selective Amplification technology, that we believe will enable the isolation, purification and significant expansion of stem cell populations. Although we have not yet shown the safety or efficacy of stem cells manufactured using our Selective Amplification technology or completed clinical trials for any product candidates, we believe these technologies will allow the production of well defined cellular products in therapeutically useful quantities. In addition, we have significant experience in the preservation of cells and are currently a leader in the area of private preservation of umbilical cord blood, an abundant and non-controversial source of stem cells.

We are using these assets to develop a cord blood-derived stem cell therapeutic, CB001, our lead stem cell therapy product candidate, which is currently in a Phase I clinical trial. This product candidate is a highly concentrated and purified population of stem cells that we are initially developing for the

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treatment of patients with cancers and other serious diseases. We are developing CB001 to be used as a replacement for bone marrow and other crude cell mixtures used in stem cell transplants as a current standard of care. Although the safety and efficacy of CB001 has not been, and may never be, demonstrated in humans, based on pre-clinical studies, we believe that CB001 may provide a more effective treatment with fewer side effects and faster recovery than other cell sources. We are also developing additional product candidates, alone or with corporate partners, to address other diseases, including cardiac disease and diabetes.

In December 2003, we entered into a license and collaboration agreement with Amgen under which we received a non-exclusive, royalty-free, worldwide license to certain Amgen stem cell growth factors for use in developing and manufacturing cell therapy products, and Amgen received an option to collaborate with us on any product, including CB001, that incorporates an Amgen growth factor or technology. We also have additional collaborations, licenses and strategic relationships with other companies and academic institutions.

We have built our initial commercial organization in the area of reproductive health. We market our Viacord umbilical cord blood preservation product, which is used primarily for pediatric bone marrow transplants, through Viacord Reproductive Health. Our Viacord customers are expectant parents who have entrusted us with their child s umbilical cord blood, which we process into a cellular therapeutic and cryopreserve for potential future use by that child or a sibling. We believe that we are one of the leaders in the emerging private cord blood preservation industry. We offer our customers, who have preserved their child s own cord blood, a higher probability of obtaining suitable stem cells for transplant if the need arises. In addition, we are developing a second product in the area of reproductive health intended to offer women the choice to have their fertility protected or extended, and to obtain donor oocytes for in vitro fertilization. We have exclusively licensed proprietary technology that allows the cryopreservation of oocytes by developing a cryopreservation media. A study of the application of this media published in Human Reproduction, a peer-reviewed journal, documented four pregnancies and five live births following 11 embryo transfers. To support our launch of the product, we are working with in vitro fertilization centers to seek to demonstrate additional births using this technology. Subject to our media supplier obtaining FDA 510(k) clearance for our media, we intend to commercialize Viacyte. Our media supplier has been recently advised by the FDA that it will need to conduct a clinical study to support clearance. Our media supplier has submitted existing, published third party clinical data to the FDA. While we believe this data may be sufficient to support 510(k) clearance of the media, it is likely that the FDA will require a new clinical trial to support 510(k) clearance. If the FDA requires that new clinical trials be conducted to support the submission for 510(k) clearance, subject to obtaining FDA clearance, we would expect to launch Viacyte no earlier than sometime in 2007; if new clinical trials will not be required, then, subject to obtaining FDA clearance, we would expect to be able to launch in 2005.

Opportunities in Cellular Therapy

The human body is comprised of both cells that have differentiated into specific tissues (such as skin, liver or blood) and stem cells that are not fully differentiated. There are many types of stem cells in the human body. 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. Stem cells are found in different concentrations and in different locations in the body during a person s lifetime. Current scientific findings suggest that each organ and tissue in the body is formed, maintained and possibly rejuvenated to different degrees, on a more or less continual basis under normal conditions, by specific and relatively rare stem cell populations naturally present in the body.

Stem cell therapy represents an increasingly important modality in treating and curing human disease. Stem cell therapy involves the use of living cells to replace and initiate the production of other cells that are missing or damaged due to disease or injury. Today, stem cell therapy is limited to the use of hematopoietic (blood) stem cells to regenerate healthy, functioning bone marrow to establish and maintain the blood and immune system. Additional types of stem cells which may have therapeutic use include neural (capable of differentiating into nerve and brain tissue), mesenchymal (capable of differentiating

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into bone, cartilage and fat) and pancreatic islet stem cells (capable of differentiating into cells secreting insulin). Hematopoietic stem cell therapy is a medical procedure in which bone marrow, umbilical cord blood or processed circulating blood (all of which contain hematopoietic stem cells) are infused into the patient s circulatory system, where they find their way to the bone cavity. Once established in the bone, they begin to grow, or engraft, and produce cells of the blood and immune systems. Cells for this procedure are typically obtained from a donor, though, in some cases, the patient s own cells may be used.

Hematopoietic stem cell therapy can be used to:

- replace diseased bone marrow with healthy, functioning bone marrow for patients with blood diseases such as aplastic anemia;
- replace bone marrow damaged by high-dose chemotherapy or radiation therapy used to treat patients with a variety of cancers such as leukemia and lymphoma; and
- provide genetically healthy and functioning bone marrow to treat patients with genetic diseases such as sickle cell anemia.

Hematopoietic stem cell therapy has been successfully employed in the treatment of a variety of cancers and other serious diseases, beginning with bone marrow transplants that were first pioneered in the 1960s. According to the International Bone Marrow Transplant Registry, 45,000 hematopoietic stem cell transplants were performed worldwide in 2002. We estimate that this correlates to a market size of roughly $900 million, using an average cost of cellular material per treatment of $20,000 based on data from the International Bone Marrow Transplant Registry. Many more patients needed transplants, but suitably compatible cells could not be found. Although the safety and efficacy of CB001 has not yet been, and may never be, demonstrated in humans, we believe that CB001 may provide a more effective treatment with fewer side effects and faster recovery than current therapies and will enable this therapy to reach more patients in need.

Current scientific and clinical research indicates that stem cells have tremendous promise in the treatment of diseases in addition to those currently addressed with hematopoietic stem cell therapy. Researchers have reported progress in the development of new therapies utilizing stem cells for the treatment of cancer, cardiac, neurological, neuromuscular, immunological, genetic, pancreatic, liver and degenerative diseases.

The success of current and emerging stem cell therapies is dependent on the presence of a rich and abundant source of stem cells. Umbilical cord blood has emerged as an excellent source for these cells. As information about the potential therapeutic value of stem cells has entered the mainstream, and following the first successful cord blood transplant performed in 1988, cord blood collection has grown rapidly. Based on a survey of private cord blood banks conducted for us in 2000 by the Boston Healthcare Associates consulting firm, there were approximately 24,000 units stored by private cord blood banks as of June 1999. That number had increased to 178,000 units as of September 2003, according to a survey by the independent organization Parent s Guide to Cord Blood Banks, representing an increase of over seven-fold over the past four years. We believe, based on the demographic profile of our average Viacord customer, that the total available target market could grow to 25% of US births driven by:

- increased awareness about the availability and benefits of preserving cord blood;
- growing endorsement by the medical community;
- new applications for cell therapy; and
- potential for expanding the number of stem cells in a single unit of cord blood, making it possible to treat larger, adult patients or multiple patients within a family.

Another opportunity in the use of cells for therapy relates to oocytes, which are female egg cells essential to reproduction. The ability to preserve these cells outside the body could be a significant breakthrough in the field of reproductive health with multiple applications in infertility (extending fertility and preventing infertility).

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Women choosing to extend their fertility represent a large segment of our potential market opportunity. 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, increasing from age 21 in 1970, according to the Center for Disease Control and Prevention. This trend is driven in part by rising birth rates for women in their 30 s and 40 s. Despite this trend, female fertility actually begins to decline at around age 26, and declines more rapidly after age 35. Declining oocyte viability due to the natural aging process is one of the major factors contributing to compromised fertility in women. Cryopreservation stops the aging of cells, and, although the long-term safety of cryopreserved oocytes has not been, and may never be, demonstrated, we believe this product candidate could allow a woman to have a child later in life, using one of her own younger and potentially healthier oocytes. According to the 2000 US Census, there are approximately 4.3 million women in the United States between the ages of 27 and 36 with household income exceeding $65,000, who we believe would be potential users of this product.

Our oocyte product candidate, Viacyte, may 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 prior to undergoing or immediately following chemotherapy or radiation in order to preserve their ability to have a child in the future.

Other significant market opportunities for oocyte cryopreservation include using our product candidate to aid women (or couples) who require IVF, but who have ethical concerns about embryo cryopreservation and those individuals seeking donor oocytes, but for whom the logistics of coordinating a donor-recipient cycle present a challenge. We do not intend to use our oocyte product in connection with the use or harvesting of stem cells from embryos.

Current Limitations of Cellular Therapy

Despite the proven clinical utility of hematopoietic stem cell therapy and the potential to use other types of cellular therapies to treat and cure disease, widespread application of cellular therapy is presently hindered by the following factors:

Lack of Compatible Stem Cells

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

Difficulties Collecting Stem Cells

In general, harvesting sufficient quantities of stem cells from a donor or a patient is extremely difficult. All current methods of obtaining hematopoietic stem cells for therapy have significant limitations. Stem cells can be collected from bone marrow through a painful, costly and invasive surgical procedure. There are not enough donors registered and, when called upon, a large number of donors fail to follow through with the procedure.

Stem cells can also be collected from blood of the circulatory system through a procedure in which drugs are injected into the donor to stimulate the movement of stem cells from the bone marrow into the blood stream, where they can be harvested and then separated from the whole blood. This procedure is time-consuming and uncomfortable for the donor.

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Umbilical cord blood is also rich in stem cells, but the volume of blood collected is limited. Although there are banks of cord blood available for transplant, units are often too small to be suitable to treat adult patients.

Stem cells can also be derived from human embryonic tissue. However, their utility is presently technically limited and is hampered by ethical and regulatory issues that restrict their use.

Insufficient Number 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. The likelihood and speed of successful stem cell engraftment are directly related to the number of stem cells transplanted. Consequently, the ideal approach to a successful transplant is to use a large number of stem cells. Researchers have been working for decades on methods for expanding populations of donated stem cells, but their efforts have been largely unsuccessful.

Most attempts to increase the number of stem cells involve methods of growing or culturing stem cells in batches. Batch production of stem cells is not effective because differentiated cell populations outgrow stem cells and create by-products that hinder the growth and maintenance of stem cells. Few stem cells, if any, are produced using this process. Mixed populations of cells that result are also difficult to characterize, creating the possibility of clinical side effects as compared with a pure stem cell population. Furthermore, batch production of cells is expensive; large amounts of materials and production capacity are required to accommodate large cultures necessitated by the low concentration of stem cells.

Variability in Quality and Composition of Stem Cell Products

Bone marrow, processed circulating blood and umbilical cord blood are crude mixtures of largely differentiated cells with small numbers of stem cells, contributing to unpredictability in clinical responses. Cord blood samples, for example, vary in stem cell count as well as composition. Because stem cells harvested from bone marrow are collected from individuals of different ages in various states of health, the stem cell quality and consistency is affected. Additional variability arises from inconsistencies in handling and processing in different transplant centers.

Difficulties in Preserving Oocytes

While methods for preserving sperm and embryos are well-established and have been utilized in *in vitro* fertilization procedures for the past three decades, methods for preserving oocytes have not been widely employed due to difficulties encountered in freezing this cell. The oocyte is the largest cell in the body and, due to its large liquid volume, tends to form ice crystals during the freezing process. Formation of ice crystals can damage this cell, making it unsuitable to develop into a healthy embryo. These obstacles represent a significant barrier to the preservation of oocytes for treatment of chemotherapy-treated, donor-recipient, IVF and age-related infertility patients.

Our Solutions in Cellular Therapy

We have developed proprietary technologies that we believe will overcome the barriers to the widespread use of cellular therapies. Although the safety and efficacy of stem cell populations expanded using our Selective Amplification technology has not been, and may never be, demonstrated in humans, in pre-clinical studies we have significantly expanded populations of stem cells using this technology to produce highly purified, highly defined stem cells in clinically useful quantities. We believe that this breakthrough has the potential to enable important new treatments for a broad range of cancers and other serious diseases.

Our Selective Amplification technology involves the expansion of stem cell populations using growth stimulating factors together with cycles of purification to remove differentiated cells using antibodies that target proteins on their surface. By repeating growth and purification cycles, we are able to greatly expand highly defined populations of stem cells in what we expect to be a commercially feasible system.

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We are focusing our initial clinical efforts on developing CB001, a hematopoietic stem cell therapeutic comprised of expanded cord blood stem cell populations. We are developing CB001 as a replacement for bone marrow and other crude cell mixtures currently used in hematopoietic stem cell transplants under the current standard of care and are currently evaluating CB001 in a Phase I clinical trial. We believe that expanding hematopoietic stem cells through Selective Amplification can overcome the current limitations of hematopoietic stem cell therapy by:

Increasing the Likelihood of Locating Compatible Stem Cells. Most cord blood units collected, preserved and stored do not contain sufficient stem cells to treat an adult patient. Through Selective Amplification, we believe we will be able to expand the number of stem cells contained in each unit so that every unit is potentially suitable to treat a patient, regardless of size. In addition to size limitations, HLA matching limitations exist particularly for racial minorities that are proportionally under represented in current inventories. If every cord blood unit that is collected, preserved and stored can be expanded, the likelihood of locating compatible stem cells is increased.

Obtaining Stem Cells From an Abundant Source. Umbilical cord blood contains a rich supply of stem cells. With approximately 4 million births per year in the United States, cord blood represents a large, natural resource provided it can be efficiently and cost-effectively converted into standardized medicine. With the use of Selective Amplification, we believe that this source will be more than adequate for patients of all sizes and all racial and genetic backgrounds and for treating a large variety of disease indications.

Increasing the Number of Stem Cells. We have increased hematopoietic stem cell populations by up to 150-fold, with an average of 35-fold expansion within a 14-day period. The potency of a cord blood unit has been correlated with the number of hematopoietic stem cells in the graft. The number of stem cells in an average cord blood unit are generally considered to be insufficient to engraft an adult by a factor of 2 to 10. The increase in stem cell populations that we have achieved may therefore be highly significant in producing therapeutic effects.

Producing Stem Cell Products of a Consistent Quality. Although we have not yet scaled up our Selective Amplification manufacturing process to commercial levels, we believe that Selective Amplification can be incorporated into a robust manufacturing process that provides a consistent, highly defined stem cell product. As hematopoietic stem cell populations grow, they produce differentiated cells that dilute the therapeutic population of stem cells. Using selection techniques that eliminate differentiated cells from the cell population, we are able to maintain high purities in our candidate cell products. In addition to our Selective Amplification technology, we are developing other technologies, especially those based on the propagation of Unrestricted Somatic Stem Cells (USSCs), that we expect to have therapeutic potential in cardiac repair, and other indications, although we have not yet demonstrated the safety and efficacy of USSCs for any indication in humans and may not be able to do so.

Additionally, we believe that the current limitations associated with cellular therapy for the treatment of infertility can be overcome by effectively preserving and storing oocytes.

Preserving and Storing Oocytes. Slow freezing techniques using high choline media have improved oocyte survival rates and have produced live births. We believe that our procedures for preserving and storing umbilical cord blood can be leveraged to launch our proprietary oocyte cryopreservation product candidate Viacyte. Results to date using these procedures have indicated an ability to predictably cryopreserve oocytes and produce live births. Subject to obtaining FDA 510(k) clearance for our proprietary media, we believe that we will be in a position to leverage our sales and marketing experience in the field of reproductive health to provide women with the choice of preserving their fertility.

Our Business Strategy

We believe that we have the infrastructure in place, combined with proprietary technologies and strategic partnerships, to be a leader in cellular therapy and reproductive health.

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We intend to use our existing assets to implement a business strategy having the following principal elements:

Demonstrate the Clinical Benefit of and Obtain Approval for our Lead Stem Cell Product Candidate, CB001

We are seeking to establish the clinical and therapeutic validity of our Selective Amplification technology by initially developing CB001 for hematopoietic cell transplantation, currently the most widely used form of stem cell therapy. We believe that seeking approval for a product candidate which addresses an established market and is a highly purified and characterized version of an existing therapy represents the most rapid and low risk route to commercialization of our technology. Focusing on the hematopoietic market also allows us to demonstrate the potential of our lead stem cell product candidate, CB001, to significantly improve patient health while addressing a large, unmet need in the marketplace.

Leverage our Technology to Commercialize Additional Products to Effectively Treat and Potentially Cure Patients with Unmet Clinical Needs

We intend to follow the advancement of CB001 with the development of product candidates for indications historically not treated with stem cell therapy. While research has demonstrated the potential for applying stem cell technology to a number of indications, such as diabetes and heart disease, advancement in these areas has been slow. We believe our Selective Amplification and other technologies can overcome the limitations which have to date prevented the successful application of stem cell therapies in these areas. We have active programs for the development of cell therapies for cardiac disease and diabetes.

Leverage ViaCell Reproductive Health to Provide Financial Stability and Create Additional Value

We intend to leverage the cash flow and assets generated from our reproductive health activities to provide financial stability. Viacord s processing and storage revenue has grown rapidly, with an increase in revenues of 19% in 2004 over 2003, while direct costs of revenues increased 3% over the same period. We intend to continue to invest in the reproductive health area and expand our obstetrician and consumer-directed education and marketing program. In addition, we plan to further leverage our investments in these areas with the launch of our oocyte cryopreservation product candidate Viacyte.

Continue to Develop and Grow Areas of Our Business that are Complementary to Each Other

Our stem cell therapy product candidates are expected to make use of the readily available source of stem cells present in umbilical cord blood. We offer cord blood preservation to customers who want to preserve this blood to take advantage of these therapeutic products in the future. The storage of cord blood from related individuals greatly increases the probability of an HLA match and, when combined with our expansion technologies, potentially allows whole families to benefit from banked stem cells. In addition, our cord blood preservation product has established our presence in the reproductive health field. Leveraging our presence in this field and our cryopreservation expertise, we have in-licensed technology which allows the preservation of human oocytes in a frozen state. We intend to develop and commercialize this technology within our existing commercial infrastructure by leveraging the assets invested in this business, and we may seek to expand our business in other complementary areas in the future.

Continue to Build Strategic Business Relationships

We believe that our Selective Amplification and other technologies have extremely broad potential applications. While we are focused on the development of our own proprietary therapeutic product portfolio using these technologies, we will seek to partner with third parties to develop other applications of these technologies. These could include applications that fall outside our core areas of interest, or applications where the involvement of a strategic partner may significantly improve the chances of commercial success. An example of the latter is our recent collaboration with Amgen. Where strategically

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advantageous, we will continue to look to structure high value collaborative relationships with industry leaders. We intend to pursue collaborations with companies that possess the resources and expertise to develop and commercialize products for indications outside the scope of our internal development programs.

Strategically In-License or Acquire Complementary Products, Technologies and Businesses

We intend to supplement our product development efforts through the acquisition of products and technologies that support our business strategy. An example of this is our acquisition of Kourion Therapeutics AG completed in September 2003, pursuant to which we gained access to USSCs. Also in 2004, we exclusively in-licensed an oocyte preservation technology that is highly complementary to our presence in cord blood preservation. This technology is expected to allow women to better preserve their fertility. In the future, we may pursue additional strategic acquisitions of technologies, product candidates and businesses to further strengthen or expand our current programs.

Our Technology

Selective Amplification Our Method to Expand Stem Cell Populations

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

The Selective Amplification process is described below:

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

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

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

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

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

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The Selective Amplification process results in a highly characterized population of stem cells. Systems for the selection of cells and techniques to culture cells to expand populations have existed for decades. Our patented Selective Amplification technology employs the combination of selection with growth. We believe that the proprietary methods we have developed may potentially limit the ability of others from selecting cells that are being or have been expanded.

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Unrestricted Somatic Stem Cells (USSCs) Our Proprietary Type of Stem Cell

To date researchers have identified many different types of stem cells from many sources. These include, for example, embryonic stem cells from embryos, neural stem cells from the brain, hematopoietic stem cells from bone marrow and pancreatic islet stem cells from the pancreas. Each type of stem cell appears to have unique properties, and the overall properties of different stem cells can be quite diverse. For instance, some propagate well but are difficult to differentiate efficiently, some differentiate efficiently but are difficult to propagate; some appear to be unipotential in that they can only make one class of tissue, while others appear to be pluripotential in that they can make a variety of tissue types.

We are developing applications of a proprietary type of stem cell called Unrestricted Somatic Stem Cells (USSCs) derived from umbilical cord blood. Our pre-clinical research indicates that USSCs are a pluripotent class of stem cells that have the ability to differentiate into many cell types, including fat, bone, cartilage and precursor neuronal cells under specified *in vitro* culture conditions. Furthermore, our evidence in animal models suggests that this cell type is capable of differentiating in many tissue types as shown by distribution and function of human cells in the liver, bone, bone marrow, brain and heart of transplanted animals. Although USSCs have not been tested in humans and their safety and efficacy has not been, and may never be, established, based on our preclinical results, we believe that USSCs may be a suitable starting population to produce a variety of stem cell therapies. Patents are pending on therapeutic uses and compositions of matter for this previously undiscovered cell type. The discovery that such cells exist in cord blood may solve major concerns about matching non-hematopoietic cell products into diverse patient populations without graft rejection or the use of immune-suppression, as large reserves of banked cord blood units provide suitably matched source material. We are currently developing this technology for use in the treatment of cardiac disease.

The addition of the USSC technology into our portfolio is complementary to both the cell therapy and reproductive health aspects of our business. With USSCs, we believe we will have the raw material to develop products for additional critical indications involving diseases of the liver, muscle, bone marrow, pancreas, brain and heart. We believe that the controlled *in vitro* production of specific cell products from USSCs may benefit from the use of our patented Selective Amplification technology. We also believe that further development of USSCs may, if successful, benefit our cord blood preservation customers who may need to access such cells from their stored cord blood for future medical applications.

Cryopreservation of Oocytes

We have exclusively in-licensed technology that we believe will allow the successful cryopreservation of human oocytes using a cryopreserving media. We are currently engaged in pre-commercial development of this technology. Our current efforts are focused on optimizing and standardizing this procedure. In addition, we are continuing to evaluate other technologies for the cryopreservation of human oocytes in order to provide the best solution for our customers.

Our Product and Product Candidates

The following table summarizes our product and pipeline of programs:

Product/Program	Intended Use	Status
Viacord	Pediatric hematopoietic stem cell transplantation for the donor and siblings	Marketed
Viacyte	Preservation of fertility	Pre-Commercial Stage
Hematopoietic (CB001)	Hematopoietic stem cell transplantation for a variety of cancers and other serious diseases	Phase I
Cardiac Disease	Congestive heart failure; Myocardial infarction	Preclinical
Other	Diabetes	Research

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Hematopoietic Program (CB001)

Background/ Target Market. Hematopoietic stem cell therapy is an accepted medical procedure that provides for regeneration of blood and immune systems in patients for the treatment of cancer and other serious genetic and acquired diseases. Patients requiring this type of therapy are typically very sick. The treatment is usually undertaken when there are few, if any, alternatives, and consequently patients needing therapy who do not obtain it often die. According to the International Bone Marrow Transplant Registry, in 2002, clinicians performed approximately 45,000 hematopoietic stem cell transplants worldwide using cells obtained from bone marrow, peripheral blood and, to a lesser extent, umbilical cord blood.

CB001 consists of a highly concentrated and purified population of hematopoietic stem cells which are selectively amplified from umbilical cord blood that we currently obtain from public cord blood banks. Although the safety and efficacy of CB001 has not yet been, and may never be demonstrated, because of its high stem cell concentration and purity relative to transplant mixtures obtained from other sources, we believe that CB001 may provide a more effective treatment with fewer side effects and faster recovery. In particular, we believe that the administration of CB001 will result in less GVHD, often a severe complication of transplant therapy, and accelerate hematopoietic reconstitution which drives the generation of early neutrophil recovery. Neutrophils are the body s first defense against infections. Early neutrophil recovery is associated with fewer opportunistic infections and a reduced length of hospital stay. Our belief that treatment with CB001 may result in lower incidence of GVHD and enhance early neutrophil recovery is based on the historically low incidence of GVHD when using cord blood as a transplantation source, in combination with the expectation that more stem cells will increase the rate of engraftment, an assumption based on extensive clinical data reported in the literature to that effect. Furthermore, although the efficacy of CB001 for other indications has not been demonstrated, because of its attributes, we believe CB001 has the potential to significantly expand the market for stem cell therapy to new indications.

Program Status. In preclinical studies, CB001 exhibited no acute toxic effects when injected into mice at doses comparable to and higher than that planned in the clinical trial program. When tested in a variety of laboratory tests and standard animal models, the components used to manufacture CB001 similarly exhibited no toxicity. In addition, when CB001 was injected into a special immunocompromised mouse breed, CB001 went to the bone marrow of the mice, and human hematopoietic and immune cells grew and appeared in the blood of the mice, indicating that CB001 contains functional stem cells. We cannot guarantee that the results we have observed for CB001 in animals, including lack of toxicity, will be duplicated in humans.

We submitted an Investigational New Drug application (IND) with the US Food and Drug Administration (FDA) in October 2001. We instituted certain manufacturing improvements and design changes to our clinical protocol and submitted a redesigned clinical protocol and other supportive information in November 2003. We are currently enrolling patients in a Phase I clinical trial to assess the safety and preliminary clinical efficacy activity of CB001. Our Phase I study will initially be limited to 10 patients. The patient population eligible for participation in this trial includes children and adult patients (ages 2-60) with acute lymphocytic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, and non-Hodgkin lymphoma. The patients will receive CB001 plus a standard cord blood transplant (derived from different donors) following high dose chemotherapy and radiation therapy. The patients will be closely monitored to ensure their safety, and all adverse events will be reported to the FDA and institutional review boards following standard procedures and regulations for a Phase I clinical trial. When new hematopoietic cells begin to grow (engraft) in the patients, we will be able to differentiate between cells coming from CB001 and cells coming from the standard cord blood due to genetic differences in the two types of donor cells. We estimate that we will enroll and treat 10 patients and complete patient follow-up by the end of 2005. We intend for the data generated from this trial to be used to support Phase II clinical trials. To date, CB001 has been administered to six patients in this clinical trial and more patients are being screened for enrollment. We are currently optimizing the CB001 manufacturing process to increase the levels of stem cell amplification, and we may add up to six additional patients to the Phase I study to evaluate the safety and efficacy of the optimized process. We anticipate that adding patients would potentially lengthen the study by approximately six months.

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If there are no significant safety issues related to CB001 and there is evidence of CB001 engraftment in the Phase I clinical trial, then we plan to initiate Phase II clinical trials. If evidence of engraftment with CB001 is shown in the Phase I clinical trials, we plan to conduct Phase II clinical trials designed to demonstrate that CB001 can serve as a sole source of hematopoietic stem cells in patients requiring hematopoietic stem cell transplantation who are unable to find suitable stem cell donors. However, the Phase I clinical trial may not provide evidence of CB001 engraftment due to competition between CB001 and the standard cord blood transplant. If there are no significant safety issues in the Phase I clinical trial but CB001 engraftment is not shown, then we may need to perform additional pre-clinical and/or clinical studies prior to commencing the Phase II clinical trials. If Phase II clinical trials show strong evidence of efficacy and a favorable safety profile in patients unable to find suitable donors, we will consider filing an application with the FDA based on the Phase II data and seek priority review. We expect that any Phase III clinical trials will be designed to demonstrate superiority of CB001 compared to standard transplantation methods. We intend to select the Phase III clinical trial outcome measures to establish that CB001 is superior to standard stem cell sources based on clinically meaningful endpoints. In addition, if approved by the FDA, we intend to subsequently seek regulatory approval for CB001 in other countries.

Viacord

Our Viacord product involves the collection, testing, processing and preserving of umbilical cord blood. Our customers are expectant parents who choose to collect and store umbilical cord blood at the birth of their child for potential use in a pediatric hematopoietic stem cell transplantation for the donor and family members. We have established a leading position in this emerging field of private umbilical cord blood preservation, with an estimated market share of approximately 21% total units stored and 25% of revenue generated in the United States, based on estimates by the independent organization Parent s Guide to Cord Blood Banks of total units stored in family cord blood banks (178,000 as of September 2003) and by an independent market researcher of industry revenue ($128 million in 2003). Based on our phone surveys of, and public statements by, private cord blood banks regarding their number of units stored, we estimate that in 2003, 70,000, or 1.7%, of the 4 million birthing families chose to preserve their child s umbilical cord blood for potential future use in the family. Over the past three years, the number of customers in this industry has grown significantly. We believe, based on the demographic profile of our average Viacord customer, that the total available target market could grow to 25% of US births. Our current list price for collecting, testing and cryopreservation of a child s umbilical cord blood is $1,800, and our current list price for annual storage of the cryopreserved blood is $125. Our list prices vary from time to time, and we offer discounts from our list prices under certain circumstances from time to time.

Family cord preservation has been growing in acceptance by the medical community and has become increasingly popular with families. To date, we have performed facilitated collections at over 2,000 hospitals in the United States. We currently store over 64,000 cord blood units for customers. We provide the following services to each customer:

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

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

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

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

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We believe that our Viacord product complements our ability to deliver cellular medicines by providing:

- experience in providing banked umbilical cord blood for stem cell transplantation, with sixteen of our customers umbilical cord blood units used in transplantations to date;
- strong relationships in the cell therapy community, including leading transplant centers;
- expertise in cord blood collection, testing and preservation; and
- overall financial stability.

Moreover, we believe that the advancement of hematopoietic stem cell therapy, and the introduction of new stem cell therapies, will further drive demand for cord blood products.

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

Oocyte Cryopreservation Program

Background/ Target Market. Our cryopreserved oocyte product candidate, Viacyte, may provide women the opportunity to extend or protect their fertility, or obtain donor oocytes for IVF. However, to date, oocyte cryopreservation has not been widely practiced because these cells become damaged by the freezing or thawing process using current methods. According to our estimates based in part on the 2000 US Census, there are approximately 4.3 million women in the United States between the ages of 27 and 36, with household income exceeding $65,000, who we believe would be potential users of this product for the purpose of extending their fertility. We have licensed proprietary technology that allows the cryopreservation of oocytes by developing a cryopreservation media that helps protect the cells from damage. A study of the application of this media published in *Human Reproduction,* a peer-reviewed journal, documented four pregnancies and five live births following 11 embryo transfers.

We believe that Viacyte will complement our existing Viacord product by:

- using our existing operational infrastructure and facilities, including our cell processing and storage facility in Hebron, Kentucky where long-term storage of oocytes would be maintained; and
- utilizing our sales, marketing and clinical support staff and our current marketing channels to educate consumers and healthcare professionals, including obstetricians, gynecologists, and oncologists.

We believe that oocyte preservation represents an attractive opportunity for us to expand on our commitment to offer innovative options to patients and physicians related to reproductive health.

Program Status. We are currently engaged in pre-commercial development of Viacyte. Our efforts are focused on optimizing and standardizing this patented procedure for freezing oocytes and maintaining maximum cell viability following cryopreservation. Prior to marketing Viacyte, 510(k) clearance must be obtained from the FDA for our proprietary oocyte cryopreserving media. Our media supplier submitted a 510(k) on November 12, 2004. The 510(k) clearance process typically takes three to twelve months from the time of submission to being able to market a product, but can take significantly longer. Our media supplier was recently advised by the FDA that it will need to conduct a clinical study to support clearance. Our media supplier has submitted existing, published third party clinical data to the FDA. While we believe this data may be sufficient to support 510(k) clearance of the media, it is likely that the FDA will require a new clinical trial to support 510(k) clearance. If the FDA requires that new clinical trials be conducted to support the submission for 510(k) clearance, subject to obtaining FDA clearance, we would expect to launch Viacyte no earlier than sometime in 2007; if new clinical trials will not be required, then, subject to obtaining FDA clearance, we would expect to be able to launch in 2005.

In any event, in 2005, we intend to commence a human clinical study to seek to demonstrate additional healthy live births from previously frozen oocytes using this technology. We are also evaluating

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other technologies in order to develop the best product candidate, including the possibility of in-licensing or otherwise acquiring other oocyte technologies.

We anticipate that our first sales and marketing efforts will be directed at women seeking to extend their own fertility. This product will be marketed and sold by ViaCell Reproductive Health, leveraging our Viacord field sales personnel (clinical specialists) and marketing infrastructure.

Cardiac Disease Program

Background/ Target Market. 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 that has formed on a plaque formed by arteriosclerosis. If the blood supply is cut off drastically or for a long time, heart muscle cells suffer irreversible injury and die. According to a study by the National Heart, Lung and Blood Institute, there are approximately 1.2 million cases of myocardial infarction each year in the United States, with a fatal outcome in about 42% of cases. Many patients who survive develop a chronic form of heart disease called congestive heart failure (CHF) which is associated with a progressive deterioration of the heart muscle. According to the National Heart, Lung and Blood Institute, about 2.4 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 or regenerating damaged heart tissue. Recent clinical data obtained with crude preparations of stem cells isolated from the patient s own bone marrow, however, indicate that cardiac function may be able to be improved by the application of stem cells. Based on these clinical studies and our preclinical investigations, we believe that USSCs may regenerate damaged heart tissue and may be an effective, standardized product for heart repair.

Program Status. We are currently evaluating USSCs in mouse and pig models of CHF and myocardial infarction in collaboration with researchers at the Toronto University Hospital, Canada and at the Wolfgang Goethe University, Frankfurt, Germany and at the American Cardiovascular Research Institute, Atlanta, Georgia. These experiments are intended to allow us to evaluate the ability of USSCs to repair damaged heart tissue in these animals and determine the dose and route of administration to be used in our initial human clinical studies. In December 2004, we entered into a Material Transfer Agreement with Advanced Cardiovascular Systems, Inc. (ACS), a subsidiary of Guidant Corporation, under which ACS will provide intracoronary catheters to us for our evaluation of USSCs in our animal studies, as well as partial funding for this study. If we successfully complete pre-clinical development, we expect to complete an IND and initiate a Phase I clinical trial in 2006.

Other Programs

Research Stage Programs. In addition to our programs described above, we also have a research-stage program in collaboration with Genzyme targeting applications in diabetes. Our diabetes program uses a novel population of stem cells isolated from the pancreas that can be significantly expanded in culture. To date, we have successfully expanded these pancreatic stem cells and they have shown the ability to produce insulin in mouse models of diabetes. Our diabetes program is based on technology that has been licensed to us by Massachusetts General Hospital.

Other Potential Applications. In addition to the applications we are pursuing, we believe that our Selective Amplification and USSC technologies may be applied potentially to treat a wide variety of other diseases, including autoimmune and other immune system disorders, and other degenerative disorders, as well as genetic diseases such as sickle cell anemia and various metabolic diseases.

Sales and Marketing

Viacord. Our ViaCell Reproductive Health sales and marketing organization consists of 65 sales and marketing professionals supporting our Viacord product. Our staff of 30 internal sales personnel interact

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with over 20,000 potential customers per month and enroll those customers who decide to purchase our Viacord product. We have an expanding field sales organization, with representatives in territories which cover 800 of the 1,000 largest birthing centers in the United States and who educate obstetricians, child birth educators, hospitals and insurers on the benefits of cord blood preservation. In addition, our marketing staff targets two primary segments: high-birthing obstetrics practices and expectant families. We target expectant families through many mediums, including targeted advertising, direct mail and web-based marketing activities that collectively generate more than 20,000 new inquiries to ViaCell Reproductive Health each month. Historically, we have been able to convert approximately 8% of these inquiries into customers for our Viacord product.

Oocyte Preservation. We plan to market and sell Viacyte using our ViaCell Reproductive Health sales personnel and marketing infrastructure where possible. In addition, we plan to develop a specialty sales force to educate reproductive endocrinologists and other medical professionals at IVF centers throughout the United States about the benefits of Viacyte. We plan to use our internal clinical consultants in our call-center to answer questions and provide support to customers purchasing or considering to purchase our products. We may also consider potential strategic partnerings in marketing these product candidates, if successfully developed.

Cell Therapy Products. We plan to sell our cell therapy product candidates, if successfully developed, principally through our own sales force, leveraging our ViaCell Reproductive Health sales and marketing infrastructure where possible. On any product candidates which Amgen has elected to collaborate (which may include CB001 or any other of our products incorporating Amgen technology), Amgen will be responsible for regulatory matters, marketing and selling activities. We may also enter into co-marketing, licensing or other arrangements with other third parties in order to gain access to their marketing resources and distribution network in specific markets.

Manufacturing and Cell Processing

We believe that commercial manufacturing of stem cell products will be strategically important to us. In order for us to ensure strict quality control, identify and leverage cost-efficiencies, and build deep expertise in expansion and processing of cells, we intend to own and control all aspects of the cell production process. We believe that manufacturing capabilities will contribute significantly to our ability to achieve leadership in our industry.

We currently produce cells for our initial clinical trials in our cell manufacturing facility in Worcester. This facility, which we constructed in 2000, was designed to conform to FDA cGMP regulations and standards for Phase I trials, and includes approximately 3,000 square feet of space. Within the next 12 months, we intend to construct a larger scale, validated and cGMP-compliant production facility at our new headquarters in Cambridge, Massachusetts to replace our facility in Worcester. We intend to use the new facility to produce cells for our Phase II and pivotal Phase III trials and initial commercialization.

Additionally, we currently process, test and preserve umbilical cord blood at our facility in Hebron, Kentucky. This facility, which we constructed in 2002, is designed to operate following Good Tissue Practice (GTP) regulations and guidelines, and includes approximately 12,000 square feet of processing and storage space. We anticipate that this facility will meet all our needs for Viacord and, potentially, for storage of oocytes for the foreseeable future. The managers of this facility have extensive experience in operations management, blood banking, biologics and medical device manufacturing, and maintain active programs to achieve continuous improvement in cost and process quality.

We believe that the cell processing and operational capabilities that we have developed in cord blood preservation will strengthen our ability to achieve leadership in the commercial manufacture of stem cell products.

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Collaborations, Licenses and Strategic Relationships

Our most significant collaboration, licensing and strategic relationships are described below:

Amgen

In December 2003, we entered into a license and collaboration agreement with Amgen under which we received a royalty-free, worldwide, non-exclusive license to certain Amgen stem cell growth factors for use as reagents in producing stem cell therapy products, and Amgen received an option to collaborate with us on any product or products that incorporate an Amgen growth factor or technology. Amgen can exercise its option for an unlimited number of products, on a product-by-product basis. Each time Amgen exercises a collaboration option, it must partially reimburse our past development costs based on a predetermined formula on the optioned product, 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 would 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. Under this agreement, we can purchase cGMP grade growth factors manufactured by Amgen at a specified price. Upon the mutual agreement of both parties, we also may receive a license to additional Amgen growth factors or technologies that may be useful in stem cell therapy. 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. The expiration of the issued licensed Amgen patents will occur no earlier than 2018, subject to extension upon the issuance of a patent based on a pending application or a renewal, reissuance, reexamination or other continuation or extension of a covered patent.

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

GlaxoSmithKline and Glaxo Group

In January 2003, we obtained a worldwide, non-exclusive license from GlaxoSmithKline and Glaxo Group to four forms of TPO-mimetic for use as a reagent in producing stem cell therapy products, including CB001. We paid an initial fee of $115,000 and issued to the licensors 12,500 shares of our Series I preferred stock valued at $8.00 per share (equaling $0.1 million worth of preferred stock), and agreed to pay annual license maintenance fees over the next ten years totaling $1.6 million and milestone payments potentially totaling $2.1 million. Additionally, we will pay royalties on sales of any products using the licensed technology, creditable against any remaining maintenance fees. We are responsible for all manufacturing and related costs associated with our use of TPO-mimetic. Unless earlier terminated, the license extends on a country-by-country basis until the expiration of the underlying technology patents. The expiration of the issued patents will occur, no earlier than 2022, subject to extension upon the issuance of a patent based on a pending application provided that such issuance occurs within seven years of the filing date of the application. The agreement may be terminated by either party following an uncured material breach by the other party or in certain events involving the other s bankruptcy or insolvency. In addition, we can terminate the license at any time upon 30 days advanced notice. We did not incur any royalties and recognized $165,000 of expenses in connection with the annual license

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maintenance fees. Costs associated with Series I preferred stock were charged to in-process technology for the year ended December 31, 2003.

Tyho Galileo Research Laboratory

On September 1, 2004, we entered into a License Agreement with Tyho Galileo Research Laboratory for exclusive rights to U.S. Patent No. 5,985,538 in the field of oocyte cryopreservation. As part of this agreement, we also entered into a research collaboration with Galileo, which will focus on the development of technologies in the field of oocyte and embryo cryopreservation. This project includes research funding by us totaling $207,000 in the first year and $225,000 in second year as well as a license fee of $50,000, milestones totaling $24,000 and a royalty on revenues generated from the sale of Viacyte, our oocyte cryopreservation product candidate. We are also obligated to pay Galileo an annual minimum payment of $30,000 creditable against royalty payments due under the agreement. The agreement may be terminated by either party following an uncured breach by the other party. The license expires on a product-by- product, media-by-media and country-by-country basis as the underlying patents in such country expire (if the product or media is covered by a patent claim under the license), or ten years from the date of the first commercial sale in such country (if the product or media is not covered by a patent claim under the license). The patent licensed under this agreement will expire no earlier than 2017.

Genzyme

In December 2004, we entered into a Research Agreement with Genzyme. Under the Research Agreement, we provide islet stem cells to Genzyme, and Genzyme is obligated to conduct specified research using the islet stem cells. We have granted Genzyme a right of first negotiation to enter into an agreement with us in the field of diseases and disorders of glucose metabolism or insulin insufficiency, including diabetes, using the results of the research conducted by Genzyme. If we do not reach an agreement in such negotiations, we cannot, for a period of 12 months following such negotiations, enter into an agreement with another party on terms more favorable than those we last offered to Genzyme without first offering such terms to Genzyme. We and Genzyme are also required to obtain the consent of the other party to enter into an agreement using the intellectual property arising out of the research conducted under the Research Agreement for a period of 30 months following the disclosure of such intellectual property. After such 30-month period, both parties must, for an additional 12 months, offer the other any such agreement that it proposes to enter with a third party before entering into such transaction with such third party. The agreement may be terminated by either party following an uncured breach by the other party or by Genzyme if it holds a good faith belief that further research efforts are not commercially practicable. In addition, Genzyme has made several equity investments in our company, purchasing $2.0 million worth of our Series I preferred stock in 2001, an additional $1.5 million in 2002 and $1.5 million worth of our Series J preferred shares in 2003. Also, Jan van Heek, former Executive Vice President of Genzyme and currently an adviser to that company, is a member of our board of directors.

Massachusetts General Hospital

In March 2002, the Company entered into a license agreement with Massachusetts General Hospital under which the Company received exclusive, worldwide rights to make, have made, use, sell, offer for sale, and import products based on patents (currently pending) covering inventions of Dr. Joel Habener pertaining to pancreatic stem cells for treatment of diabetes. In exchange for these rights, as part of this agreement, the Company committed to spend up to $2.0 million in the first eighteen months of the agreement to achieve a defined set of research objectives which support pre-clinical development of a pancreatic stem cell product for the treatment of diabetes. As of December 31, 2003, the Company had spent approximately $1.4 million on this project, and no further financial obligation relating to this commitment is remaining. Under this agreement, the Company was also obligated to reimburse MGH for $53,300 in patent costs incurred to date, of which $26,650 was paid in April 2002 and the remaining balance of $26,650 was paid in April 2003. In addition, the Company is required to pay certain amounts to

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MGH, contingent upon the achievement of certain milestones as defined in the agreement, totaling a minimum of $0.9 million and is required to pay royalties to MGH upon commercial sale of products covered under the license. We are also obligated to pay MGH an annual minimum payment of $30,000, creditable against milestone and royalty payments due under the agreement. We have not paid any royalties in connection with this agreement. The agreement may be terminated by either party following an uncured breach by the other party, and we can terminate the agreement at any time upon notice to MGH. Unless earlier terminated, the license expires on a country-by-country basis as the underlying patents in such country expire or, if earlier, one year after the last date of sale by us, our affiliates or our sublicensees of a covered product in such country. The Company expects that any patents that may be issued on pending patent applications will expire no earlier than 2020, subject to extension upon the issuance of a patent based on a pending application or a reissuance, reexamination, extension or other continuation of a covered patent. In addition, MGH has the right to terminate the license on a country-by-country basis if no covered product is sold in such country for a continuous twelve month period following the first commercial sale of such product, subject to our right to remedy this problem.

Acquisition of Kourion Therapeutics

In September 2003, we acquired Kourion Therapeutics, a pre-clinical stage biotechnology company located in Langenfeld, Germany. Kourion Therapeutics identified USSCs, a stem cell type that can be isolated from umbilical cord blood and which we believe may be significantly expanded *in vitro.* In preclinical studies, USSCs have demonstrated the potential to differentiate into multiple other cell types, including bone, cartilage, muscle, heart and neural cells. We are currently studying USSCs in mouse and pig models of CHF and myocardial infarction. If we successfully complete pre-clinical development, we expect to complete an IND and initiate a phase I clinical trial. By acquiring Kourion Therapeutics, we acquired key intellectual property rights to USSCs (covered by one US patent application, one international application and eighteen foreign applications) and other patent applications covering technology in the field of stem cell transplantation.

In the acquisition, we issued to the former shareholders of Kourion Therapeutics 549,854 shares of our Series I convertible preferred stock, valued at approximately $4.4 million. As potential additional consideration, we issued 241,481 additional shares of Series I convertible preferred stock, valued at approximately $1.9 million, to an escrow account (escrow shares) and reserved 289,256 shares of Series I convertible preferred stock, valued at approximately $2.3 million (contingent shares) for possible issuance in the future. At the end of September 2006, the escrowed shares will be returned to us and the 289,256 contingent shares will never be issued if a change in control of the company has not occurred by that date. Upon the closing of our initial public offering, the escrow shares automatically converted, along with all other outstanding shares of Series I preferred stock, into shares of our common stock. In the transaction, we also gave promissory notes totaling $14.0 million to funds affiliated with MPM Asset Management LLC, who were the holders of all outstanding preferred shares of Kourion Therapeutics, which notes were repaid by us upon the closing of our initial public offering.

If the contingent shares issue upon a change in control, the recipients of these shares will be issued an additional number of shares equal to 8% of the initial number of contingent shares issued compounded annually from the Kourion acquisition closing date to the date of issuance. Under the Kourion acquisition agreement, we are also obligated to make payments to Kourion Therapeutics former shareholders if and when the cardiac repair program we have assumed in the acquisition achieves certain milestones. Should all these milestones be achieved, including final FDA approval of the developed products, we would have to pay a total of $12.0 million, either in stock or cash at the shareholder s option. See Management s Discussion and Analysis of Financial Condition and Results of Operations Kourion Acquisition .

In December 2004, our board of directors approved a plan to transfer the operations of Kourion Therapeutics to the United States and to close the laboratory in Langenfeld, Germany. We expect to complete this transfer by the end of the second quarter 2005. We recorded a restructuring charge of approximately $1.2 million in the fourth quarter of 2004.

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Intellectual Property

The protection of our intellectual property is a strategic part of our business. We currently own or have exclusively in-licensed the six US patents identified below.

Patent Number	Title	Expiration Date
US Patent No. 5,674,750	Continuous Selective Clonogenic Expansion of Relatively Undifferentiated Cells	10/7/2014
US Patent No. 5,925,567	Selective Expansion of Target Cell Populations	10/7/2014
US Patent No. 6,338,942	Selective Expansion of Target Cell Populations	10/7/2014
US Patent No. 6,429,012	Cell Population Containing Non-Fetal Hemangioblasts and Method for Producing Same	10/6/2017
US Patent No. 5,985,538	Cryopreservation and cell culture medium comprising less than 50 mM sodium ions and greater than 100 mM choline salt	8/1/2017
US Patent No. 6,886,843	Method of Transplanting in a Mammal and Treating Diabetes Mellitus by Administering Pseudo-Islet Like Aggregate Differentiated from a Nestin-Positive Pancreatic Stem Cell	12/5/2020

Three of our owned and issued US patents are directed to methods of manufacturing target populations of primary cells for use as cellular medicines. These patents broadly cover the use of selection elements to select a target population of cells continuously, intermittently during, or after a culture phase. The Selective Amplification technology covered by these patents is core to the manufacture of our lead stem cell product candidate, CB001. These patents expire in 2014 if not extended. Corresponding international applications are pending.

One of our owned and issued US patents is directed to the method of making hemangioblast cells from a neonatal source. This patent broadly covers the derivation and growth of human hemangioblasts from a non-fetal source. This patent expires in 2017 if not extended. Corresponding international applications are pending.

One of our exclusively in-licensed and issued US patents is directed to a method of cryopreserving human oocytes. This patent is broadly directed at cryopreservation of a human oocyte, using proprietary media so that the oocyte enters into a dormant state and is then stored for future use. This patent expires in 2017 if not extended.

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

We own two pending US patent applications directed to compositions and methods of using USSCs to treat a broad class of diseases.

Furthermore, we own outright or have exclusively in-licensed 52 international patent applications. In addition, we have non-exclusive licenses to 30 US patents and patent applications and 86 foreign patents and patent applications, including patents covering growth factors used in our Selective Amplification process.

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 confidentiality agreements with us, generally stating that they will not disclose any confidential

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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.

The patent positions of companies like ours involve complex legal and factual questions and, therefore, their enforceability 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 thereunder 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. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Expiration of patents we own or license could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

Competition

We are aware of products manufactured or under development by competitors that are used for the prevention or treatment of diseases and health conditions which we have targeted for product development. Stem cell therapy competitors with products that could potentially compete with CB001 include commercial and development-stage companies offering or intending to offer stem cell products derived from bone marrow, cord blood or mobilized peripheral blood, or devices or services for processing and producing cells derived from these tissues, for use in stem cell transplants. Specific competitors include Aastrom Biosciences, Celgene, Cellerant, Gamida-Cell and Osiris Therapeutics. Companies with the most advanced products potentially competitive with CB001 include Gamida-Cell and Osiris Therapeutics.

Gamida-Cell, a private company based in Israel, has a hematopoetic stem cell product candidate made from umbilical cord blood that is intended for use in hematopoietic stem cell transplants, similar to CB001. Gamida-Cell s product candidate has been evaluated in a Phase I clinical trial. Osiris Therapeutics, a private company based in the US, has a mesenchymal stem cell product candidate isolated from bone marrow that is intended for use in conjunction with transplantation of conventional bone marrow or cord blood cells. Osiris product candidate has already completed Phase I testing.

In addition to these cell therapy products, competition for CB001 may be in the form of new and better drugs to treat leukemias, lymphomas, myelomas and certain genetic diseases. At this time, we cannot evaluate how our products would compare technologically, clinically or commercially to any of these or other potential products being developed by competitors because we cannot predict the cost, efficacy and safety of those products nor when any such products would be available for sale. However, our Selective Amplification technology is designed to produce cellular products that are both highly amplified and highly characterized. Because of these intended attributes, we believe that CB001 may result in better efficacy and safety than potential alternative products. We believe that CB001, if successfully developed, will compete with these products principally on the basis of efficacy and safety, cost and intellectual property positions. However, we have only recently begun our Phase I clinical study with CB001 and it is uncertain whether we will be successful in demonstrating these attributes.

We are aware of several competitors developing stem cell therapies for the treatment of cardiac disease, including GenVec, Genzyme, Bioheart, Osiris Therapeutics, and potentially others. GenVec, Genzyme, and Bioheart are all developing products consisting of skeletal myoblasts isolated from muscle, expanded in culture, and injected into a patient s heart to repair dead tissue. All three companies products are currently in clinical studies: Bioheart completed a Phase I study in 2002; GenVec is currently conducting its Phase I study; and Genzyme is currently recruiting patients for its Phase II study. Osiris s product candidate consists of mesenchymal stem cells isolated from donor bone marrow, expanded in culture, and is intended to be injected into a patient s heart to prevent scar tissue. In March 2005 it was announced that a Phase I study is being conducted at Johns Hopkins (Baltimore) using adult mesenchymal stem cells to repair muscle damaged by a heart attack. This study, supported by Osiris Therapeutics, is designed to test the safety of injecting adult stem cells at varying doses in patients who

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have recently suffered a heart attack. Other companies, including Hydra Biosciences, have pre-clinical development efforts using growth factors to stimulate repair of endogenous heart tissue. At this time, we cannot evaluate how our product candidate for cardiac disease would compare technologically, clinically or commercially to these other stem cell therapies or other drugs being developed and not yet commercialized. However, our USSC technology is designed to produce cellular products that are both highly amplified and highly pure, without the need for a muscle biopsy and, in some cases, without the delay due to the biopsy and three to four week culture process. Because of these intended attributes, we believe that our cardiac repair product may result in better efficacy, more rapid treatment and less discomfort to the patient than potential alternative products. However, we have not begun any clinical studies with any product candidates for cardiac disease and it is uncertain that we will be successful in demonstrating any of these attributes.

Our competitors in the cord blood preservation industry include the approximately 20 other national private family cord blood banks in the United States, including California Cryobank, Cbr Systems (Cord Blood Registry), Cryo-Cell International, CorCell, LifeBankUSA, and New England Cord Blood Bank. Some of our competitors, including Cryo-Cell, CorCell, and LifeBankUSA, charge a lower price for their products than we do. Other competitors such as LifeBankUSA, a division of Celgene, a publicly traded corporation, may have greater financial resources than we do. There are also more than fifty public cord blood banks throughout the world, including the New York Blood Center (National Cord Blood Program), University of Colorado Cord Blood Bank, Milan Cord Blood Bank, Düsseldorf Cord Blood Bank, and others. Our ability to compete with other private family and public cord blood banks will depend on our ability to distinguish ourselves as a leading provider of comprehensive, quality cord blood preservation products with clinical stem cell transplant experience and a research and development organization focused on the development and commercialization of cell therapies derived from cord blood. Our ability to compete with public cord blood banks will also depend on the extent to which related cord blood transplants show better efficacy and safety than unrelated cord blood transplants.

Our competitors in oocyte preservation are expected to include IVF centers and individual companies that offer oocyte preservation. We are aware of approximately 20 IVF centers already offering oocyte preservation, which may make it more difficult for us to establish our product or achieve a significant market share. IVF centers currently offering this service include Florida Institute for Reproductive Medicine, Stanford University, The Jones Institute for Reproductive Medicine, and Egg Bank USA (through Advanced Fertility Clinic). Companies offering oocyte preservation include Extend Fertility. Our ability to compete with these entities will depend on our ability to demonstrate the success of our oocyte preservation method with healthy births from previously cryopreserved oocytes, as well as our ability to distinguish ourselves as a leading provider of a high quality oocyte preservation product and our ability to prevent others from using our proprietary method. We anticipate that we will face increased competition in the future from new companies and individual IVF centers that offer oocyte cryopreservation using alternative methods.

Cord Blood Stem Cell Act. The Cord Blood Stem Cell Act of 2003, or the CBSCA, is currently being considered by the U.S. Congress. If enacted, it would provide federal funding for a national system of public cord blood banks in order to increase the number of available cord blood units to at least 150,000 units. It also contains provisions designed to encourage cord blood donations from an ethnically diverse population. Under the CBSCA, a public cord blood bank could obtain federal funding from this program if the bank meets eligibility requirements established by the CBSCA. The CBSCA is not applicable to family cord blood banks such as Viacord, and Viacord would not be eligible for federal funding under the CBSCA.

ViaCell plans to obtain cord blood units to manufacture CB001 from public cord blood banks. An increase in the number and availability of public cord blood units could increase the available units for use in manufacturing CB001. Alternatively, an increase in the number of available cord blood units in public banks could have an adverse effect on the market for CB001 or other of our potential cell therapy products. If public cord blood banks are able to increase their inventories and obtain more units with a higher volume of stem cells, then public cord blood banks may be able to better compete with our potential cell therapy products.

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Government Regulation

Regulations Relating to ViaCell

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

FDA Regulation of Biologics, Drugs, and Medical Devices

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

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

- preclinical laboratory and animal tests to assess a drug s biological activity and to identify potential safety problems;
- submission to the FDA of an investigational new drug or IND application, 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 (BLA) or new drug application (NDA) for marketing that includes adequate results of preclinical testing and clinical trials; and
- FDA review of the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses.

Typically, clinical testing involves a three-phase process although the phases may overlap. Phase I clinical trials typically involve a small number of healthy volunteers or patients (10-30) and are designed to provide information about both product safety and the expected dose of the drug. Phase II clinical trials generally provide additional information on dosing and safety in a limited patient population (40-100). Phase III clinical trials are generally large-scale, well-controlled studies of 80-200 or more patients. The goal of Phase III clinical trials generally is 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 grant filing and review of 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. In addition, the manufacturing facilities must be inspected and found to be in full compliance with cGMP standards before approval for marketing. Further clinical trials may be required to gain approval to promote the use of the product for any additional indications. Such additional indications are obtained through the approval of a supplemental BLA or NDA.

Premarket Clearance or Approval of Medical Devices. Medical devices are also subject to extensive regulation by the FDA, including 510(k) clearance or PMA approval 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

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safety and effectiveness to a previously 510(k) cleared device or a device that was commercially distributed before May 28, 1976 and for which FDA has not yet called for submission of a PMA. Some low risk devices are exempt from 510(k) clearance requirements.

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

The FDA generally requires manufacturers of medical device kits to obtain 510(k) clearance or PMA approval of the kits before marketing them in interstate commerce. Some kits are exempt from these requirements. Devices and media for cryopreservation of oocytes are generally subject to 510(k) clearance.

Medical device manufacturers are required to comply with numerous regulatory requirements, including:

QSRs, which require manufacturers to follow elaborate design, testing, control, documentation, and other quality assurance procedures during the manufacturing process;

labeling regulations;

FDA s general prohibition against promoting products for unapproved or off-label uses;

Medical Device Reporting regulation, which requires manufacturers to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

special controls, such as performance standards, post-market surveillance, patient registries, and FDA guidelines that apply to Class II devices.

Compliance Requirements after BLA Licensure, NDA Approval, 510(k) Clearance, or PMA Approval. Manufacturers of BLA licensed, NDA approved, 510(k) cleared, or PMA approved products 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, including:

issuance of warning letters;

fines, injunctions, and civil penalties;

recall or seizure of products;

cessation of clinical studies;

operating restrictions, partial suspension or total shutdown of production;

the FDA s delay in granting BLA licensure, NDA approval, 510(k) clearance, or PMA approval or refusal to grant BLA licensure, NDA approval, 510(k) clearance, or PMA approval of new products;

withdrawal of the BLA licensed, NDA approved, 510(k) cleared, or PMA approved product from the market; or

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the imposition of civil or criminal penalties against the manufacturer, responsible persons within the company and/or holder of the BLA license, NDA approval, 510(k) clearance, or PMA approval.

Products developed using our Selective Amplification technology will be regulated as biological products. If we receive marketing approval or licensure, we must comply with the above FDA requirements. Discovery of previously unknown problems with a marketed product may result in either FDA compliance action or voluntary withdrawal of the product from the market, which could reduce our revenue sources and hurt our financial results. Additionally, we will most likely have to obtain approval for manufacturing and marketing of each product from regulatory authorities in foreign countries prior to the commencement of marketing of the product in those countries. The approval procedure varies among countries, may involve additional preclinical testing and clinical trials, and the time required may differ from that required for FDA approval or licensure. Although there is now a centralized European Union approval mechanism in place, each European country may nonetheless impose its own procedures and requirements, many of which could be time-consuming and expensive. Additionally, European approval standards for cellular therapy are still under development and consequently approval of cell therapy products in Europe may require additional data that we may not be able to satisfy.

Privacy Law. Federal and state laws govern our ability to obtain and, in some cases, to use and disclose data we need to conduct research 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. Most health care providers were required to comply with the Privacy Rule as of April 14, 2003.

Because ViaCell does not engage in certain electronic transactions related to reimbursement for health care, ViaCell is not a covered health care provider subject to the Privacy Rule. Many of the health care providers and research institutions with whom we collaborate, however, are subject to the Privacy Rule. These entities may share identifiable patient information with ViaCell for our research purposes only as permitted by the Privacy Rule (for example, with written patient authorizations which comply with certain detailed requirements). Although ViaCell is not directly subject to the Privacy Rule, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a research collaborator who has not satisfied the Privacy Rule s disclosure requirements.

HIPAA does not preempt, or override, state privacy laws that provide even more protection for individuals health information. These laws requirements could further complicate our ability to obtain necessary research data from our collaborators. In addition, certain state privacy and genetic testing laws may directly regulate our research activities, affecting the manner in which we use and disclose individuals health information, potentially increasing our cost of doing business, and exposing us to liability claims. In addition, patients and research collaborators may have contractual rights that further limit our ability to use and disclose individually identifiable health 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.

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

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Regulations Relating To Viacord

FDA Regulations. The Viacord cord blood preservation product is subject to FDA regulations requiring infectious disease testing. We have registered Viacord with the FDA as a cord blood preservation service, listed our products with the FDA, and are subject to FDA inspection. In addition, the FDA has recently adopted good tissue practice (GTP) regulations that establish a comprehensive regulatory program for human cellular and tissue-based products and finalized rules for donor eligibility and that will become effective in May of 2005. We believe that we comply with existing regulatory requirements and will be in compliance with the new GTP regulations as recently adopted. Furthermore, the FDA may develop standards for these products.

Consistent with industry practice, the Viacord cord blood collection kits have not been cleared as a medical device. The FDA could at any time require us to obtain 510(k) clearance or PMA approval for the collection kits. Securing any necessary medical device clearance or approval for the cord blood collection kits may involve the submission of a substantial volume of data and may require a lengthy substantive review. The FDA also could require that we cease distributing the collection kits and require us to obtain 510(k) clearance or PMA approval prior to further distribution of the kits.

Privacy Law. Federal and state privacy laws govern our ability to obtain and, in some instances, to use and disclose identifiable patient information. Because blood and tissue procurement and banking activities are expressly exempted from the scope of the Privacy Rule, we are not a covered health care provider subject to the Privacy Rule. The Privacy Rule indirectly impacts us to the extent that hospitals, obstetricians, and other health care providers who enroll our customers and transfer to us umbilical cord blood (and, in the future, human oocytes) are subject to HIPAA. These providers may share with us identifiable information about individuals only as permitted by the Privacy Rule. Although we are not directly subject to the Privacy Rule, we could still face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider who has not satisfied the Privacy Rule s disclosure requirements. In addition, certain state privacy laws may apply directly to us, restricting how we may use and disclose individually identifiable health information.

Moreover, patients and participating health care providers may have contractual rights that further limit our ability to use and disclose individually identifiable health 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.

Other Regulations. Regulation of cord blood preservation in foreign jurisdictions is still evolving. Of the states in which we provide cord blood preservation services, only New Jersey, New York, Maryland, Kentucky, Illinois and Pennsylvania currently require that cord blood banks be licensed or registered. We are currently licensed or registered to operate in New Jersey, New York, Kentucky and Illinois and we believe that we will be able to comply with the license and registration requirements in Maryland and Pennsylvania, which we recently identified. If we identify other states with requirements or if other states adopt requirements for licensing or registration of cord blood services, we would have to obtain licenses or registration to continue providing services in those states.

Regulations Relating To Oocyte Cryopreservation

There are no established precedents related to the US and international regulation of oocyte cryopreservation. In the United States, we anticipate that the cryopreservation of oocytes may be regulated similarly to Viacord s family umbilical cord blood cryopreservation service (Public Health Service Act, Section 361). This means that clinical trials to establish safety and efficacy will not be required to commercialize the service, however, under this regulatory mechanism, we will not be able to make safety and efficacy claims related to the service in advertising and promotional materials.

The FDA will require some of the components used in the process to be regulated as medical devices and cleared through the agency s 510(k) process. Prior to marketing Viacyte, 510(k) clearance must be

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obtained from the FDA for our proprietary oocyte cryopreserving media. Our media supplier submitted a 510(k) on November 12, 2004. The 510(k) clearance process typically takes three to twelve months from the time of submission to being able to market a product, but can take significantly longer. In November of 2004, our media supplier submitted a 510(k) to the FDA for clearance of the oocyte cryopreservation media. In January of 2005, our media supplier informed us that they had received a letter from the FDA that included the following information:

- a statement that our media supplier will need to conduct a clinical study that produces pregnancy and birth rates data to support the application; and

- a request that various additional information be submitted, including stability, toxicity testing, biocompatibility and labeling information.

Clinical data were not included in the original 510(k) application. Our media supplier has responded to the FDA letter and submitted existing, published third party clinical data and additional information to the pending 510(k) application. We believe that the existing, published clinical data may be sufficient to support 510(k) clearance of the media; however, it is likely that a new clinical trial will be required which could substantially delay 510(k) clearance and our launch of Viacyte until at least 2007.

In addition, although the letter from the FDA did not suggest that any other approval process would be required other than the 510(k) process, the FDA could at any time determine that some of the components used to cryopreserve the oocytes require PMA approvals, which would increase the planned developmental timeline for commercialization of this service. Clinical trials required to support either a 510(k) or PMA submission for the oocyte cryopreservation media would need to be conducted in accordance with the FDA device regulations.

We anticipate that we may be required to register any long-term cryopreservation facility with the FDA as a tissue banking service, list our products with the FDA, and will be subject to FDA inspection. Our facility would also be subject to the recently adopted GTP regulations that establish a comprehensive regulatory program for human cellular and tissue-based products as well as just finalizing rules for donor eligibility. There may also be state specific license requirements that may also be required for the operation of a long-term cryopreservation facility.

Regulations for the cryopreservation of oocytes in foreign jurisdictions have not yet been investigated, however we anticipate that we will encounter similar regulatory mechanisms as those planned by the FDA, and that these mechanisms will vary on a country-by-country basis.

Employees

As of December 31, 2004, we employed 181 individuals, of which 17 hold an M.D. or Ph.D. degree. 96 of our employees are engaged in cord blood commercial operations, 49 are engaged in research and development activities, and 36 are engaged in senior management and administrative functions. Of our 181 employees, 165 are based in the United States, 9 are in Germany and 7 are in Singapore. All of our employees are at-will employees, other than Marc Beer, Chris Adams, Stephen Dance, Kurt Gunter, Morey Kraus and Stephan Wnendt, who have employment agreements, and our employees in Germany who have local employment agreements. None of our employees is represented by a labor union or is covered by collective bargaining agreements. We have not experienced any work stoppages, and believe we maintain satisfactory relations with our employees.

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

We currently lease and occupy two facilities in Massachusetts, with development and clinical trial-scale manufacturing operations in Worcester and our corporate headquarters in Cambridge, Massachusetts. Our operations in Worcester total approximately 11,000 square feet of space. Our corporate headquarters, which also house our cord blood preservation sales, customer support, marketing and administrative personnel, comprise approximately 18,000 square feet of office space. We have also leased approximately 25,000 square feet of laboratory space in the same facility for a term of ten years, expiring in 2014. We are

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currently building out the laboratory space and expect to move our operations currently in Worcester into this location in the second half of 2005. The majority of the build-out costs will be covered by a tenant improvement allowance from the landlord. We have negotiated early termination of the Worcester lease coincident with the planned completion of that move, without incurring any penalty. The annual rent for this new leased facility is approximately $1.4 million in the first year, increasing to $1.7 million by the end of the term, inclusive of maintenance expenses.

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 lease approximately 3,800 square feet of laboratory space to house our research operations in Singapore, and, as a result of our acquisition of Kourion Therapeutics, we lease approximately 17,000 square feet of laboratory and administrative space in Langenfeld, Germany; the leases expire in 2007 and 2008, respectively, although we can extend the German lease for up to an additional five years. We intend to transfer our German operations to the United States in 2005 and close our operations there and in January, 2005 we entered into an agreement with a third party to sub-lease our German facility for the next two years, with options to extend the sub-lease through the end of our lease term.

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

ITEM 3. ***LEGAL PROCEEDINGS***

We were sued by PharmaStem Therapeutics, Inc. for allegedly infringing two patents relating to our Viacord umbilical cord stem cell cryopreservation business after we rejected PharmaStem s initial requests seeking a license arrangement because we believe that we do not infringe these patents and that they are invalid. PharmaStem filed a complaint on February 22, 2002 and an amended complaint on March 25, 2002, against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 and No. 5,192,553, which relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We counterclaimed that the patents are invalid and unenforceable, and for violation of the antitrust laws resulting from an improper use of PharmaStem s patents, and sought a declaration of non-infringement. Following an October 2003 trial, the jury ruled against us and the other defendants, Cbr Systems, CorCell and Cryo-Cell, who represent a majority of the family cord blood preservation industry, and 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. The jury also found that our infringement was willful. Following the trial, we placed the amount of the award in an escrow account pending final disposition of this case.

On September 15, 2004, the Delaware Court overturned the earlier judgment against ViaCell. The Court ruled that we did not infringe the 553 method patent as a matter of law, and ordered a new trial on infringement and damages, if any, related to the 681 composition patent. PharmaStem s motions for an injunction against us and the other defendants and for prejudgment and postjudgment interest, as well as enhanced damages and attorneys fees based upon the jury s finding of willful infringement, were denied. The judge also denied our motion challenging the validity and enforceability of the patents. On September 24, 2004, our $2.9 million escrow payment was released to the Company. On December 14, 2004, the Delaware Court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the 681 composition patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent. With respect to the 681 patent for which a new trial was granted, PharmaStem filed a motion on October 5, 2004 with the court for a preliminary injunction. Also on October 5, 2004, we filed a complaint with the Delaware court, alleging antitrust and trade violations by PharmaStem concerning misuse of its patents and other deceptive business practices. The court held a hearing on these motions on November 3, 2004, and denied PharmaStem s

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motion for a preliminary injunction on December 14, 2004 when it overturned the jury verdict on that patent. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005, PharmaStem s Motion to Expedite the Appeal was denied. PharmaStem s appeal brief was filed on March 22, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both the 553 method patent and the 681 composition patent based on the prior art. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 patent as invalid over prior art. PharmaStem has until April 2, 2005 to respond to this Office Action. We expect that the PTO will issue an Office Action relating to the 681 composition patent shortly.

Should the US PTO find the claims of these patents to be unpatentable, then the litigation proceedings between ViaCell and PharmaStem with respect to the unpatentable claims would cease. If the Court s judgment as to non-infringement of the 553 or 681 patent is reversed on appeal and if we are subsequently enjoined from further engaging in our umbilical cord stem cell cryopreservation business, we will not be able to conduct this business unless PharmaStem grants a license to us, which PharmaStem previously informed us that it would not do after October 15, 2004. While we do not believe this outcome is likely, if, in the event of an injunction, we are not able to obtain a license under the disputed patents or operate under an equitable doctrine known as intervening rights, we will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products.

PharmaStem also filed a complaint against us on July 29, 2004 in the United States District Court for the District of Massachusetts, alleging infringement of US Patents No. 6,461,645 and 6,569,427, which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. By agreement of the parties, ViaCell responded to the complaint on December 16, 2004. We continue to believe that the patents in this new Massachusetts action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That Motion is currently stayed. If this Motion is granted, we could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if we lose the case. We believe that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, we believe that PharmaStem s Motion will be denied. If we are ultimately found to infringe, we could have a significant damages award entered against us, and 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 on the disputed patents. We believe the issues presented in this case are substantially the same as the issues presented in the 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 January 21, 2005, the Massachusetts case was stayed pending a ruling on this request. On February 16, 2005, our request was granted. The cases have thus been consolidated in Delaware.

The timing and order of the litigations involving ViaCell and PharmaStem are not presently known. Decisions in the re-examination proceedings, now pending before the US PTO, of the 681 and 553 patents may also affect these factors.

We may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all.

On May 13, 2004, we received a First Amended Complaint filed in the Superior Court of the State of California by Kenneth D. Worth, by and for the People of the State of California, and naming as defendants a number of private cord blood banks, including us. The complaint alleges that the defendants have made fraudulent claims in connection with the marketing of their cord blood banking services and seeks restitution for those affected by such marketing, injunctive relief precluding the defendants from continuing to abusively and fraudulently market their services and requiring them to provide certain

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information and refunds to their customers, unspecified punitive and exemplary damages and attorney s fees and costs. Subsequently, we received a Notice of Ex Parte Application for Leave to Intervene filed on behalf of the Cord Blood Foundation by the same individual and seeking similar relief. On October 7, 2004, the Court orally granted a motion to strike the complaint under the California anti-SLAPP statute and dismissed the complaint as to all defendants without leave to amend. Judgment has been entered, dismissing the complaint, and plaintiff has filed a notice of appeal and a petition for a writ of mandate. The petition has been dismissed and we believe that the appeal will proceed. We are not yet able to conclude as to the likelihood that the plaintiff s claims would be upheld if the judgment of dismissal were reversed on appeal, nor can we estimate the possible financial consequences should the plaintiff prevail. However, we believe this suit to be without merit and intend to continue to vigorously defend ourselves until the judgment becomes final.

On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against us in the United States District Court for the Northern District of California alleging false and misleading advertising by us in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. We are evaluating Cbr s allegations and intend to vigorously defend ourselves in this action.

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

On December 30, 2004, our stockholders authorized by written consent the following actions:

the amendment of our corporate charter to adjust the minimum initial public offering price required under the corporate charter to implement the automatic conversion of our preferred stock into common stock;

an increase in the number of shares of common stock available for issuance under our Amended and Restated 1998 Equity Incentive Plan by 1,200,000 shares to a total of 7,200,000 shares;

the further amendment and restatement of our Amended and Restated 1998 Equity Incentive Plan with amended provisions which became effective upon the closing of the initial public offering of our common stock;

the approval and adoption of our 2004 Employee Stock Purchase Plan, which became effective upon the closing of the initial public offering of our common stock; and

the approval of a research agreement entered into with Genzyme Corporation.

All such actions were effected pursuant to an action by written consent of our stockholders. The written consent was adopted by holders of 18,395,535 shares of our stock out of 28,813,999 shares issued and outstanding as of October 23, 2004, including 17,695,535 shares out of 26,052,413 shares of our Series A, Series B, Series D, Series E, Series F, Series G, Series H, Series I, Series J and Series K preferred stock issued and outstanding.

PART II

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

Market for Common Equity

Our common stock has been traded on the NASDAQ National Market System under the symbol VIAC since January 21, 2005. Prior to that time there was no established public trading market for our common stock. The closing share price for our common stock on March 29, 2005, as reported by the NASDAQ National Market System, was $8.35.

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Holders

As of March 28, 2005, there were approximately 193 stockholders of record of our common stock.

Dividends

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

Sales of Unregistered Securities

During 2004, we issued 104,107 shares of common stock to employees, former employees, consultants and directors upon option exercises for compensation for services provided, for an aggregate sale price of approximately $249,001. We also granted options to employees, consultants and directors to purchase 903,500 shares of common stock at an exercise price of $5.00 per share. There were no underwriters employed in connection with any of these transactions. Each option grant and stock issuance was deemed exempt from registration under the Securities Act under Rule 701 promulgated thereunder, because the security was offered and sold pursuant to either a written compensatory plan or a written contract relating to compensation.

Use of Proceeds from Registered Securities.

We registered shares of our common stock in connection with our initial public offering under the Securities Act of 1933, as amended. 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 First Boston 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 will be approximately $53,600,000.

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, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

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). Pending the use of such proceeds, the proceeds were invested into short-term, investment grade, interest bearing securities.

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 consolidated financial statements for the five years ended December 31, 2004. The financial statements for each of the years ended December 31, 2004, 2003, 2002 and 2001 have been audited by PricewaterhouseCoopers LLP, independent registered public accounting firm. The financial statements for the year ended December 31, 2000 have been audited by Arthur Andersen LLP, independent public accountants.

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

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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,				
	2004	2003(1)	2002	2001	2000
	(In thousands, except share and per share data)				
Consolidated Statement of Operations Data:					
Revenues	$ 38,274	$ 31,880	$ 20,375	$ 7,298	$ 2,394
Operating expenses:					
Cost of processing and storage revenues:(2)					
Direct costs	7,364	7,141	5,877	3,070	991
Royalty (recovery) expense	(3,258)	3,258			
Total cost of revenues	4,106	10,399	5,877	3,070	991
Research and development	15,134	13,226	11,429	6,978	3,854
Sales and marketing	19,322	20,959	16,578	9,349	2,177
General and administrative	13,468	15,222	10,920	7,086	3,879
In-process technology(3)		23,925	5,889	594	
Stock-based compensation(4)	3,429	3,232	6,464	4,490	196
Restructuring	2,945				
Total operating expenses	58,404	86,963	57,157	31,567	11,097
Operating loss	(20,130)	(55,083)	(36,782)	(24,269)	(8,703)
Interest (expense) income, net	(967)	(385)	744	2,136	991
Income taxes					
Net loss	$ (21,097)	$ (55,468)	$ (36,038)	$ (22,133)	$ (7,712)
Net loss attributable to common stockholders	$ (34,168)	$ (64,884)	$ (44,182)	$ (28,753)	$ (10,262)
Net loss per common share, basic and diluted	$ (12.62)	$ (24.63)	$ (17.60)	$ (12.22)	$ (5.55)
Weighted average shares used in computing net loss per common share, basic and diluted	2,707,219	2,634,096	2,510,632	2,352,468	1,849,073

	Years Ended December 31,				
	2004	2003(1)	2002	2001	2000
	(In thousands, except share and per share data)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents, short- and long-term investments	$ 28,585	$ 46,832	$ 29,188	$ 53,787	$ 55,287
Working capital	14,437	22,857	25,407	46,062	53,144
Total assets	61,091	78,161	56,119	70,981	67,775
Long-term debt obligations, including current portion	18,737	19,238	5,173	1,586	656
Redeemable convertible preferred stock	175,173	162,141	110,912	101,268	79,727
Total stockholders deficit	(160,957)	(130,151)	(70,487)	(38,749)	(15,376)

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(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 banking revenues through October 29, 2003, based on a claim of patent infringement. As a result we recorded an expense of $3.3 million, included in cost of revenues, in the fourth quarter of 2003 to cover our exposure for the jury award to PharmaStem plus 6.125% of our revenues for the remainder of 2003. We also recorded an expense of $0.5 million for the three months ended March 31, 2004, also based on 6.125% of our revenues. In September 2004, the federal district court overturned the jury verdict on one of the two patents in litigation and vacated the verdict and granted a new trial on the issues of infringement and damages (if any) concerning the second patent. Based on the judge s ruling, we reversed the entire royalty accrual of $3.8 million in the quarter ended June 30, 2004. On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In his September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent.

(3) In-process technology expense for the year ended December 31, 2003 included $22.1 million, being the fair value of technology acquired in the purchase of Kourion Therapeutics, and $1.8 million in respect of technology acquired from Amgen and GlaxoSmithKline. The expense in the years ended December 31, 2002 and 2001 represented the fair value of warrants related to technology licensed from Amgen of $5.9 million and stock options granted to Genzyme for a research collaboration valued at $0.6 million, respectively.

(4) Stock-based compensation expense represents the amortization of the excess of the fair value on the date of grant of the stock underlying the options granted to employees over the exercise price and the expense related to options granted to nonemployees. Total stock-based compensation for employees and nonemployees for the periods reported, and the allocation of these expenses to operating expenses, is as follows:

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
Cost of revenues	$ 32	$ 7	$ 20	$	$
Research and development	896	1,073	2,489	2,249	98
Sales and marketing	175	414	670	222	30
General and administrative	2,082	1,738	3,285	2,019	68
Restructuring	244				
Total stock-based compensation	$ 3,429	$ 3,232	$ 6,464	$ 4,490	$ 196

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 the Risk Factors That May Affect Results section of this report.

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Overview

We are a biotechnology company dedicated to enabling the widespread application of human cells as medicine. To date, the widespread application of human cells as medicine has not been proven to be possible. We are in an early stage of development for our cellular therapeutic products, and we are developing a pipeline of proprietary product candidates intended to address cancer, cardiac diseases, diabetes and infertility, and a commercial business dedicated to the preservation of umbilical cord blood. Our research and development efforts focus primarily on developing cord blood-derived stem cell product candidates in therapeutically useful quantities. We are also developing Viacyte, a product candidate for cryopreserving and storing human oocytes. Since our inception on September 2, 1994, our principal activities have included:

developing our Selective Amplification and other stem cell therapy technologies;

expanding our ViaCell Reproductive Health franchise in the United States;

expanding our pipeline of novel stem cell and other product candidates through internal development, and the acquisition of third party technologies;

expanding and strengthening our intellectual property position through internal programs, third party licenses, and acquisitions;

recruiting management, research, clinical, and sales and marketing personnel; and

forming alliances with larger, more experienced biotechnology and pharmaceutical companies, including Amgen.

As of December 31, 2004, our accumulated deficit was approximately $158.8 million. From inception through December 31, 2004, we have raised $137.2 million in common and preferred stock issuances. We have incurred net losses since inception as a result of research and development, sales and marketing and general and administrative expenses in support of our operations. We anticipate incurring net losses for at least the next several years due to:

the increasing costs of conducting clinical trials for our lead hematopoietic stem cell product candidate, CB001;

the working capital costs associated with anticipated growth of our ViaCell Reproductive Health franchise within the United States;

the increasing costs associated with preclinical and clinical studies for our other stem cell therapy product candidates; and

the increasing costs associated with the development of Viacyte, our oocyte cryopreservation product candidate.

Our financial success will depend on many factors, including our ability to grow our umbilical cord blood preservation business, establish the safety and efficacy of our therapeutic product candidates, obtain necessary regulatory approvals and successfully commercialize new products.

Our management currently uses consolidated financial information in determining how to allocate resources and assess performance. We may organize our business into more discrete business units when and if we generate significant revenue from the sale of stem cell therapies. For these reasons, we have determined that we conduct operations in one business segment. Substantially all of our revenue since inception has been generated in the United States, and the majority of our long-lived assets are located in the United States.

Revenues

Our current revenue is derived primarily from fees charged to families for the preservation and storage of a child s umbilical cord blood collected at birth. These fees consist of an initial fee for collection,

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processing and freezing of the umbilical cord blood and an annual fee for storage. The annual storage fee provides a growing annuity of future revenue as the number of stored cords increases. Our revenues are recorded net of discounts and rebates that we offer our customers under certain circumstances from time to time. Our revenues have increased substantially over the last several years as the concept of cord blood banking has gained popularity. We offer our customers the opportunity to pay their fees directly to us or to finance them via G.E. Capital, a third party credit provider. Since we finance some receivables ourselves, we assume the risk of losses due to unpaid accounts. We maintain a reserve for doubtful accounts to allow for this exposure and consider the amount of this reserve to be adequate at December 31, 2004. Following the September and December 2004 rulings of the district court in the ongoing patent litigation with PharmaStem Therapeutics, Inc., which overturned the jury verdict of infringement on both PharmaStem patents at issue in such suit, we do not expect the PharmaStem litigation to have a materially adverse impact on our net sales, revenues or income from continuing operations. However, should we ultimately lose this litigation, it could have a material adverse effect on our net sales, revenue or income from continuing operations.

In addition to the revenue generated by our ViaCell Reproductive Health franchise, we record revenue from grant agreements with the governments of Singapore and Germany, where we maintain research facilities, and from contract research performed at our research laboratories in the United States. We decided to close our German facility in December 2004, and are transitioning research activities that had been performed there to the United States. Therefore, revenue from grants in Germany has ceased.

Operating Expenses

Cost of revenues reflects the cost of transporting, testing, processing and storing umbilical cord blood at our cord blood processing facility in Hebron, Kentucky, as well as a royalty to PharmaStem relating to ongoing patent infringement litigation. We recorded a royalty expense of approximately $3.3 million in the fourth quarter of 2003 following an unfavorable jury verdict in October 2003. This expense included a royalty of approximately $2.9 million on revenues from cord blood preservation through October 29, 2003, plus an accrual of a royalty of 6.125% of subsequent revenues through December 31, 2003. We recorded an additional royalty expense of $0.5 million for the three months ended March 31, 2004, also based on 6.125% of revenues. In September 2004, the court overturned the jury verdict on one of the two patents in litigation and vacated the verdict and granted a new trial concerning infringement and damages, if any, on the second patent. Based on the judge s ruling, we reversed the entire royalty accrual of $3.8 million in the quarter ended June 30, 2004.

On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent. Pending further action by the courts, including the separate action recently filed in Massachusetts, we do not intend to record a royalty expense in future periods, since we believe PharmaStem s claims are without merit. It is possible that the final outcome of these litigations could result in damages payable regarding PharmaStem s patents, at a higher or lower amount than previously awarded by the jury in Delaware. Should this occur, our financial position and results of operations could be materially affected. In addition, we may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts by us to PharmaStem, or what those amounts might be. Our cost of revenues also include expenses incurred by third party vendors relating to the transportation of cord blood to our processing facility and certain assay testing performed 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 revenues does not include costs associated with our grant revenue. Such costs are included in research and development expense.

Our research and development expenses consist primarily of costs associated with our lead stem cell product candidate, CB001, and the continued development of our technologies, including Selective

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Amplification, oocyte cryopreservation and other cellular therapy product candidates. 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 by external service providers, including license agreements and consulting expenses. The major expenses relating to our CB001 clinical trial include external services provided for outside quality control testing, clinical trial monitoring, data management, and fees relating to the general administration of the clinical trial. Other direct expenses relating to our CB001 clinical trial include site costs and the cost of the cord blood.

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

We believe that it is not possible at this stage to provide a meaningful estimate of the total cost to complete each project and bring our product candidates to market. Cell therapy is an emerging area of medicine, and it is not known what clinical trials will be required by the FDA in order to gain marketing approval. Costs to complete could vary substantially depending on the number of clinical trials required and the number of patients needed for each study. Over the next two years, we anticipate spending approximately $25.0 million on clinical studies and related development and manufacturing activities, primarily related to our lead product candidate, CB001, in order to complete the current Phase I clinical trial and evaluate the commercial viability of proceeding with the next trial. We also expect to spend approximately $3.0 million over the next 12 to 18 months to complete existing pre-clinical studies and related development activities in the cardiac disease program, following which we will assess the commercial viability of continuing this program. It is possible that the completion of these studies could be delayed for a variety of reasons, including difficulties in enrolling patients, delays in manufacturing, incomplete or inconsistent data from the trial and difficulties evaluating the trial results. Any delay in completion of a trial would increase the cost of that trial, which would harm our result of operations. Due to these uncertainties, we cannot reasonably estimate the size, nature nor timing of the costs to complete, or the amount or timing of the net cash inflows of the CB001, cardiac disease and other product candidates. Until we obtain further relevant clinical data, we will not be able to estimate our future expenses related to these programs or when, if ever, and to what extent we will ever receive cash inflows from them.

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

Our general and administrative expenses include our costs related to the finance, legal, human resources, information technology, business development 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 advisers, business consultants and others. We expect that these costs will increase in future years as we expand our business activities and as we incur additional costs associated with being a publicly-traded company.

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In September 2004, we restructured our operations to reduce operating expenses and concentrate our resources on four key products and product candidates, and related business initiatives. These products and product candidates consist of Viacord, Viacyte, CB001 and the cardiac development program. As a result, we recorded a $1.7 million restructuring charge in the third quarter of 2004 related to employee severances, contract termination costs and the write-down of excess equipment. In December 2004 we restructured our German operations. As a result we 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 consisted of the write off of the leasehold improvements and fixed assets in our German facility. At December 31, 2004, restructuring charges of $1.2 million were paid out, the net book value of fixed assets was written down by $0.9 million and the accrued liability relating to the restructurings was $0.9 million. The majority of the contract termination costs relate to our exercising the termination provision in our agreement with Gamete Technologies, under which we were required to pay $175,000 to Gamete Technologies.

The American Jobs Creation Act of 2004 (the Act) was signed into law on October 22, 2004. The Act contains numerous amendments and additions to the U.S. corporate income tax rules. While we continue to analyze these new provisions in order to determine their impact on our financial statements, none of these changes, either individually or in the aggregate, is expected to have a significant effect on our income tax liability.

Kourion Acquisition

In September 2003, we acquired all outstanding shares of Kourion Therapeutics AG in exchange for 549,854 shares of our Series I convertible preferred stock, valued at approximately $4.4 million, and a promissory note in the principal amount of $14.0 million. As further potential consideration, we issued 241,481 additional shares of Series I convertible preferred stock to an escrow account (escrow shares) and reserved 289,256 shares of Series I convertible preferred stock (contingent shares) for possible issuance in the future. Under the acquisition agreement, we are also obligated to make payments to Kourion Therapeutics former shareholders if certain USSC-related product development milestones are achieved, namely:

$3 million if by December 31, 2006 we receive final Phase II outcome data positive for a cardiac indication;

$3 million if by June 30, 2007 we receive final Phase II outcome data positive for a non-cardiac indication;

$3 million if by December 31, 2011 we receive all regulatory approvals to market a USSC product for cardiac indications in the United States and the European Union; and

$3 million if by December 31, 2012 we receive all regulatory approvals to market a USSC product for non-cardiac indications in the United States and the European Union.

These milestones would be paid either in stock or cash at each shareholder s option. We agreed that the escrowed shares would be released, and the contingent shares would be issued, upon either a change in control of our company or an initial public offering of our common stock at a price per share of at least $9.70 resulting in net proceeds of at least $50.0 million. Since our initial public offering in January 2005 did not trigger that issuance threshold, if a change in control of our company does not occur prior to September 30, 2006, the escrow shares will revert back to us and the contingent shares will never be issued. If the contingent shares are issued upon a change in control, the recipients of these shares will be issued an additional number of shares equal to 8% of the initial number of shares issued compounded annually from the acquisition closing date to the date of issuance. Upon the closing of our initial public offering in January 2005, the escrow shares converted automatically into shares of common stock along with all other outstanding shares of Series I convertible preferred stock.

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Results of Operations

Years Ended December 31, 2004, 2003 and 2002 (table amounts in millions, year over year changes based on rounded amounts in millions)

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Processing revenues	$ 31.7	$ 27.8	$ 18.5	$ 3.9	14%	$ 9.3	50%
Storage revenues	5.1	3.1	1.6	2.0	65%	1.5	94%
Total	36.8	30.9	20.1	5.9	19%	10.8	54%
Grant and contract revenues	1.5	1.0	0.3	0.5	50%	0.7	233%
Total revenues	$ 38.3	$ 31.9	$ 20.4	$ 6.4	20%	$ 11.5	56%

The increase in processing and storage revenues of $5.9 million or 19% from 2003 to 2004 and $10.8 million or 54% from 2002 to 2003 was due primarily to an increase in the number of cords processed for customers, as well as an increase in the number of cords stored. The increase in grant and contract revenues of $0.5 million or 50% from 2003 to 2004 and $0.7 million or 233% from 2002 to 2003 was primarily due to the increase in grant revenue of $0.6 million and $0.4 million in 2004 and 2003 respectively from Kourion Therapeutics, which was acquired on September 30, 2003. From 2002 to 2003 an additional $0.1 million in grant revenue was recorded from the Government of Singapore and contract revenue derived from research activities in the United States revenue decreased by $0.2 million from 2003 to 2004 and increased by $0.2 million from 2002 to 2003. As noted above, we will not receive any additional German grant revenue as a result of closing our German operations.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Cost of revenues:							
Direct costs	$ 7.4	$ 7.1	$ 5.9	$ 0.3	4%	$ 1.2	20%
Royalty expense	(3.3)	3.3		(6.6)	(200)%	3.3	100%
Total cost of revenues	$ 4.1	$ 10.4	$ 5.9	$ (6.3)	(61)%	$ 4.5	76%

The increase in direct costs of $0.3 million or 4% from 2003 to 2004 and $1.2 million or 20% from 2002 to 2003 was due primarily to increased variable expenses of $0.2 million and $2.0 million in 2004 and 2003 relating to transportation of, materials for collecting, and testing of the cord blood due to an increase in cords processed. The increased costs in 2003 were offset by a decrease of $0.8 million primarily relating to consulting costs incurred in 2002.

The increase in royalty expense of $3.3 million or 100% in 2003 was due to our accrual of $3.3 million in connection with the PharmaStem lawsuit, to cover our cumulative royalty expense from August 2000 through

December 31, 2003 following the jury verdict that was announced in October 2003. The jury verdict of infringement was subsequently overturned by the judge in September and December 2004.

The decrease in royalty expense of $6.6 million or 200% in 2004 was due to the reversal of the accrued liability in connection with the PharmaStem lawsuit following the judge s ruling in September 2004 that overturned a prior jury verdict, announced in October 2003, based on which we recorded a royalty expense. On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent.

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While PharmaStem has filed a Notice of Appeal, we believe that the lawsuit is without merit and that, in light of the judge s ruling, no royalty accrual or expense is required.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Clinical development	$ 7.9	$ 7.3	$ 6.8	$ 0.6	8%	$ 0.5	7%
Pre-clinical programs	3.5	2.1	1.5	1.4	67%	0.6	40%
Basic research	3.0	3.1	2.5	(0.1)	(3)%	0.6	24%
Other R&D	0.7	0.7	0.6			0.1	17%
Total research and development	$ 15.1	$ 13.2	$ 11.4	$ 1.9	14%	$ 1.8	16%

Clinical development expense is related primarily to outside services and clinical trial expenses for CB001, and the increases in 2004 and 2003 reflected the cost of conducting the human clinical trials that commenced in late 2003. Expenses for our pre-clinical programs were primarily in connection with our muscular dystrophy program in 2003 and 2002, which we are not currently pursuing, and our cardiac repair program. The increase in pre-clinical expenses was due to an increase of $2.2 million and $0.7 million in 2004 and 2003 related to Kourion Therapeutics, which was acquired in September 2003. Kourion Therapeutics expenses related primarily to the cardiac disease program, and were offset by a decrease of $0.7 million in 2004 related to other pre-clinical programs. Basic research expenses are primarily related to activity at our Singapore research center. Other research and development expense related primarily to our umbilical cord blood processing and storage business.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Sales & marketing	$ 19.3	$ 21.0	$ 16.6	$ (1.7)	(8)%	$ 4.4	27%

In 2004 we reduced the number of call center employees following the implementation of call center automation technology. The decrease in sales and marketing expenses of $1.7 million or 8% from 2003 to 2004 was due primarily due to cost savings attributed to the restructuring of our call center. The increase in expenses of $4.4 million or 27% from 2002 to 2003 was due primarily to direct to consumer marketing expenses of $1.0 million, professional marketing expenses of $0.9 million and employee related costs of $2.2 million. The increase in employee related costs was due primarily to the full year impact of salary and commission expenses related to the expansion of our call center. We increased the number of call center employees in the middle of 2002 and maintained the increased number of call center employees throughout 2003. Additionally, the employee related costs in 2003 increased over 2002 due to general payroll increases for existing employees. Since we acquired Viacord in April 2000 we have increased our sales and marketing spending significantly to establish a strong market presence and achieve sales growth.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003

General & administrative	$ 13.5	$ 15.2	$ 10.9	$ (1.7)	(11)%	$ 4.3	39%

The decrease in general and administrative expenses of $1.7 million or 11% from 2003 to 2004 was due primarily to the decrease in litigation expenses of $2.3 million, relating to the PharmaStem lawsuit, a decrease in transaction costs of $0.7 million relating to the acquisition of Kourion Therapeutics, our German subsidiary, in September 2003, and a reduction in bad debt expense of $0.3 million due to continued improvements in our collection efforts in 2004. These decreases were offset by additional consulting costs related to our oocyte program of $0.3 million, increase in general legal costs of $0.3 million, an increase of $0.3 million relating to additional accounting and audit fees related to quarterly

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reviews in preparation for our IPO and increased employee related costs of $0.7 million, primarily due to employee severance and payroll increases related to existing employees.

General and administrative expenses increased by $4.3 million or 39% from 2002 to 2003. This increase was due primarily to an increase of $2.1 million in legal fees associated with the PharmaStem lawsuit, Viacord sales collection related expenses of $0.6 million, professional fees of $0.7 million, various license agreement expenses of $0.4 million, expenses of $0.8 million related to Kourion Therapeutics, and employee related costs of approximately $1.0 million to support our growing business. The increase in employee related costs was due primarily to an executive hire and relocation in 2003 and an employee severance as the company continued to build the senior management infrastructure. Additionally, the employee related costs increased due to payroll increases for existing employees. These increases were offset by a $1.6 million charge in 2002 relating to our previous S-1 filing that did not recur in 2003.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
In-process technology		$ 23.9	$ 5.9	$ (23.9)	(100)%	$ 18.0	305%

No in-process technology expenses were incurred in 2004. The expense for the year ended December 31, 2003 consisted primarily of the portion of the Kourion Therapeutics purchase price allocated to acquired in-process technology, representing $22.1 million. In addition, $1.7 million represented the stem cell growth factor technology licensed from Amgen, and $0.1 million related to technology acquired from GlaxoSmithKline. The expense for the year ended December 31, 2002 resulted from the licensing of technology from Amgen.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Stock-based compensation	$ 3.4	$ 3.2	$ 6.5	$ 0.2	6%	$ (3.3)	(51)%

The expense for 2004 amounted to $3.4 million, of which net $0.2 million related to the modification of employee options to extend the option exercise period for employees terminated in our restructuring to exercise their vested options offset by the reversal of the accelerated amortization expense related to their unvested options. Stock-based compensation expense decreased by $3.3 million, or 51% from 2002 to 2003 and was related to less options granted in the current year below fair value. Stock-based compensation expense represents the amortization of the excess of the fair value on the date of the grant of the stock underlying the options granted to employees, over the exercise price. The amortization is based on the vesting period of the related options. The amount of stock-based compensation actually recognized in future periods could decrease if options for which accrued but unvested compensation has been recorded are forfeited.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Restructuring	$ 2.9			$ 2.9	100%		

In September 2004, we restructured our operations to reduce operating expenses and concentrate our resources on four key products and product candidates, and related business initiatives. These products and product candidates consist of Viacord, Viacyte, CB001 and the cardiac development program. As a result, we recorded a $1.7 million restructuring charge in the third quarter of 2004 related to employee severances, contract termination costs and the write-down of excess equipment. In December 2004 we restructured our German operations and sub-leased our German facility to a third party. As a result we recorded a restructuring charge of $1.2 million in the fourth quarter of 2004, including facility costs of $1.1 million and $0.1 million related to a contract termination fee. The majority of the facility related costs consist 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. At December 31, 2004, restructuring-related costs of $1.2 million had been paid out, the net book value of fixed assets was written down by $0.9 million and the accrued liability remaining was $0.9 million. The majority of the contract

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termination costs relate to our exercising the termination provision in our agreement with Gamete Technologies, under which we were required to pay $175,000 to Gamete Technologies.

	2004	2003	2002	$ Change 2003 to 2004	% Change 2003 to 2004	$ Change 2002 to 2003	% Change 2002 to 2003
Interest income	$ 0.5	$ 0.3	$ 0.9	$ 0.2	67%	$ (0.6)	(67)%
Interest expense	(1.5)	(0.7)	(0.2)	(0.8)	(114)%	(0.5)	(250)%
Total interest income (expense), net	$ (1.0)	$ (0.4)	$ 0.7	$ (0.6)	(150)%	$ (1.1)	(157)%

Interest income is earned from the investment of our cash in short and long term securities and money market funds. The changes in the amount of interest income recorded in 2004, 2003 and 2002 are primarily due to the changes in our average cash balance during those periods. Interest expense relates to interest payable on our credit facility and, in 2004, $1.1 million of interest was recorded in 2004 on the $14.0 million note we issued in connection with the acquisition of Kourion.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private sales of preferred stock resulting in gross proceeds of $137.2 million through December 31, 2004. In January 2005, we completed our initial public offering resulting in net proceeds to us of approximately $53.6 million after underwriters discounts and offering expenses. We used approximately $15.5 million of these net proceeds to repay in full the related party note, including accrued interest. As of December 31, 2004, we had approximately $28.6 million in cash, cash equivalents and investments, which, together with the remaining net proceeds from our initial public offering, we believe is sufficient to meet our anticipated liquidity needs for at least the next three years.

	Years Ended December 31,				
	2004	2003	2002	$ Change 2003 to 2004	$ Change 2002 to 2003
Net cash used in operating activities	$ (15.1)	$ (22.5)	$ (21.1)	$ 7.4	$ (1.4)
Net cash provided by (used in) investing activities	(15.9)	6.3	18.5	(22.2)	(12.2)
Net cash provided by (used in) financing activities	(1.0)	39.6	1.4	(40.6)	38.2
Cash & cash equivalents, end of period	$ 6.7	$ 39.0	$ 15.2	$ (32.3)	$ 23.8

Net cash used in operating activities was $15.1 million for the year ended December 31, 2004, and increased to $22.5 million in 2003 from $21.1 million in 2002. For the year ended December 31, 2004, the $15.1 million cash used by operations was due to our net loss of $21.1 million and, a decrease in working capital of $8.7 million, offset by $9.6 million in non-cash expenses, $4.1 million deferred revenue and deferred rent and $1.0 million in fixed asset additions reimbursed by landlord. The decrease in the net cash used in 2004 was primarily related to the increased revenue from our cord blood preservation business, a reduction in operating expenses primarily relating to legal

litigation costs related to PharmaStem and the refund of the $2.9 million royalty escrow payment following the judge s ruling in September 2004 that overturned the PharmaStem jury verdict of October 2003. The increases in net cash used in operating activities in fiscal years 2002 and 2003 were due to the increasing costs associated with the clinical development of CB001, the expansion of our sales and marketing efforts, the legal fees and the $2.9 million royalty escrow payment made in 2003 related to the PharmaStem litigation and the preclinical efforts in the muscular dystrophy, cardiac disease and other programs, partially offset by increased revenues from our cord blood preservation business and increases in accrued expenses.

Net cash used in investing activities for the year ended December 31, 2004 was $15.9 million. Net cash provided by investing activities was $6.3 million in 2003 as compared to net cash provided of $18.5 million in 2002. In 2004, $22.7 million of US Government and high-rated corporate securities matured and $36.7 million was reinvested in similar securities. Of these investments, $15.8 million

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matured during 2003 and $9.7 million was reinvested in similar securities. In addition, we acquired approximately $2.4 million, $1.8 million and $4.8 million in property and equipment in 2004, 2003 and 2002, respectively. In 2002 our investments included approximately $2.9 million to construct and equip a cord blood processing laboratory and storage facility in Hebron, Kentucky, which became fully operational in July 2002. These costs consisted of laboratory and blood processing equipment, cryogenic freezers and facility improvements. We also invested approximately $1.1 million, $1.9 million and $1.6 million in laboratory equipment in the years ended December 31, 2004, 2003 and 2002, respectively. The remaining investments in property and equipment consisted of computer equipment, software and furniture and fixtures. We expect to incur approximately $2.5 million in capital expenditures during 2005 in order to complete the build out of our laboratory in Cambridge, of which approximately $2.5 million is reimbursable by our landlord under the lease agreement. This facility, when completed, will allow us to complete Phase II and Phase III clinical trials and proceed to initial commercialization of CB001, if successfully developed; however, we will need to build or acquire a manufacturing facility in order to fully commercialize CB001 and our other product candidates. The timing and cost of such a facility is not known at this time, however the cost is likely to be substantial. Other assets decreased by approximately $0.5 million in the year ended December 31, 2004 primarily related to the reduction in the deposit required with the credit facility that was entered into in October 2003 with General Electric Capital Corporation.

Net cash used in financing activities in 2004 was $1.0 million, excluding the effect of the change in exchange rates of $0.2 million. Net cash provided by financing activities amounted to $39.6 million in 2003 and $1.4 million in 2002, excluding the effect of the change in exchange rates. This includes the proceeds from the issuance of redeemable convertible preferred stock of $36.9 million and $1.5 million in the years ended December 31, 2003 and 2002, respectively. In 2003, we issued promissory notes totaling $14.0 million to former stockholders of Kourion Therapeutics in connection with our acquisition of that company in September 2003. In 2002, certain property and equipment additions were financed with the proceeds of a credit facility. In 2003, we replaced that credit facility with the $5.0 million credit facility from General Electric Capital Corporation. As a result of replacing the original credit facility, we were able to reduce the amount of cash required to be held as collateral for the amount borrowed, with the result that our restricted cash balance was reduced by $3.2 million in 2003. In 2004 no additional financing occurred, however we repaid $1.6 million on our credit facility.

We anticipate that our current cash, cash equivalents and investments, together with the net proceeds from our IPO in 2005, will be sufficient to fund our operations for at least the next three years. However, our forecast for the period of time during which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more clinical trials, or other aspects of our operations.

$15.5 million of the net proceeds from our January 2005 IPO was used to repay in January 2005 the $14.0 million note (plus interest) issued to a related party as partial consideration in our acquisition of Kourion. We currently anticipate that we will use the remaining net proceeds to fund our clinical trial activities, pre-clinical research and development activities and other general corporate purposes including capital expenditures and working capital to fund anticipated operating losses. We expect to incur substantial costs and losses as we continue to expand our research and development activities, particularly as we move product candidates into additional clinical trials, and we expect that these expenditures will increase significantly over at least the next several years.

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Commitments and Contingencies

The table below summarizes our commitments and contingencies at December 31, 2004 (in millions and does not include our accounts payable and accrued expenses):

		Payments due by Period			
Contractual Obligations	**Total**	**Less than One Year**	**One to Three Years**	**Four to Five Years**	**After Five Years**
Operating lease obligations	$ 17.3	$ 2.0	$ 5.6	$ 3.4	$ 6.3
Capital lease obligations	0.2	0.1	0.1		
Short and long-term debt(1)	3.4	1.8	1.6		
Notes payable(1)(2)	15.4	15.4			
Consulting agreements	1.5	0.8	0.5	0.1	0.1
License agreements(3)	2.9	0.3	0.9	0.6	1.1
Total contractual obligations	$ 40.7	$ 20.4	$ 8.7	$ 4.1	$ 7.5

(1) Includes interest and principal obligations.

(2) These notes relate to our acquisition of Kourion Therapeutics in September 2003 and are payable in full at the earliest to occur of an initial public offering of our common stock (IPO), the sale of the Company, or September 2007. Because our IPO closed in January 2005 this note was paid in full at that time.

(3) We have included several patent license agreements for technologies that are in early stages of development. While we are currently making license payments under some of these agreements, we can cancel each of these agreements at any time without further financial obligation. Of the $2.9 million payable under license agreements, $2.0 million relates to these cancelable agreements.

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.

During 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 agree to pay reasonable defense costs resulting from such litigation, providing that the physician allows us to manage his or her defense. In addition, we agree to indemnify the physician against all potential financial liability resulting from such litigation, and we will pay additional remuneration of $100,000 should PharmaStem prevail in any patent infringement action against the physician. In order to qualify for this indemnification, the physician is required to comply with certain requirements, including returning a signed acknowledgement form regarding the particulars of the indemnification program. We recorded a reserve associated with this program in our financial statements in the quarter ended September 30, 2004. The reserve was equal to the estimated fair value of the indemnifications in place

as of September 30, 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 re-evaluated this reserve at December 31, 2004 and concluded that no change in the reserve was necessary. We may record additional charges if more physicians participate in this program.

We did not have any off balance sheet obligations as of December 31, 2004.

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Loan Obligation

In October 2003, we entered into a $5.0 million loan agreement with General Electric Capital Corporation. Borrowings under this agreement bear interest at 6.9% percent per annum and are collateralized by our fixed assets. Payments of principal and interest are due monthly through October 2006, and approximately $3.2 million remained outstanding under this loan as of December 31, 2004. In accordance with the terms of the loan, we are required to maintain a cash deposit of approximately $1.4 million with the lender as additional collateral. This deposit is classified as other assets in the consolidated balance sheet.

Lease Obligations

We entered into a new operating lease commitment in December 2003 to consolidate our headquarters and US laboratory facilities in one location in Cambridge, Massachusetts. Rent expense on the office portion of this 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 is $0.4 million per year for the first two years of the lease, increasing to $0.5 million per year through the remainder of the lease. 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. We also expect to incur approximately $2.5 million in capital expenditures for leasehold and other improvements associated with our move to this new laboratory facility. Our lease agreement provides for an allowance from our landlord of approximately $2.5 million to offset these capital improvements. In connection with this operating lease commitment with a commercial bank, we entered into a letter of credit 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 has laboratory and office space. This lease has a term of five years, with a right to one-year extensions each year for an additional five years ending in 2013, with an annual rent of approximately $0.3 million per year. Effective January 1, 2005 we entered into an agreement with a third party to sub-lease our German facility, including our clean room and other laboratory equipment, for the next two years, with options to extend the sub-lease through the end of our lease term in 2013. The sub-lease also includes an option under which the sub-lessee can purchase the clean room and equipment for a pre-determined price, in exchange for a reduction in rent. In addition, should the sub-lessee choose not to extend the sub-lease beyond the initial two year period, the sub-lessee must pay us a termination penalty of approximately $270,000.

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

Acquisition of Kourion Therapeutics

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

Milestones. In addition, there are potential future payments totalling up to $12.0 million payable to former shareholders of Kourion Therapeutics if certain USSC-related product development milestones are

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achieved. See Management s Discussion and Analysis of Financial Condition and Results of Operation Kourion Acquisition. 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 seller. Also, in our acquisition of Kourion Therapeutics, we issued and deposited 241,481 shares of our Series I preferred stock into an escrow account, which we agreed would be released immediately following the sooner of the closing of a qualified public offering, which is an underwritten initial public offering of our common stock at a price to the public of at least $9.70 that results in net proceeds to us of $50.0 million or more, or a change in control of the Company, should either event occur prior to September 30, 2006. If either event occurred, we would also issue to certain former shareholders of Kourion Therapeutics an additional 289,256 shares of our Series I convertible preferred stock (or of the common stock into which the preferred stock, including the aforementioned escrowed shares, automatically converted upon completion of our initial public offering in January 2005). Since our initial public offering was not a qualified public offering, the escrowed shares will only be released and the 289,256 contingent shares will only be issued, if a change in control of our company occurs prior to September 30, 2006. If there is no change in control prior to September 30, 2006, the escrowed shares will be returned to us and the contingent shares will never issue.

License Agreements

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

Other Arrangements

Amgen Collaboration Agreement. In April 2002, we entered into an agreement with Amgen Inc. under which we received a royalty-free, worldwide, non-exclusive license to patent rights covering Amgen s Stem Cell Factor. In December 2003, we entered into a new agreement with Amgen that superseded the 2002 Amgen agreement. Under the 2003 Agreement, we licensed on a non-exclusive basis, certain stem cell growth factor technology from Amgen and granted Amgen an option to collaborate with us on any product or products that incorporate any of those growth factors (Collaboration Product). There is no limit on the number of such products for which Amgen can exercise its option. Each time Amgen exercises its option, it must partially reimburse our past development costs for that Collaboration Product, share in the future development costs, pay us a milestone if and when the first regulatory approval for the first indication of the Collaboration Product in the United States is obtained, and take primary responsibility for clinical development, regulatory approval, marketing and commercialization of the Collaboration Product. The parties would share in profits and losses resulting from the Collaboration Products worldwide sales. Either we or Amgen may later opt-out of any product collaboration upon advance notice. The 2003 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. In conjunction with the 2003 agreement, Amgen made a $20 million investment in our Series K preferred stock.

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

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Net Operating Loss Carryforwards

At December 31, 2004, we had federal and state net operating loss carryforwards of approximately $73.1 million and $71.9 million, respectively. These carryforwards begin expiring in 2009 and 2005, respectively. We also had federal and state credit carryforwards of approximately $2.6 million and $1.3 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.

Legal Proceedings

We were sued by PharmaStem Therapeutics, Inc. for allegedly infringing two patents relating to our Viacord umbilical cord stem cell cryopreservation business after we rejected PharmaStem s initial requests seeking a license arrangement because we believe that we do not infringe these patents and that they are invalid. PharmaStem filed a complaint on February 22, 2002 and an amended complaint on March 25, 2002, against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 and No. 5,192,553, which relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We counterclaimed that the patents are invalid and unenforceable, and for violation of the antitrust laws resulting from an improper use of PharmaStem s patents, and sought a declaration of non-infringement. Following an October 2003 trial, the jury ruled against us and the other defendants, Cbr Systems, CorCell and Cryo-Cell, who represent a majority of the family cord blood preservation industry, and 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. The jury also found that our infringement was willful. Following the trial, we placed the amount of the award in an escrow account pending final disposition of this case.

On September 15, 2004, the Delaware Court overturned the earlier judgment against ViaCell. The Court ruled that we did not infringe the 553 method patent as a matter of law, and ordered a new trial on infringement and damages, if any, related to the 681 composition patent. PharmaStem s motions for an injunction against us and the other defendants and for prejudgment and postjudgment interest, as well as enhanced damages and attorneys fees based upon the jury s finding of willful infringement, were denied. The judge also denied our motion challenging the validity and enforceability of the patents. On September 24, 2004, our $2.9 million escrow payment was released to the Company. On December 14, 2004, the Delaware Court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the 681 composition patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent. With respect to the 681 patent for which a new trial was granted, PharmaStem filed a motion on October 5, 2004 with the court for a preliminary injunction. Also on October 5, 2004, we filed a complaint with the Delaware court, alleging antitrust and trade violations by PharmaStem concerning misuse of its patents and other deceptive business practices. The court held a hearing on these motions on November 3, 2004, and denied PharmaStem s motion for a preliminary injunction on December 14, 2004 when it overturned the jury verdict on that patent. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005, PharmaStem s Motion to Expedite the Appeal was denied. PharmaStem s appeal brief was filed on March 22, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both the 553 method patent and the 681 composition patent based on the prior art. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 patent as invalid over prior art. PharmaStem has until April 2, 2005 to respond to this Office Action. We expect that the PTO will issue an Office Action relating to the 681 composition patent shortly.

Should the US PTO find the claims of these patents to be unpatentable, then the litigation proceedings between ViaCell and PharmaStem with respect to the unpatentable claims would cease. If the

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Court s judgment as to non-infringement of the 553 or 681 patent is reversed on appeal and if we are subsequently enjoined from further engaging in our umbilical cord stem cell cryopreservation business, we will not be able to conduct this business unless PharmaStem grants a license to us, which PharmaStem previously informed us that it would not do after October 15, 2004. While we do not believe this outcome is likely, if, in the event of an injunction, we are not able to obtain a license under the disputed patents or operate under an equitable doctrine known as intervening rights, we will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products.

PharmaStem also filed a complaint against us on July 29, 2004 in the United States District Court for the District of Massachusetts, alleging infringement of US Patents No. 6,461,645 and 6,569,427, which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. By agreement of the parties, ViaCell responded to the complaint on December 16, 2004. We continue to believe that the patents in this new Massachusetts action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That Motion is currently stayed. If this Motion is granted, we could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if we lose the case. We believe that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, we believe that PharmaStem s Motion will be denied. If we are ultimately found to infringe, we could have a significant damages award entered against us, and 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 on the disputed patents. We believe the issues presented in this case are substantially the same as the issues presented in the 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 January 21, 2005, the Massachusetts case was stayed pending a ruling on this request. On February 16, 2005, our request was granted. The cases have thus been consolidated in Delaware.

The timing and order of the litigations involving ViaCell and PharmaStem are not presently known. Decisions in the re-examination proceedings, now pending before the US PTO, of the 681 and 553 patents may also affect these factors.

We may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all.

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

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On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against us in the United States District Court for the Northern District of California alleging false and misleading advertising by us in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. We are evaluating Cbr s allegations and intend to vigorously defend ourselves in this action.

Critical Accounting Estimates

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

accounting for research and development expenses;

accounting for the valuation of equity instruments;

purchase accounting and in-process technology;

accounting for our product guarantee program; and

accounting for our physician indemnification program.

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

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

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

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

Accounting for royalty expense in connection with the PharmaStem litigation. Cost of revenues in 2003 includes a royalty to PharmaStem relating to a claim for patent infringement. We are currently in litigation with PharmaStem regarding this claim. We recorded a royalty expense of approximately $3.3 million in 2003 following a jury verdict in October 2003 which found infringement. This expense included a royalty of approximately $2.9 million on revenues from cord blood preservation through October 29, 2003, plus an accrual of 6.125% of subsequent revenues through December 31, 2003. We also

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recorded an expense of $0.5 million for the three months ended March 31, 2004, also based on 6.125% of revenues. In September 2004, the court overturned the jury verdict on one of the two patents in litigation and vacated the verdict and granted a new trial on the second patent. Based on the judge s ruling, we reversed the entire royalty accrual of $3.8 million in the quarter ended June 30, 2004. On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent. Pending further action by the courts, we do not intend to record a royalty expense in future periods, since we believe the claim is without merit. It is possible that the final outcome of this litigation, as well as the final outcome of the patent litigation PharmaStem recently brought against us in Massachusetts, could result in damages payable at a higher or lower amount than previously awarded by the Delaware jury. Should this occur, our financial position and results of operations could be materially affected. In addition, we may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts by us to PharmaStem, or what those amounts might be.

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

Accounting for the valuation of equity instruments. We record compensation expense related to options issued to consultants and employees based on the deemed fair value of the common stock underlying the options. Because there has been no public market for our common stock, we have estimated the fair value of these equity instruments using various valuation methods. If future market conditions dictate significant changes in the estimates of fair value, or if a public market establishes a value for our common stock that is significantly higher than our estimated value, our financial position and results of operations could be materially affected.

Purchase accounting and in-process technology. We expense costs associated with purchased licenses used in our on going research and development activities, which have not yet reached technical feasibility and have no alternative future use.

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Upon consummation of the Kourion acquisition, we immediately expensed as in-process technology a portion of the fair value allocated to in-process research and development (IPR&D).

We believe that this charge represents a reasonably reliable estimate of the future benefits attributed to purchased IPR&D. The value assigned to IPR&D was composed of the projected value of the two Kourion preclinical drug development projects. The valuation was determined using the income approach. Potential revenue and drug development expenses were projected through 2021 based on management s estimates. Specifically, we estimated that the development of the Kourion programs through clinical trials to commercial viability would take approximately eight years and would cost in excess of $31.0 million. The discounted cash flow method was applied to the projected cash flows, adjusted for the probability of success using a discount rate of 23%. The discount rate takes into consideration the uncertainty surrounding the successful development and commercialization of the IPR&D. Since the acquisition, nothing has occurred that would lead us to believe that the original estimates of the cost to develop these therapies, or their revenue potential, is materially different from the estimates used at the time of the acquisition for purposes of purchase accounting.

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

Accounting for our physician indemnification program. During September 2004, we launched an indemnification program protecting physicians from patent litigation actions taken against them by PharmaStem Therapeutics, Inc. Under this program we agree to pay reasonable defense costs resulting from such litigation, providing that the physicians allow us to manage their defense. In addition, we will pay all damages resulting from such litigation, and we will pay an additional $100,000 to the physicians if PharmaStem prevails in any patent infringement litigation against the physician. In order to qualify for this indemnification the physicians are required to comply with certain requirements including returning a signed acknowledgement form around the particulars of the indemnification program. We have recorded a reserve associated with this program of $51,000 in our December 31, 2004 financial statements in compliance with FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). The reserve is equal to the estimated fair value of the indemnification arrangements entered into as of December 31, 2004. We have determined the reserve through a probability model based on assumptions related to the likelihood of legal ramifications, and the extent of those ramifications, applicable under this program for the potential professional fees, damages, and remunerations related to the agreements executed as of December 31,

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2004. These assumptions involve judgment by management and are subject to change as additional physicians enroll in the program, if the actual amount of patent litigation and related defense costs exceed our estimates or if Pharmastem s patents are overturned by the US Patent office. We believe Pharmastem has no legal basis to pursue patent litigation against physicians who assist in collecting cord blood on behalf of our customers. However, our assumptions contemplate a wide range of possible outcomes including the possibility of Pharmastem pursuing and prevailing in such patent litigation, although we believe the likelihood of this is remote.

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Instruments with Characteristics of both Liabilities and Equity* (SFAS No. 150). This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of these instruments were previously classified as equity. This statement is effective for new or existing contracts at the beginning of the first interim period beginning after June 15, 2003. The adoption of this statement did not have a material impact on our financial statements.

In December 2003, the FASB issued FASB Interpretation No. 46-R (FIN 46-R) a revised interpretation of FASB Interpretation No. 46 (FIN 46). FIN 46-R requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The provisions of FIN 46-R are effective immediately for all arrangements entered into after January 31, 2003. For all arrangements entered into after January 31, 2003, we are required to continue to apply FIN 46-R through the end of the first quarter of fiscal 2004. We do not have any equity interests that would change its current reporting or require additional disclosures outlined in FIN 46-R. For arrangements entered into prior to February 1, 2003, we are required to adopt the provisions of FIN 46-R in the first quarter of fiscal 2004. We do not have any equity interests that would change its current reporting or require additional disclosures outlined in FIN 46-R.

On December 16, 2004, the FASB released SFAS No. 123R. This new accounting standard requires all forms of stock compensation, including stock options, to be reflected as an expense in our financial statements. Public companies must adopt the standard by their first fiscal period beginning after June 15, 2005. We intend to apply the revised standard beginning with the quarter ending September 30, 2005. Although we have not finalized our analysis, we expect that the adoption of the revised standard will result in higher operating expenses and lower earnings per share. Note 2 to the consolidated financial statements shows the pro-forma impact on net loss and net loss per common share as if we had historically applied the fair value recognition provisions of SFAS No. 123 to stock based employee awards.

In December 2004, the FASB issued Statement No. 153 (FAS 153), Exchanges of Nonmonetary Assets Accounting Principles Board Opinion No. 29, Accounting for Nonmonetary Transactions (APB 29). FAS 153 is based on the principle that nonmonetary asset exchanges should be recorded and measured at the fair value of the assets exchanged, with certain exceptions. This standard requires exchanges of productive assets to be accounted for at fair value, rather than at carryover basis, unless (i) neither the asset received nor the asset surrendered has a fair value that is determinable within reasonable limits or (ii) the transactions lack commercial substance (as defined). In addition, the FASB decided to retain the guidance in APB 29 for assessing whether the fair value of a nonmonetary asset is determinable within reasonable limits. The new standard is the result of the convergence project between the FASB and the International Accounting Standards Board (IASB). We will adopt this standard for nonmonetary asset exchanges in the event that these types of transactions are entered into by us in future periods.

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Risk Factors That May Affect Results

Our cellular therapy product candidates are at an early stage of development, and if we are not able to successfully develop and commercialize them, we may not generate sufficient revenues to continue our business operations.

Our cellular therapy product candidates are in the early stages of development. In particular, our lead stem cell product candidate, CB001, has only recently entered Phase I clinical trials. CB001 has not previously been studied in humans, and we have no safety or efficacy data on this product candidate yet. While stem cell therapy is an accepted medical procedure for the regeneration of the blood and immune systems for patients with cancer and other serious diseases a procedure for which we are developing CB001 stem cell populations expanded using our Selective Amplification technology have not yet been shown to be safe or effective for such treatments. Additionally, there has been only limited use of stem cells in treating cardiac disease in clinical trial settings, which is an additional indication we are targeting. As a result, there is substantial uncertainty about the effectiveness of CB001 for its target indication and about whether our program targeting another indication will be successful.

We expect that none of our cellular therapy product candidates will be commercially available for at least three 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 discover that manipulation of stem cells using Selective Amplification changes the biological characteristics of stem cells. For this or other reasons, therapeutic products developed with our stem cell expansion technology may fail to work as intended, even in areas where stem cell therapy is already in use. This may result from the failure of our products to:

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

provide the intended therapeutic benefits; or

achieve benefits that are better or equal to existing therapies.

While our Selective Amplification technology has shown successful results in preclinical research, those results were not obtained in humans and may not be indicative of results we may encounter in future preclinical studies or clinical trials. Since none of our product candidates have progressed past Phase I clinical trials, we cannot determine whether our preclinical testing methodologies are predictive of clinical safety or efficacy. As we obtain results from further preclinical or clinical trials, we may elect to discontinue or delay preclinical studies or clinical trials for certain product candidates in order to focus our resources on more promising product candidates. 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 preclinical or initial clinical testing.

If our product candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals for our technologies or product candidates. Even if we are successful in developing and gaining regulatory approval for CB001, we do not expect to obtain approval before 2008.

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

Revenues from our umbilical cord blood preservation and storage products have grown significantly over the past several years, from $7.1 million in fiscal 2001, to $20.1 million in fiscal 2002, to $30.9 million in fiscal 2003 to $36.8 million in fiscal 2004. We believe that this is a result of our increased marketing efforts and from increased awareness by the public generally of the concept of cord blood banking. We may not be able in the future, however, to sustain this growth rate nor the current level of Viacord s revenues. Principal factors that may adversely affect our revenue, such as litigation, competition from other private cord blood banks or risks of reputational damage, are described elsewhere in this Risk Factor section in more detail. If we are unable to sustain our revenues, we may need to reduce our product candidate development activities or raise additional funds earlier than anticipated or on unfavorable terms.

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

We have generated operating losses since our inception. As of December 31, 2004, we had cumulative net losses of approximately $158.8 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately $88.3 million since our inception. We expect our losses to increase for the next several years as we make substantial expenditures to further develop and commercialize our product candidates. In particular, we expect that our rate of spending will accelerate over the next several years as a result of increased costs and expenses associated with clinical trials, including our current Phase I trial for CB001, submissions for regulatory approvals and potential commercialization of our products, including the build out of commercial scale manufacturing facilities. Furthermore, we expect to make additional investments in the near term in our ViaCell Reproductive Health franchise, as we seek to expand the market for our Viacord product offering and develop our Viacyte product candidate. Our ability to become profitable will depend on many factors, including our ability to establish the safety and efficacy of our product candidates, obtain necessary regulatory approvals and successfully commercialize products. We cannot assure you that we will ever become profitable.

We and several other defendants, representing a majority of the industry, are defendants in lawsuits alleging infringement of patents relating to our Viacord umbilical cord stem cell cryopreservation business. If we are not able to resolve the suits favorably, we could be permanently enjoined from further engaging in this business, which would result in the loss of the current source of almost all of our revenues, or we may be required to pay a royalty.

We were sued for infringing two patents relating to our Viacord umbilical cord stem cell cryopreservation business after we rejected the initial requests of the plaintiff, PharmaStem Therapeutics, Inc., seeking a license arrangement because we believe that we do not infringe these patents and that they are invalid. In October 2003, the jury in this case in the United States District Court for the District of Delaware ruled that we and the several other defendants, who represent a majority of the family cord blood preservation industry, willfully infringed the two patents, which relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. In September 2004, the federal district court overturned the jury verdict on one of the two patents in litigation and vacated the verdict and granted a new trial on the issues of infringement and damages (if any) concerning the second patent. The Delaware Court also denied PharmaStem s motions seeking a permanent injunction against all of the defendants in the suit to enjoin our further conducting our business, as well as its motion requesting that the damages against us be increased up to three times the amount of the award for past infringement and to include legal fees and interest. We had requested that the Court find the PharmaStem patents invalid and unenforceable as a matter of law, but the Court denied this request. On December 14, 2004, the Delaware Court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. With respect to the patent for which a new trial had been granted, PharmaStem filed a motion on October 5, 2004 with the court for a preliminary injunction. The court denied that motion on December 14, 2004 when it overturned the jury verdict on that patent. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005, PharmaStem s Motion to expedite the Appeal was denied. PharmaStem s appeal brief was filed on March 22, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both of these patents based on the prior art submitted. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 method patent as unpatentable over the prior art. PharmaStem will now have an opportunity to respond to this Office Action by arguing that its claims are patentable. If the US PTO does not find the claims of the patents to be unpatentable and if an appeal in the litigation is not resolved favorably to us, we could be enjoined from further engaging in our umbilical cord stem cell cryopreservation business. In such case, we will not be able to conduct this business unless PharmaStem grants a license to us. In such event, 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 at all

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after October 15, 2004. If it becomes necessary, but we are unable, to obtain a license, or are unable to obtain a license on economically reasonable terms, we will not be able to further engage in our umbilical cord stem cell cryopreservation business. If we cannot continue our cord blood preservation business, that would have a material adverse effect on our business, results of operations and financial condition, as we would no longer have access to the current source of almost all of our revenues. We had revenues of approximately $36.8 million in 2004 from Viacord sales. The judgment in the case, which was subsequently overturned, was entered against us for approximately $2.9 million relating to past infringement, based on 6.125% royalties on our revenue from the storage of umbilical cord blood since April 2000. If it becomes necessary, and we are able, to obtain a license from PharmaStem, it may be at a royalty rate greater than 6.125% or on terms less favorable than PharmaStem has granted to other cord blood banks. For example, we understand PharmaStem has licensed other cord blood banks under its patents for royalty rates of 15%. We have also been sued again by PharmaStem in federal district court in Massachusetts on two different but related patents, as have several others in the family cord blood preservation industry, albeit in separate actions in other courts, and many of the same risks are present in that litigation as in the original Delaware litigation. We filed and were subsequently granted a motion to consolidate the Massachusetts case with six other actions in a single proceeding in the District of Delaware. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. If this Motion is granted, we could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if we lose the case. We believe that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, we believe that PharmaStem s Motion will be denied. We may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. 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. For a fuller discussion of the PharmaStem litigation, see the section entitled Item 3 Legal Proceedings.

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

As of December 31, 2004, we had approximately $28.6 million in cash, cash equivalents, short- and long-term investments. Subsequently, in January 2005, we received net proceeds of approximately $53.6 million from our initial public offering. We used $15.5 million of these net proceeds to repay a note and accrued interest. In order to develop and bring our stem cell product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials. While we anticipate that our existing cash, cash equivalents and investments, will be sufficient to fund our current operations for the next two to three years, we may need or want to raise additional funding sooner, particularly if our business or operations change in a manner that consume 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 our umbilical cord blood preservation activities;
- the scope and results of our research and development programs;
- the scope and results of our clinical trials, particularly those involving CB001, which is currently in a Phase I trial;
- the timing of and the costs involved in obtaining regulatory approvals, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s relatively little experience with cellular-based therapeutics;
- the costs of building and operating our manufacturing facilities, both in the near term to support our clinical activities, and also in anticipation of growing our commercialization activities;

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

If the potential of stem cell therapy to treat serious diseases is not realized, the value of our Selective Amplification technology and our development programs could be significantly reduced.

The potential of stem cell therapy to treat serious diseases is currently being explored by us and other companies. It has not been proven in clinical trials that stem cell therapy will be an effective treatment for diseases other than those currently addressed by hematopoietic stem cell transplants. No stem cell products have been successfully developed and commercialized to date, and none has received regulatory approval in the United States or internationally. Stem cell therapy 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. If the potential of stem cell therapy to treat serious diseases is not realized, the value of our Selective Amplification technology and our development programs could be significantly reduced.

We cannot market and sell CB001 or our other product candidates in the United States or in other countries if we fail to obtain the necessary regulatory approvals or licensure.

We cannot sell CB001, or other cellular product candidates, until regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain. It is likely to take three to five years or more to obtain the required regulatory approvals for our lead stem cell product candidate, CB001, or we may never gain necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly.

To obtain regulatory approvals in the United States for CB001, for instance, we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the US Food & Drug Administration, or FDA, that CB001 is safe, effective and potent for each disease for which we seek approval. Several factors could prevent completion or cause significant delay of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that CB001 is safe, effective and potent for use in humans. Negative or inconclusive results from or adverse medical events during a clinical trial could cause the clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful. The FDA can place a clinical trial on hold if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury. If safety concerns develop, we or the FDA could stop our trials before completion. Although we do not have particular reasons to expect

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unusual delays or a need to terminate our clinical trials, to date, some participants in our CB001 clinical trial have experienced serious adverse events, two of which have been determined to be possibly related to CB001. A serious adverse event is an event that results in significant medical consequences, such as hospitalization, disability or death and must be reported to the FDA. While we believe that the serious adverse event profiles we have observed are consistent with those of the disease conditions of patients in the trial and with those associated with stem cell and bone marrow transplants generally, we cannot assure you that safety concerns regarding CB001 will not develop.

We have only recently initiated our first clinical trial for CB001, and thus have no clinical trial history for this product candidate. Indeed, the FDA has relatively little experience with therapeutics based on cellular medicine generally. As a result, the pathway to regulatory approval for CB001 may be more complex and lengthy than for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the United States, we will need to submit clinical data concerning our products and receive regulatory approval from governmental agencies, which in certain countries includes approval of the price we intend to charge for our product. 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. If we are not able to obtain regulatory approvals for use of CB001 or other products under development, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

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

Cord blood preservation. Our Viacord cord blood preservation product is currently subject to FDA regulations requiring infectious disease testing. We have registered with the FDA as a cord blood preservation service, listed our products with the FDA, and we are subject to FDA inspection. In addition, the FDA has recently adopted new good tissue practice (GTP) regulations that establish a comprehensive regulatory program for human cellular and tissue-based products and finalized rules for donor eligibility and that will become effective in May of 2005. We believe that we comply with existing regulatory requirements and will be in compliance with the new GTP regulations as recently adopted. However, we may not be able to maintain this compliance or comply with future regulatory requirements that may be imposed on us, including product standards that may be developed. Moreover, the cost of compliance with government regulations may adversely affect our revenue and profitability. Regulation of our cord blood preservation services in foreign jurisdictions is still evolving.

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

Of the states in which we provide cord blood banking services, only New Jersey, New York, Maryland, Kentucky, Illinois and Pennsylvania currently require that cord blood banks be licensed or registered. We are currently licensed or registered to operate in New Jersey, New York, Kentucky, Illinois and Pennsylvania, and we believe that we will be able to comply with the license and registration requirements in Maryland which we recently identified. If other states adopt requirements for the licensing or registration of cord blood preservation services, we would have to obtain licenses or register to continue providing services in those states.

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Oocyte cryopreservation. There are no established precedents for US and international regulation of oocyte cryopreservation. We anticipate that in the Unites States cryopreservation of oocytes will be regulated similarly to Viacord s family umbilical cord blood cryopreservation product. We also anticipate that some of the components used in this product will be regulated as medical devices under a 510(k) clearance mechanism. For instance, prior to marketing this product, our media supplier will be required to obtain 510(k) clearance for the technology we have licensed for use in the cryopreservation of oocytes. In November of 2004, our media supplier submitted a 510(k) to the FDA for clearance of the oocyte cryopreservation media. In January of 2005, our media supplier informed us that they had received a letter from the FDA that included the following information:

a statement that our media supplier will need to conduct a clinical study that produces pregnancy and birth rates data to support the application; and

a request that various additional information be submitted, including stability, toxicity testing, biocompatibility and labeling information.

Clinical data were not included in the original 510(k) application. Our media supplier has responded to the FDA letter and has submitted existing, published third party clinical data and additional information to the pending 510(k) application. We believe that the existing, published clinical data may be sufficient to support 510(k) clearance of the media; however, it is likely that a new clinical trial will be required which could substantially delay 510(k) clearance and our launch of Viacyte.

In addition, although the letter from the FDA did not suggest that any other approval process would be required other than the 510(k) process, the FDA could at any time determine, for instance, that:

cryopreservation of oocytes requires biologic marketing approval, entailing an Investigational New Drug (IND) application to conduct clinical trials and extensive clinical and nonclinical data and a biologics license application (BLA) for market approval; and/or

components used to cryopreserve the oocytes require PMAs.

Either scenario would substantially lengthen our planned developmental timeline for and substantially increase the costs of commercializing this service. We have not investigated the regulations for the cryopreservation of oocytes in foreign jurisdictions.

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

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our product candidates, technologies and trade secrets. We own or have exclusive licenses to six US patents and two international patents. We also own or have exclusive licenses to 12 pending applications in the United States and 52 pending applications in foreign countries. Our pending patent applications may not issue, and we may not receive any additional patents. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the US Patent and Trademark Office 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 US patents and those that may issue in the future, or those licensed to us, may not offer significant protection of our Selective Amplification and other technologies. Our patents on Selective Amplification, in particular, are quite broad in that they cover selection and amplification of any targeted cell population. While Selective Amplification is covered by issued patents and we are not aware of any challenges, patents with broad claims tend to be more vulnerable to challenge by other parties than patents with more narrowly written claims. Our patent applications covering Unrestricted Somatic Stem Cells (USSCs) claim these cells as well as their use in the treatment of many diseases. It is possible that these cells could be covered by other patents or patent applications which identify, isolate or use the same cells by other markers, although we are not aware of any. Third parties may challenge, narrow, invalidate or circumvent any patents we obtain based on these applications.

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Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us in a manner that does not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. For instance, our patents on Selective Amplification issued in 1997 and will expire in 2014. To the extent our product candidates based on that technology are not commercialized significantly ahead of this date, or to the extent we have no other patent protection on such products, those products would not be protected by patents beyond 2014. Without patent protection, those products might have to compete with identical products by competitors.

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

CB001 and our other cellular product candidates represent new forms of therapy or products that the marketplace may not accept.

Even if we successfully develop and obtain regulatory approval for CB001 or other stem cell therapy products, the market may not accept them. Other than hematopoietic stem cell transplants, stem cell therapy is not currently a commonly used procedure. Similarly, our oocyte cryopreservation product candidate, if developed and cleared for commercial use, may not be accepted by the market. Market demand for our products will depend primarily on acceptance by patients, physicians, medical centers and third party payers. Commercial acceptance will be dependent upon several factors, including:

the number and relative efficacy of products that compete with our product;

our ability to supply a sufficient amount of our product to meet demand;

our ability to build and maintain, or access through third parties, a capable sales force;

our ability to successfully fund launch costs; and

our ability to obtain insurance coverage and reimbursement for our cellular therapy products.

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. We currently have strategic relationships with Amgen, Genzyme and Massachusetts General Hospital. While we are currently in discussions with a number of companies, universities, research institutions, public cord blood banks and others to establish additional relationships and collaborations, we may not reach definitive agreements with any of them. Even if we enter into these arrangements, we may not be able to maintain these relationships or establish new ones in the future on acceptable terms. Furthermore, these arrangements may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, or may have other terms that are burdensome to us, and may involve the acquisition of our securities. Our partners may decide to develop alternative technologies either on their own or in collaboration with others. If any of our partners terminate their relationship with us or

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fail to perform their obligations in a timely manner, the development or commercialization of our technology and potential products may be substantially delayed.

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

Our success depends in part on our not infringing other parties patents and proprietary rights as well as not breaching any licenses relating to our technologies and product candidates. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, there may be patents of which we are unaware, and avoiding patent infringement may be difficult. We may inadvertently infringe third party patents or patent applications. These third parties could bring claims against us, our collaborators or our licensors that, even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. For instance, in defending the Delaware claim of patent infringement brought against us by PharmaStem, which, until recently, was the only infringement claim we had faced, we have incurred total legal expenses as of December 31, 2004 of $6.5 million. Depending upon the extent of the appeals process concerning either or both patents asserted in Delaware, and the extent we litigate the additional patent infringement lawsuit originally brought by PharmaStem in Massachusetts and any related appeals, we estimate that we could incur at least an additional $1.0 million to $2.0 million in litigation expenses. Further, if other patent infringement suits were brought against us, our collaborators or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. In addition, payments under such licenses would reduce the earnings otherwise attributable to the related products.

We also may be required to pay substantial damages to the patent holder in the event of an infringement. Under some circumstances in the United States, these damages could be triple the actual damages the patent holder incurred, and we could be ordered to pay the costs and attorneys fees incurred by the patent holder. If we have supplied infringing products to third parties for marketing, or licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for any damages they may be required to pay to the patent holder and for any losses the third parties may sustain themselves as the result of lost sales or damages paid to the patent holder.

In addition to the two PharmaStem patent infringement lawsuits we are contesting, we are aware that PharmaStem owns an additional patent, U.S. Patent No. 6,605,275, in the cord blood preservation field, which is the field in which we currently do business regarding Viacord and, if approved and commercialized, our CB001 product candidate. This patent expires in 2010. We are also aware of two patents relating to compositions of purified hematopoietic stem cells and their use in hematopoietic stem cell transplantation, which could impact our stem cell therapeutics business. We believe, based on advice of our patent counsel, that we do not infringe any valid claims of this additional PharmaStem patent or of these two other patents. We cannot assure you, however, that if we are sued on any of these patents we would prevail. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe these patents and are not able to obtain a license, we may not be able to operate our business.

Any successful infringement action brought against us may also adversely affect marketing of the infringing product in other markets not covered by the infringement action, as well as our marketing of other products based on similar technology. 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 would likely delay the

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regulatory approval process, harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

We may be involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time consuming.

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 not valid or is 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.

Interference proceedings brought by the US Patent and Trademark Office 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. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

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.

In order to commercialize CB001 or other product candidates using our Selective Amplification technology, we may need to obtain additional license rights to third party patents, which may not be available to us on reasonable terms, or at all.

Some aspects of our Selective Amplification technology involve the use of antibodies, growth factors and other reagents that are, in certain cases, the subject of third party rights. We have the rights to third party patents for use of all growth factors employed in manufacturing our current product candidates for preclinical and clinical testing, including licenses from Amgen for SCF and Flt-3 and GlaxoSmithKline for Tpo mimetic. The media in which we amplify the cells is available from several commercial sources. Before we commercialize any product utilizing this technology, including CB001, we may need to obtain additional license rights to use reagents from third parties not covered by these patents or licenses. If we are not able to obtain these rights on reasonable terms or redesign our Selective Amplification process to use other reagents, we may not be able to commercialize any products, including CB001. If we must redesign our Selective Amplification process to use other reagents, we may need to demonstrate comparability in subsequent clinical trials.

The successful commercialization of CB001, or any of our other potential cell therapy products, will depend on obtaining reimbursement for use of this product from third party payers.

If we successfully develop and obtain necessary regulatory approvals, we intend to sell our lead product CB001 initially in the United States and the European Union. In the United States, the market for many pharmaceutical products is affected by the availability of reimbursement from third party payers such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. CB001 and our other 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

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more difficult for us to obtain adequate reimbursement from third party payers, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payers may also deny coverage or offer inadequate levels of reimbursement for CB001 or any of our other potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate. In the countries of the European Union and in some other countries, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control.

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

Although we are aware of a small fraction of Viacord customers receiving reimbursement, we believe our Viacord cord blood preservation product, like other private cord blood banking, is not generally subject to reimbursement. However, if our potential cell therapy products, like CB001, are not reimbursed by the government or third party insurers, the market for those products would be limited. We cannot be sure that third party payers will reimburse sales of a product or enable us or our partners to sell the product at prices that will provide a sustainable and profitable revenue stream.

We have only limited experience manufacturing cell therapy product candidates in connection with our preclinical and clinical work to date, and we may not be able to manufacture our product candidates in quantities sufficient for later stage clinical studies or for commercial scale.

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

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

Certain antibodies, growth factors and other reagents are critical components used in our stem cell production process. Our Selective Amplification process currently uses components sold to us by certain manufacturers, and we need to establish relationships with other suppliers to manufacture cGMP grade products for commercial sale. We are materially dependent on our suppliers for such components. Some of these components are supplied to us by Amgen, GlaxoSmithKline and Miltenyi Biotec, with whom we have agreements to supply SCF, Flt-3 Tpo mimetic and cGMP grade antibodies conjugated with magnetic particles and who are our only single-source suppliers on whom we currently materially rely. Other components, such as research grade materials that are suitable for production of stem cells used for research and in Phase I human clinical studies, are purchased as catalog products from vendors, such as

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StemCell Technologies and R&D Systems, with which we do not have relationships. In order to continue our clinical trials and commercialize our Selective Amplification products, we will need to establish relationships with some of these suppliers. In the event that our suppliers are unable or unwilling to produce such components on commercially reasonable terms, and we are unable to find substitute suppliers for such components, we may not be able to commercialize our stem cell products. We depend on our suppliers to perform their obligations in a timely manner and in accordance with applicable government regulations. In the event that any of these suppliers becomes unwilling or unable to continue to supply necessary components for the manufacture of our stem cell products, we will need to repeat certain development work to identify and demonstrate the equivalence of alternative components purchased from other suppliers. If we are unable to demonstrate the equivalence of alternative components in a timely manner, or purchase these alternative components on commercially reasonable terms, development of our products may be delayed and we may not be able to complete development of or market our stem cell products.

Material for clinical studies and future cellular products must be manufactured using components made to a certain standard, and we may have difficulty finding sources of these components made to this standard.

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 enter into supply agreements with firms who manufacture these components to cGMP standards. We are currently in discussions with multiple firms who we may engage as suppliers for these components. Once we engage these third parties, we may be materially dependent on them for supply of cGMP grade components. If we are unable to obtain cGMP grade biological components for our products, we may not be able to market our stem cell products.

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

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

We have a clinical manufacturing facility located in Worcester, Massachusetts that is capable of producing stem cells for Phase I and II clinical trials. We are building out a facility in Cambridge, Massachusetts that we intend to replace our Worcester facility and be capable of producing stem cells for Phase II and III clinical trials and initial commercialization. In January 2005, we closed our facility in Langenfeld, Germany and transferred all manufacturing and development activities that had been conducted in Germany to the United States. For the next several years, we expect to manufacture all of our stem cell product candidates in our new Cambridge facility. If this facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. In the event of a temporary or protracted loss of this facility or equipment, we may be able to transfer manufacturing to a third party, but the shift would likely be expensive, and the timing would depend on availability of third party resources and the speed with which we could have a new facility approved by the FDA.

While we believe that we have insured against losses from damage to or destruction of our facilities consistent with typical industry practices, if we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies. Currently, we maintain insurance coverage totaling $20.9 million against damage to our property and equipment, and an additional $18.0 million to cover incremental expenses and loss of profits resulting from such damage.

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

Our success is highly dependent on the retention of the principal members of our scientific, management and sales personnel. Marc D. Beer, our President and Chief Executive Officer, is critical to our ability to execute our overall business strategy. Morey Kraus, our Chief Technology Officer and co-founder, is a co-inventor of our Selective Amplification technology and has significant and unique expertise in stem cell expansion and related technologies. We maintain key man life insurance on the lives of Marc D. Beer and Morey Kraus. Additionally, we have several other scientific personnel that we consider important to the successful development of our technology. Although we are not aware that any of our key employees are currently planning to retire or leave the company, any key employee 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.

Although we have been successful recruiting and retaining key personnel in the past, 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 services in the United States. This expansion could put significant strain on our management, operational and financial resources. Currently, our only facilities abroad are offices and laboratories in Singapore. To manage future growth, we would need to hire, train and manage additional employees, particularly a specially-trained sales force. We plan to begin commercializing our oocyte cryopreservation technology if and when the cryopreservation media obtains FDA 510(k) clearance, which would not occur earlier than 2007, unless the FDA were to no longer require a clinical trial to support the current application for clearance, in which case we believe we may be able to receive clearance and begin commercialization in 2005. To commercialize this product, we would be required to institute additional and distinct sales and marketing, manufacturing and storage capacities in addition to leveraging our existing capabilities in these areas. Concurrent with expanding our reproductive health activities, we will also be increasing our research and development activities, most significantly the clinical development of our lead product candidate, CB001, with the expectation of ultimately commercializing that product candidate.

Prior to our recently completed initial public offering in January, we maintained a small finance and accounting staff because we were a private company. Our new 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 National Market, will place significant additional demands on our finance and accounting staff, on our financial, accounting and information systems and on our internal controls. We intend to add to 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.

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If we acquire other businesses or technologies and are unable to integrate them successfully with our business, our financial performance could suffer.

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

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 pharmaceutical and biotechnology businesses are highly competitive. We compete with many organizations that are developing cell therapies for the treatment of a variety of human diseases, including companies such as Aastrom Biosciences, Cellerant, Gamida-Cell, Geron, Genzyme, Neuronyx, Osiris Therapeutics and Stem Cells. We also face competition in the cell therapy field from academic institutions and governmental agencies. Some of these competitors, and future competitors, may have similar or better product candidates or technologies, greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities. Specifically, Gamida-Cell, a private company based in Israel, is developing a hematopoetic stem cell therapy product candidate similar to CB001. This product has been evaluated in a Phase I trial. Another competitor, Osiris Therapeutics, a private company based in the United States, has a mesenchymal stem cell product candidate made from bone marrow that is intended for use in conjunction with transplantation of conventional bone marrow or cord blood cells. Osiris s product candidate has already completed Phase I testing. Either of these product candidates, and potentially others, could have equal or better efficacy than CB001 or could potentially reach the market more quickly than CB001. In addition, public cord blood banks may, as a result of a recent legislative initiative, be able to better compete with our potential cell therapy products, such as CB001. The Cord Blood Stem Cell Act of 2003, which has not yet been enacted into law, sought to authorize up to $15 million in federal funding for a national system of public cord blood banks and encourage cord blood donations in fiscal year 2004 and up to $30 million in fiscal year 2005 from an ethnically diverse population. The purpose of the legislation is to create a national network of cord blood stem cell banks that contains at least 150,000 units of human cord blood stem cells. An increase in the number and diversity of publicly-available cord blood units from public banks could diminish the necessity of cord blood-derived therapeutics produced with our Selective Amplification technology.

In private cord blood banking, we compete with companies such as Cbr Systems, Cryo-Cell International, CorCell and LifeBank USA. LifeBank USA is owned by Celgene Corporation, a public company, and may have more resources to invest in sales, marketing, research and product development than we have. In cord blood banking, we also compete with public cord blood banks such as the New York Blood Center (National Cord Blood Program), University of Colorado Cord Blood Bank, Milan Cord Blood Bank, Düsseldorf Cord Blood Bank, and approximately 50 other cord blood banks around the world. Public cord blood banks provide families with the option of donating their cord blood for public use. There is no cost to donate and, as public banks grow in size and increase in diversity, which is, for instance, the aim of the Cord Blood Stem Cell Act of 2003, the probability of finding suitably matched cells for a family member may increase, which may result in a decrease in demand for private cord blood banking. In addition, if the science of human leukocyte antigen (HLA) typing advances, then unrelated

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cord blood transplantation may become safer and more efficacious, similarly reducing the clinical advantage of related cord blood transplantation.

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

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

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

Our cord blood preservation and our potential oocyte cryopreservation products are and will be activities in which our reputation among clients and the medical and birthing services community will be extremely important to our commercial success. This is due in significant part to the nature of the product and service we provide. For instance, as part of our Viacord product, we are assuming custodial care of a child s umbilical cord blood tissue entrusted to us by the parents for potential future use as a therapeutic for the child or its siblings. We believe that our reputation enables us to market ourself 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 mishaps. 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 mishaps, particularly if publicized in the media or otherwise, could negatively impact our reputation, which could adversely affect our business and business prospects.

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

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The manufacture and sale of stem cell 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 stem cell products produced using our technology are alleged or found to have caused injury. While we believe that our current liability insurance coverage is adequate for our present commercial activities, we will need to increase our insurance coverage if and when we begin commercializing stem cell therapy products. We may not be able to obtain insurance for potential liability arising from any such potential products on acceptable terms with adequate coverage 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.

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 Heath Insurance Portability and Accountability Act of 1996, or HIPAA (Privacy Rule). Although we ourselves are not directly regulated by the HIPAA Privacy Rule, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider who has not satisfied the HIPAA Privacy Rule s disclosure standards. In addition, certain state privacy laws and genetic testing laws may apply directly to our operations and impose restrictions on our use and dissemination of individuals health information. Moreover, patients about whom we obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

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, Singapore and Germany 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

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

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

Quantitative and Qualitative Disclosure 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 subsidiary Kourion Therapeutics are recorded in euros. Exchange gains or losses resulting from the translation of Kourion s financial statements into US dollars are included as a separate component of stockholders deficit. We hold euro-based currency accounts to mitigate foreign currency transaction risk. Since both the revenues and expenses of this subsidiary are denominated in euros, the fluctuations of exchange rates may adversely affect our results of operations, financial position and cash flows.

Interest Rate Risk

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

ITEM 8. ***CONSOLIDATED FINANCIAL STATEMENTS***

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

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

None.

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2004 and, based on their evaluation, our principal executive officer and principal financial officer have concluded that these controls and procedures are effective. Disclosure controls and procedures are our controls and other procedures that are designed to

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ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

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

The information required with respect to directors is incorporated herein by reference to the information contained in the definitive proxy statement for our 2005 Annual Meeting of Stockholders (the Proxy Statement). The information with respect to our audit committee financial expert is incorporated herein by reference to the information contained in the section captioned Audit Committee of the Proxy Statement.

We have adopted a Code of Business Conduct and Ethics for our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and employees. Our Code of Business Conduct and Ethics is available in the Corporate 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 Code of Business Conduct and Ethics on our website. Stockholders may request a free copy of the Code of Business Conduct and Ethics by writing to us at ViaCell, Inc., 245 First Street, Cambridge, Massachusetts 02142, Attention: Investor Relations.

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

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MANAGEMENT

Executive Officers and Key Employees

Set forth below is information regarding our executive officers and key employees as of March 29, 2005.

Name	Age	Positions
Executive Officers:		
Marc D. Beer	40	President, Chief Executive Officer and Director
Stephen G. Dance	54	Senior Vice President, Finance and Chief Financial Officer
Christoph M. Adams, Ph.D	48	Senior Vice President, Business Development
Kurt C. Gunter, M.D	50	Senior Vice President, Clinical and Regulatory Affairs and Government Relations
Mary T. Thistle	45	Senior Vice President, General Manager, ViaCell Reproductive Health
Stephan Wnendt, Ph.D	42	Senior Vice President, Research and Development
Key Employees:		
Morey Kraus	46	Vice President and Chief Technical Officer
Mary Larson-Marlowe	39	Vice President, Therapeutic Development Operations

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. Prior to this, from 1996 until April 2000, he was a senior manager at Genzyme Corporation most recently serving in the role of Vice President, Global Marketing for Genzyme Therapeutics WorldWide, a division of Genzyme Corporation. Mr. Beer has more than 15 years experience in profit and loss management, sales and marketing management, and research and development program management in therapeutic, surgical, and in vitro diagnostic systems businesses. Mr. Beer has served as a member of the board of directors of Nephros Therapeutics, a private company, since 2001. Mr. Beer has a B.S. from Miami University (Ohio).

Stephen G. Dance. Mr. Dance joined us as Senior Vice President, Finance and Chief Financial Officer in January 2004. Prior to this, he was Senior Vice President, Finance at SangStat Medical Corporation, a biotechnology company, from April 1999 until December 2003, 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 (later part of the Roche group), in a variety of increasingly responsible finance positions including controller of US sales, marketing and manufacturing operations. 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.

Christoph M. Adams, Ph.D. Dr. Adams has served as our Senior Vice President, Business Development since joining our company in July 2001. Prior to joining us, from March 1994 until February 2001, Dr. Adams was Vice President, Business Development for Transkaryotic Therapies Inc., a publicly traded biotechnology company, where he was responsible for strategic planning, commercial product development and corporate partnerships. Prior to that, Dr. Adams was Director of Business Development for the Pharmaceutical Division of Ciba-Geigy Limited, Basel, Switzerland, a publicly traded biotechnology company. He has a diploma in organic chemistry and biochemistry and a Ph.D. in organic

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chemistry from the University of Zurich. Dr. Adams also holds an M.B.A. from INSEAD of Fontainebleau, France.

Kurt C. Gunter, M.D. Dr. Gunter has served as our Senior Vice President, Clinical and Regulatory Affairs and Government Relations and our Medical Director since joining our company in July 2001. From 1996 until 2001, Dr. Gunter was Vice President, Clinical and Regulatory Affairs at Transkaryotic Therapies Inc., where he was responsible for clinical development activities and all regulatory affairs. Prior to that, from 1995 until 1996, Dr. Gunter was the Director of Stem Cell Processing, Hematology and the Blood Donor Center in the Department of Laboratory Medicine at Children s National Medical Center in Washington, D.C. Dr. Gunter has also held positions at the FDA s Center for Biologics Evaluation and Research, including Acting Deputy Director for the Division of Cellular and Gene Therapies and Chief of the Cytokine and Cell Biology Branch. Dr. Gunter is board-certified in Clinical and Anatomical Pathology and Transfusion Medicine. Dr. Gunter has a B.S. from Stanford University and an M.D. from the University of Kansas School of Medicine.

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

Mary T. Thistle. Ms. Thistle has served as a Senior Vice President since February 2005, General Manager, ViaCell Reproductive Health, since October 2004 and, prior to that, as our Vice President, Viacord Operations since 2002. Prior to this role, she served as our Vice President of Financial and Corporate Planning and Treasurer since joining our company in October 2000. Prior to joining us, Ms. Thistle provided audit, tax and management consulting services to various companies, including serving as consultant to Viacord while at the accounting firm of Yoshita, Croyle & Sokolski from January 1996 to October 2000. From October 1998 to October 1999, she was responsible for all financial aspects, risk management, information technology and human resources of S.R.T, a subsidiary of Thermo Electron, a publicly traded materials analysis solutions company. Prior to that, she served various financial management positions at Nashua Corporation, a publicly traded manufacturing company and Deloitte & Touche, a global professional services organization delivering assurance, tax and consulting services. Ms. Thistle has a B.S. in accounting from the University of Massachusetts.

Key Employees

Morey Kraus. Mr. Kraus is the co-founder of ViaCell, has served as our Vice President and Chief Technology Officer since April 2000, and also serves on our medical and scientific advisory board. Mr. Kraus served as our Chairman and Chief Executive Officer from our inception in September 1994 until March 2000. 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 Larson-Marlowe. Ms. Larson-Marlowe has been Vice President of Therapeutic Development Operations since December 2002. Prior to this role, she served as Director of Program Management since joining the company in August 2000. Her previous experience includes nine years at Genzyme Corporation, serving in Marketing and Program Management roles in the Therapeutic and Diagnostic business areas, during which time she led several protein development projects from research through

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clinical trials to FDA licensing. Ms. Larson-Marlowe has a B.S. in Molecular Biology and Psychology from the University of Wisconsin and an M.B.A. from Boston University.

Medical and Scientific Advisory Board

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

C. Glenn Begley, M.D., Ph.D. Dr. Begley is Vice President, Global Head of Hematology and Oncology Research at Amgen. Previously he was Professor of Medicine at the University of Melbourne in Australia. He has published over 190 papers in scientific and medical journals. His awards include the annual prizes of the Royal Australasian College of Physicians and the Australian Society for Medical Research. He was elected to the Royal College of Pathologists, UK and was the first Foreign Member of the American Society for Clinical Investigation. He trained at the Royal Melbourne Hospital, specializing in hematology and medical oncology and graduated in medicine from the University of Melbourne in 1978, winning the Clinical Prize. He received his Ph.D. in molecular biology at the Walter and Eliza Hall Institute of Medical Research in 1986.

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

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

Peter Wernet, Ph.D. Dr. Wernet has been the co-chairman of our medical and scientific advisory board since September 2003. He is the director and professor at the Institute of Transplantation Immunology and Cell Therapeutics of the Heinrich-Heine-University, Düsseldorf, Germany. In 1992 he established the José Carreras Cord Blood Bank Düsseldorf. He has served as President of the International NETCORD Foundation since 1998, which initiated a world accreditation program jointly with the Federation for Accreditation of Cell Therapy (FACT) in the United States. In 1999, he founded Kourion Therapeutics of Germany, which we acquired in September 2003. He studied Medicine in Cologne, Geneva and London and received his doctorate from the Institute of Physiology at the University of Göttingen. He was postdoctoral fellow from 1971 to 1973 and assistant professor for Immunology from 1973-1976 at Rockefeller University in New York City. He obtained board certification in Transfusion Medicine at the University of Tübingen, Germany.

Leonard I. Zon, M.D. Dr. Zon is an attending physician in hematology at Children s Hospital Boston and in Oncology at Dana-Farber Cancer Institute. He is an Associate in Medicine-Hematology/ Oncology, at Children s Hospital and Professor of Pediatric Medicine at Harvard Medical School. He is also an Investigator for Howard Hughes Medical Institute. Dr. Zon is board certified in Medical Oncology and Hematology. He received a B.S. degree in chemistry and natural sciences from Muhlenberg College and

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an M.D. degree from Jefferson Medical College. He subsequently did an internal medicine residency at New England Deaconess Hospital and a fellowship in medical oncology at Dana-Farber Cancer Institute. His postdoctoral research was in the laboratory of Stuart Orkin.

Viacord Executive Medical Director

Robert Dracker, M.D., M.H.A. Dr. Dracker serves as our Executive Medical Director for Viacord and is responsible for all strategic medical clinical issues and policies related to the operation of the Viacord cord blood bank. Dr. Dracker is a pediatric hematologist with expertise in blood banking and transfusion medicine. Dr. Dracker founded Infusacare, Inc. of Syracuse, New York, where he practices. Dr. Dracker is board certified by the American Association of Pediatrics and by the American Board of Pathology in Blood Banking/ Transfusion Medicine. Dr. Dracker is the Chair of the Hematopoietic Cellular Therapy Advisory Board for the New York State Department of Health and a member of the New York Governor s Council on Blood and Blood Transfusion. Dr. Dracker was instrumental in drafting the New York State regulations for cord blood banking.

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***

Information about security ownership of certain beneficial owners and management appears under Stock Ownership of Certain Beneficial Owners and Management in the Proxy Statement, which portion of the Proxy Statement is incorporated by reference into this report.

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

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

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

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

PART IV

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

(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.

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(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) *Current Reports on Form 8-K*

None filed in the quarter ended December 31, 2004.

(c) *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(7)	Form of Warrant to purchase Common Stock, together with a list of holders.
4.3(1)	Warrant issued to Amgen Inc. on April 9, 2002 to purchase 560,000 shares Common Stock.
4.4	Form Warrant issued to former investors in the Company s Series J convertible preferred stock on January 26, 2005 to purchase up to a total aggregate amount of 2,190,000 shares of common stock. Filed herewith.
10.1(6)	Amended and Restated 1998 Equity Incentive Plan.**
10.1.2	Form of Nonstatutory Stock Option Certificate. Filed herewith**
10.1.3	Form of Incentive Stock Option Certificate. Filed herewith**
10.2(6)	2004 Employee Stock Purchase Plan.**
10.3(1)	Early Separation Agreement and Mutual General Release dated January 2, 2004 between ViaCell and Jeffrey Sacher.**
10.4(1)	Early Separation Agreement and Mutual General Release dated February 18, 2004 between ViaCell and Grant Bogle.**
10.5(7)	Letter Agreement dated June 7, 2001 between ViaCell and Chris Adams.**
10.6.(7)	Letter Agreement dated May 2, 2000 between ViaCell and Marc Beer.**
10.7(7)	Letter Agreement dated May 14, 2001 between ViaCell and Kurt Gunter.**
10.8(7)	Letter Agreement dated April 11, 2000 between ViaCell and Morey Kraus.**
10.9(1)	Letter Agreement dated September 12, 2003 between ViaCell and Jan van Heek.**

10.10(1)	Letter Agreement dated November 4, 2003 between ViaCell and Vaughn M. Kailian.**
10.11(7)	Letter Agreement dated December 15, 2002 between ViaCell and Paul Hastings.**
10.12(1)	Letter Agreement dated August 13, 2003 between ViaCell and George Daley.**
10.13(1)	Stock Purchase Agreement dated September 30, 2003 by and among ViaCell, Kourion Therapeutics AG and the shareholders of Kourion Therapeutics signatory thereto.
10.14(3)	Amendment to Stock Purchase Agreement dated October 25, 2004 by and among ViaCell, Kourion Therapeutics AG and the shareholders of Kourion Therapeutics signatory thereto. Filed previously.
10.15.1(1)	Form of Promissory Note issued by ViaCell to General Electric Capital Corporation.
10.15.2(1)	Master Security Agreement dated October 16, 2003 by and between ViaCell and General Electric Capital Corporation, as amended by an Amendment dated October 16, 2003.
10.15.3(1)	Form of Security Deposit Pledge Agreement by and between ViaCell and General Electric Capital Corporation. Filed previously.
10.16 (1)	Non-Exclusive License Agreement dated January 1, 2003 between ViaCell and SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Glaxo Group Limited.
10.17 (1)	Co-Development and License Agreement dated July 15, 2003 between ViaCell and Gamete Technology, Inc.

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Exhibit No.	Description of Document
10.17.1(4)	Letter Agreement dated October 18, 2004 between Gamete Technology, Inc. and ViaCell.
10.18 (1)	Collaboration Agreement dated December 23, 2003 between ViaCell and Amgen Inc.
10.19 (1)	License Agreement dated January 18, 2001 between Cerebrotec, Inc., now ViaCell Neuroscience, Inc., and the General Hospital Corporation, d/b/a Massachusetts General Hospital.
10.20 (1)	License Agreement dated March 15, 2002 between ViaCell Endocrine Science, Inc. and the General Hospital Corporation, d/b/a Massachusetts General Hospital.
10.21 (1)	License Agreement dated August 1, 2002 between ViaCell and Massachusetts Institute of Technology.
10.23(7)	Sublease Agreement dated November 1, 2001 between ViaCell and ARIAD Corporation.
10.24(7)	Lease Agreement dated April 20, 1999 between Viacord, Inc. and Molded Antennas for Telecommunications, Inc.
10.25(1)	Lease Agreement dated April 12, 2002 between ViaCell and Dugan Financing LLC.
10.26(1)	Sublease Agreement dated April 11, 2002 between ViaCell and Advanced Cell Technology, Inc.
10.26.1(3)	The First Amendment to Sublease Agreement, dated February 14, 2003, between ViaCell and ARIAD Corporation.
10.26.2(3)	The Second Amendment to Sublease Agreement, dated December 18, 2003, between ViaCell and ARIAD Corporation. Filed previously.
10.27(1)	Lease Agreement dated March 25, 2002 between ViaCell and Singapore Science Park Limited.
10.28(7)	Lease Agreement dated February 24, 2000, as amended May 31, 2001, between ViaCell and ARE-One Innovation Drive, LLC.
10.28.1(3)	The Second Amendment to Lease Agreement, dated April 4, 2002, between ViaCell and ARE-One Innovation Drive, LLC.
10.28.2	The Third Amendment to Lease Agreement, dated December 17, 2004, between ViaCell and ARE-One Innovation Drive, LLC. Filed herewith.
10.29(1)	Lease Agreement dated December 22, 2003 between ViaCell and MA-Riverview/245 First Street, LLC.

10.30(1)	Summary of Lease Agreement dated October 1, 2002 between Kourion Therapeutics AG and W.H.L. Grundstücksgemeinschaft GbR
10.31(1)	Letter Agreement dated March 11, 2004 between ViaCell and Stephen Dance.**
10.32 (3)	License Agreement dated September 1, 2004 between Tyho Galileo Research Laboratory, LLC and ViaCell, Inc.
10.33 (5)	Research Agreement dated December 13, 2004 between Genzyme Corporation and ViaCell.
10.34(6)	Letter Agreement dated December 29, 2004 from ViaCell to Stephan Wnendt.**
10.35	Letter Agreement dated October 10, 2004 from ViaCell to Mary Thistle. ** Filed herewith
21.1(1)	Subsidiaries of ViaCell.
23.1	Consent of PricewaterhouseCoopers LLP. Filed herewith
31.1	Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer. Filed herewith
31.2	Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer. Filed herewith
32.1	Section 1350 Certification of Chief Executive Officer. Filed herewith
32.2	Section 1350 Certification of Chief Financial Officer. Filed herewith

(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 05, 2004.

(2) Incorporated by reference to the Company s Amendment No. 1 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on, May 25, 2004.

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(3) Incorporated by reference to the Company s Amendment No. 3 to the registration statement on Form S-1 (No. 33-114209) filed with the SEC on October 26, 2004.

(4) Incorporated by reference to the Company s Amendment No. 4 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC on, December 15, 2004.

(5) Incorporated by reference to the Company s Amendment No. 5 to the registration statement on Form S-1 (No. 333-114209) filed with the SEC) on, December 27, 2004.

(6) Incorporated by reference to the Company s Amendment No. 6 to the registration statement on Form S-1 (No. 33-114209) filed with the SEC on January 3, 2005.

(7) Incorporated by reference to the Companys registration statement on Form S-1 (No. 333-81650) filed with the Securities and Exchange Commission (the SEC) on January 30, 2002.
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 Beer

Marc Beer
Chief Executive Officer

Date: March 31, 2005

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, 2005.

Signature	Title	Date
/s/ Marc D. Beer Marc D. Beer	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2005
/s/ Stephen G. Dance Stephen G. Dance	Chief Financial Officer (Principal Financial Officer and Principal Accounting	March 31, 2005
/s/ Vaughn M. Kailian Vaughn M. Kailian	Director	March 31, 2005
/s/ George Daley, M.D., Ph.D. George Daley, M.D., Ph.D.	Director	March 31, 2005
/s/ Ansbert Gadicke, M.D. Ansbert Gadicke, M.D.	Director	March 31, 2005
/s/ Paul Hastings Paul Hastings	Director	March 31, 2005
/s/ Denise Pollard-Knight Denise Pollard-Knight	Director	March 31, 2005
/s/ James Tullis James Tullis	Director	March 31, 2005
/s/ Jan van Heek	Director	

Jan van Heek	March 31, 2005

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ViaCell, Inc.

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Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related statements of operations, comprehensive loss, stockholders deficit and cash flows present fairly, in all material respects, the financial position of ViaCell, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 29, 2005

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ViaCell, Inc.
Consolidated Balance Sheets

	As of December 31,	
	2004	**2003**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,745,727	$ 39,007,880
Short-term investments	21,339,471	7,823,852
Accounts receivable, net	10,807,837	7,676,439
Prepaid expenses and other current assets	4,765,967	4,106,358
Restricted cash	161,818	
Total current assets	43,820,820	58,614,529
Property and equipment, net	6,738,211	7,892,116
Goodwill	3,620,750	3,620,750
Intangible assets, net	3,024,997	3,274,721
Long-term investments	499,797	
Restricted cash	1,952,889	2,834,109
Other assets	1,433,218	1,924,870
Total assets	$ 61,090,682	$ 78,161,095
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Current portion of long-term debt obligations	$ 1,742,447	$ 1,611,604
Accounts payable	1,271,130	3,363,875
Accrued expenses	7,489,795	10,011,022
Note payable to related party	15,422,400	14,280,000
Contingent purchase price		4,245,896
Deferred revenue	3,458,443	2,244,972
Total current liabilities	29,384,215	35,757,369
Deferred revenue	6,728,393	3,157,884
Deferred rent	1,035,062	
Contingent purchase price	8,155,000	3,909,104
Long-term debt obligations, net of current portion	1,572,040	3,346,672
Total liabilities	46,874,710	46,171,029
Redeemable convertible preferred stock (at redemption value) authorized 30,396,809 shares in 2003 and 2004, issued and outstanding 25,628,075 in 2003 and 2004	175,172,875	162,141,437
Commitments and contingencies (Notes 8 and 9)		
Stockholders deficit:		
Convertible preferred stock, $0.01 par value; authorized	1,829	1,829

428,191 shares; issued and outstanding 182,857 shares (liquidation preference of $245,000) in 2003 and 2004.		
Common stock, $0.01 par value; authorized 35,000,000 and 80,000,000 shares in 2003 and 2004 respectively; issued and outstanding 2,659,854 and 2,763,961 shares in 2003 and 2004, respectively	27,640	26,599
Additional paid-in capital		1,437,260
Deferred compensation	(2,529,830)	(3,422,375)
Accumulated deficit	(158,765,668)	(128,678,779)
Accumulated other comprehensive income	309,126	484,095
Total stockholders deficit	(160,956,903)	(130,151,371)
Total liabilities, redeemable convertible preferred stock and stockholders deficit	$ 61,090,682	$ 78,161,095

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

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ViaCell, Inc.
Consolidated Statements of Operations

	Years Ended December 31,		
	2004	**2003**	**2002**
Processing and storage revenues	$ 36,804,554	$ 30,884,201	$ 20,087,773
Grant and contract revenues	1,469,085	995,494	286,862
Total revenues	38,273,639	31,879,695	20,374,635
Operating expenses:			
Cost of processing and storage revenues:			
Direct costs	7,364,053	7,141,581	5,877,402
Royalty expense	(3,257,639)	3,257,639	
Total cost of processing and storage revenues	4,106,414	10,399,220	5,877,402
Research and development	15,133,646	13,225,957	11,429,043
Sales and marketing	19,322,331	20,959,187	16,578,500
General and administrative	13,467,847	15,221,356	10,919,794
In-process technology		23,925,023	5,888,713
Stock-based compensation(1)	3,428,930	3,232,179	6,463,519
Restructuring	2,945,260		
Total operating expenses	58,404,428	86,962,922	57,156,971
Loss from operations	(20,130,789)	(55,083,227)	(36,782,336)
Interest income (expense):			
Interest income	529,435	348,476	891,772
Interest expense	(1,495,942)	(733,499)	(147,464)
Total interest income (expense), net	(966,507)	(385,023)	744,308
Net loss	(21,097,296)	(55,468,250)	(36,038,028)
Accretion on redeemable convertible preferred stock	(13,070,414)	(9,416,114)	(8,143,606)
Net loss attributable to common stockholders	$ (34,167,710)	$ (64,884,364)	$ (44,181,634)
Net loss per share			
Net loss per common share, basic and diluted	$ (12.62)	$ (24.63)	$ (17.60)
Weighted average shares used in basic and diluted net loss per share computation	2,707,219	2,634,096	2,510,632

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

	Years Ended December 31,		
	2004	2003	2002
Cost of processing and storage revenues	$ 32,035	$ 7,282	$ 19,792
Research and development	895,706	1,073,325	2,488,801
Sales and marketing	174,889	413,571	670,412
General and administrative	2,082,683	1,738,001	3,284,514
Restructuring	243,617		
Total stock-based compensation expense	$ 3,428,930	$ 3,232,179	$ 6,463,519

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,		
	2004	**2003**	**2002**
Net loss	$ (21,097,296)	$ (55,468,250)	$ (36,038,028)
Foreign currency translation adjustment	(174,969)	484,095	
Comprehensive loss	$ (21,272,265)	$ (54,984,155)	$ (36,038,028)

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

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ViaCell, Inc.
Consolidated Statement of Stockholders Deficit

	Preferred Stock		Common Stock						
	Shares	Par Value	Shares	Par Value	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Deficit
Balance, December 31, 2001	182,857	$ 1,829	2,427,879	$ 24,279	7,321,178	$ (8,923,891)	$ (37,172,501)	$	$ (38,749,106)
Stock option exercises			102,362	1,024	30,319				31,343
Stock warrant exercises			13,333	133	39,866				39,999
Issuance of common stock			15,000	150	19,900				20,050
Stock warrants issued to collaborator					5,888,713				5,888,713
Non-employee stock compensation					449,012				449,012
Deferred compensation					3,216,296	(3,216,296)			
Amortization of deferred compensation						6,014,507			6,014,507
Accretion of redeemable preferred stock to redemption value					(8,143,606)				(8,143,606)
Net loss							(36,038,028)		(36,038,028)
Balance, December 31, 2002	182,857	1,829	2,558,574	25,586	8,821,678	(6,125,680)	(73,210,529)		(70,487,116)
Stock option exercises			101,280	1,013	52,996				54,009
Issuance of stock warrant					1,449,826				1,449,826
Accretion of redeemable preferred stock					(9,416,114)				(9,416,114)
Non-employee stock compensation					251,480				251,480

Deferred compensation					804,323	(804,323)			
Amortization of deferred compensation					(526,929)	3,507,628			2,980,699
Net loss							(55,468,250)		(55,468,250)
Translation adjustment								484,095	484,095
Balance, December 31, 2003	182,857	1,829	2,659,854	26,599	1,437,260	(3,422,375)	(128,678,779)	484,095	(130,151,371)
Stock option exercises			89,915	899	107,294				108,193
Accretion of redeemable preferred stock					(4,080,821)		(8,989,593)		(13,070,414)
Non-employee stock compensation			14,192	142	414,751				414,893
Deferred compensation					2,882,201	(2,882,201)			
Forfeiture of stock options					(413,601)	413,601			
Modification of stock options					774,294				774,294
Amortization of deferred compensation					(1,121,378)	3,361,145			2,239,767
Net loss							(21,097,296)		(21,097,296)
Translation adjustment								(174,969)	(174,969)
Balance, December 31, 2004	182,857	$ 1,829	2,763,961	$ 27,640	$	$ (2,529,830)	$ (158,765,668)	$ 309,126	$ (160,956,903)

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

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ViaCell, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2004	**2003**	**2002**
Cash flows from operating activities:			
Net loss	$ (21,097,296)	$ (55,468,250)	$ (36,038,028)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,577,151	2,517,646	1,987,743
Stock-based compensation	3,428,930	3,232,179	6,463,519
Reserve for bad debt	248,465	776,687	158,277
Non-cash charge for acquired in-process research and development		23,925,023	5,888,713
Non-cash interest expense on related party note payable	1,142,400	280,000	
Loss on write-down of fixed assets	2,154,450		
Fixed asset additions reimbursed by Landlord	1,004,000		
Other	29,153	4,359	
Changes in assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(3,376,176)	(2,033,456)	(3,212,616)
Prepaid expenses and other current assets	(615,472)	(2,266,483)	10,465
Accounts payable	(2,191,575)	414,683	757,354
Accrued expenses	(2,542,108)	4,629,771	1,308,179
Deferred revenue	4,091,719	1,497,998	1,580,282
Deferred rent	31,062		
Net cash used in operating activities	(15,115,297)	(22,489,843)	(21,096,112)
Cash flows from investing activities:			
Purchase of property and equipment	(2,392,354)	(1,825,870)	(4,816,312)
Proceeds from maturities of investments	22,681,759	15,812,672	38,973,455
Purchase of investments	(36,697,176)	(9,687,260)	(15,579,979)
(Increase) decrease in other assets	488,269	(1,751,350)	(71,631)
Cash acquired in acquisition, net of acqusition costs		3,737,929	
Net cash provided by (used in) investing activities	(15,919,502)	6,286,121	18,505,533
Cash flows from financing activities:			
Proceeds from issuance of redeemable convertible preferred stock, net		36,887,171	1,500,000
Proceeds from exercise of stock options and warrants	108,193	42,599	71,342
Proceeds from issuance of common stock			20,050
(Increase) decrease in restricted cash	731,966	3,210,105	(3,792,909)
Proceeds from credit facilities		5,000,000	4,900,000

Repayments on credit facilities	(1,562,331)	(5,451,556)	(1,087,050)
Repayment of note payable to related party			(215,247)
Payments on capital lease principal	(267,203)	(49,375)	(11,074)
Net cash provided by (used in) financing activities	(989,375)	39,638,944	1,385,112
Effect of change in exchange rates on cash	(237,979)	333,569	
Net increase (decrease) in cash and cash equivalents	(32,262,153)	23,768,791	(1,205,467)
Cash and cash equivalents, beginning of period	39,007,880	15,239,089	16,444,556
Cash and cash equivalents, end of period	$ 6,745,727	$ 39,007,880	$ 15,239,089
Supplemental disclosures of cash flow information and non cash transactions			
Interest paid	$ 325,338	$ 260,117	$ 183,452
Acquisitions (Note 3)		28,705,000	
Accretion of redeemable convertible preferred stock	13,070,414	9,416,114	8,143,606
Equipment purchased under capital lease (Note 2)	139,593	154,855	

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) was incorporated in the State of Delaware on September 2, 1994 as t.Breeders Inc. The Company was in the development stage until April 11, 2000 at which time the Company completed a merger with Viacord, Inc. (Viacord), an umbilical cord blood collection, processing and preservation company, and changed its name to ViaCell, Inc.

The Company is a biotechnology company engaged in sourcing, developing and commercializing cellular therapies to address cancer, infertility and cardiac diseases. ViaCell s mission is to enable the widespread application of human cells as medical therapy. ViaCell s lead stem cell product candidate, CB001, is manufactured using one of the Company s proprietary technologies which allows the isolation, purification and significant expansion of populations of stem cells, and enables the production of well defined cellular products in therapeutically useful quantities. The Company is developing CB001 for use in bone marrow and other hematopoietic stem cell transplants. The Company s current commercialized service is Viacord, a leading brand in the cryopreservation of umbilical cord stem cells, primarily for pediatric bone marrow transplantations. In addition, the Company is developing a product expected to offer women the ability to preserve or extend their fertility through the cryopreservation of oocytes.

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

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

On January 26, 2005 the Company completed its initial public offering (IPO). The Company issued 8,625,000 shares at $7.00 per share resulting in net proceeds to the Company of approximately $53,600,000 after underwriters discounts and offering expenses. As a result of the IPO, all shares of the Company s preferred stock immediately converted into 25,810,932 shares of common stock. On January 26, 2005, the Company paid in full the related party note of $15,509,760, which included all outstanding principal and interest owed at that date.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of

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

the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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.

	2004			2003		
	Amortized Cost	Fair Value	Unrealized (Loss)	Amortized Cost	Fair Value	Unrealized (Loss)
Cash and cash equivalents						
Money market accounts	$ 3,612,939	$ 3,612,939	$	$ 30,393,707	$ 30,393,707	$
Government securities	1,485,208	1,485,208		1,725,006	1,725,006	
Cash	1,647,580	1,647,580		6,889,167	6,889,167	
Total cash and cash equivalents	6,745,727	6,745,727		39,007,880	39,007,880	
Short-term investments						
Commercial paper	21,339,471	21,261,698	(77,773)	7,823,852	7,815,775	(8,077)
Long-term investments						
Commercial paper	499,797	498,394	(1,403)			
Total investments	21,839,268	21,760,092	(79,176)	7,823,852	7,815,775	(8,077)
Total cash, cash equivalents, short- and long-term investments	$ 28,584,995	$ 28,505,819	$ (79,176)	$ 46,831,732	$ 46,823,655	$ (8,077)

In connection with Company s commitments under various agreements (Notes 8 and 9) and one of the Company s operating bank accounts, the Company issued letters of credit totaling $2.1 million collateralized by certificates of

deposit totaling $2.1 million that 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 from 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

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

Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). EITF 00-21 requires the following criteria to be met for an element to represent a separate unit of accounting:

a) The delivered items have value to a customer on a standalone basis;

b) There is objective and reliable evidence of the fair value of the undelivered items; and

c) Delivery or performance is probable and within the control of the vendor for any delivered items that have a right of return.

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

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

Revenue recognized from the collection, testing and freezing of cord blood units was $31,737,000, $27,768,000, and $18,473,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

Revenue from storage fees is recognized over the contractual period on a straight-line basis and amounted to approximately $5,068,000, $3,116,000, and $1,614,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Deferred revenue of $10,187,000 and $5,403,000 at December 31, 2004 and 2003, respectively, consist primarily of the unearned portions of annual storage fees and deposits paid by customers prior to completion of our processing service. Deferred revenue at December 31, 2004 also included approximately $154,000 of unearned revenue related to the Company s economic development grant with Singapore.

The Company recognizes shipping costs billed to customers as revenues and records a corresponding amount as cost of 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 $334,000, $783,000, and $75,600 for the years ended December 31, 2004, 2003, and 2002, respectively. The rebates have been recorded as a reduction in processing revenue.

Revenues from short-term research contracts are recognized over the contract period as services are provided. Revenue from research contracts amounted to $192,000, $363,000, and $157,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

The Company recognized approximately $1,277,000, $633,000, and $130,000 in grant revenue in the years ended December 31, 2004, 2003, and 2002, respectively, under grants from the Economic Development Boards of Singapore and Germany. Under these grant agreements, the Company is reimbursed for certain defined expenses.

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

Cost of Revenues

Cost of revenues reflects the cost of transporting, testing, processing and storing cord blood at the Company s cord blood processing facility in Hebron, Kentucky, as well as a royalty to PharmaStem Therapeutics, Inc. relating to ongoing patent infringement litigation. The Company recorded a royalty expense of approximately $3.3 million in the fourth quarter of 2003 following an unfavorable jury verdict in October 2003 which found infringement. This expense included a royalty of approximately $2.9 million on revenues from cord blood preservation through October 29, 2003, plus an accrual of 6.125% of subsequent revenues through December 31, 2003. The Company recorded an additional royalty expense of $0.5 million for the three months ended March 31, 2004, also based on 6.125% of revenues. In September 2004, the court overturned the jury verdict on one of the two patents in litigation and ordered a new trial on the second patent. Due to the judge s ruling, the Company reversed the entire royalty accrual of $3.8 million in the quarter ended June 30, 2004. On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In his September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent. Pending further action by the courts, the Company does not intend to record a royalty expense in future periods, since it believes the claim is without merit.

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

Advertising Costs

Costs of media advertising are expensed at the time the advertising takes place and are classified as sales and marketing expense. Advertising expense totaled approximately $2,515,000, $1,815,000, and $1,782,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

Research and Development Expenses

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

In-process Technology

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

Foreign Currency Translation

The financial statements of the Company s German subsidiary, Kourion, are translated in accordance with Statement of Financial Accounting Standards (SFAS) No. 52, *Foreign Currency Translation.* The functional currency of Kourion is the local currency (euro), and accordingly, all assets and liabilities of the foreign subsidiary are translated using the exchange rate at the balance sheet date except for capital accounts which are translated at historical rates. Revenues and expenses are translated at average rates during the period. Adjustments resulting from the translation from the financial statements of Kourion into US dollars are excluded from the determination of net loss and are accumulated in accumulated other comprehensive income within stockholders equity. Foreign currency translation gains and losses are reported in the accompanying consolidated statements of operations and are immaterial to the results of operations.

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

Income Taxes

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

Property and Equipment

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

Useful lives are as follows:

Asset Classification	Estimated 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

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

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, capital lease obligations, equipment loans and notes payable to related party. The carrying value of the short-term financial instruments approximates their fair value due to their short maturities and the carrying value of the long-term financial instruments approximate their 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;

purchased technology rights;

customer lists; and

trademarks.

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

Effective January 1, 2002, the Company adopted SFAS No. 142, *Goodwill and Other Intangible Assets,* which requires that amortization of goodwill and certain intangibles be replaced with periodic tests of goodwill s impairment 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 it is sold; and

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, short-term investments, restricted cash and accounts receivable. At December 31, 2004 and 2003, 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, 2004 and 2003, 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 receivables balances are limited due to the diverse number of customers comprising the Company s customer base.

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

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

Description	Balance at Beginning of Period	Additions to Costs and Expenses	Deductions	Balance at End of Period
Allowance for doubtful accounts receivable				
Year ended December 31, 2004	$ 1,043,568	248,465	(95,175)	$ 1,196,858
Year ended December 31, 2003	$ 268,981	776,667	(2,080)	$ 1,043,568
Year ended December 31, 2002	$ 150,200	158,277	(39,496)	$ 268,981

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

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

Redeemable Convertible Preferred Stock

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

Stock-Based Compensation

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

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

During the years ended December 31, 2004, 2003, and 2002, the Company issued, 903,500, 713,436 and 1,383,468 options, respectively, with an exercise price below deemed fair market value as subsequently determined. In 2004, 2003, and 2002, in connection with the grant of employee stock options, the Company recorded deferred stock compensation of approximately $2,900,000, $800,000, and $3,200,000, respectively, representing the difference between the exercise price and the deemed fair value for financial reporting purposes of the Company s common stock on the date these stock options were granted. Deferred compensation is included as a reduction of stockholders deficit and is amortized over the vesting period of the individual award, generally four years, consistent with the method described in FASB Interpretation

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

No. 28. During the years ended December 31, 2004, 2003, and 2002, the Company recorded amortization of deferred stock compensation of approximately $3,000,000, $3,000,000, and $6,000,000, respectively. When stock options are forfeited prior to vesting, any previously recognized stock-based compensation is reversed and any remaining deferred compensation is eliminated. At December 31, 2004, approximately $2,500,000 of deferred stock compensation related to stock options remained unamortized.

During the years ended December 31, 2004, 2003 and 2002, the Company recorded stock-based compensation expense of approximately, $415,000, $251,000, and $449,000, respectively, related to options granted to nonemployees. The Company recorded approximately $5,900,000 of expense in 2002 in connection with issuance of warrants in exchange for a technology license.

Had all employee stock-based compensation expense been determined using the fair value method and amortized on a straight-line basis over the vesting period of the related options consistent with SFAS No. 123 (see Note 12 for additional disclosure), the pro forma net loss per share would have been as follows:

	2004	2003	2002
Net loss attributable to common stockholders as reported	$ (34,167,710)	$ (64,884,364)	$ (44,181,634)
Add: employee stock-based compensation expense included in reported net loss	3,014,179	2,980,699	6,014,507
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards	(5,175,664)	(4,256,829)	(4,017,251)
Pro forma net loss attributable to common stockholders	$ 36,329,195	$ (66,160,494)	$ (42,184,378)
Basic and diluted net loss per share			
As reported	$ (12.62)	$ (24.63)	$ (17.60)
Pro forma	$ (13.42)	$ (25.12)	$ (16.80)

The Company has computed the pro forma disclosures required under SFAS No. 123 for all stock options granted to employees and directors of the Company as of December 31, 2004, 2003 and 2002 using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The weighted average assumptions used for the years ended December 31 are as follows:

	December 31,		
	2004	2003	2002
Risk-free interest rate	2.86%	2.00%	3.82%
Expected life	5 years	5 years	5 years
Expected volatility	100%	100%	110%
Dividend yield	0%	0%	0%
Per share grant date fair value	$8.00	$8.15	$5.00

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

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

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 revenue 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, 2004 and 2003, respectively.

	December 31, 2004	December 31, 2003
Long-lived assets		
United States	$ 6,310,040	$ 6,161,717
Germany	87,892	1,408,991
Singapore	340,279	321,408
Total long-lived tangible assets	$ 6,738,211	$ 7,892,116

The following table presents revenues by geographic area for the period ended December 31, 2004 and 2003, respectively.

	December 31, 2004	December 31, 2003
United States	$ 36,996,639	$ 31,246,807
Germany	990,057	381,372
Singapore	286,943	251,516
Total Revenue	$ 38,273,639	$ 31,879,695

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 other comprehensive loss.

Net Loss Per Common Share

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

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

The following sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31,		
	2004	**2003**	**2002**
Basic and diluted net loss per share			
Net loss attributable to common stockholders	$ (34,167,710)	$ (64,884,364)	$ (44,181,634)
Weighted average number of common shares outstanding	2,707,219	2,634,096	2,510,632
Basic and diluted net loss per share	$ (12.62)	$ (24.63)	$ (17.60)

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

	Year Ended December 31,		
	2004	**2003**	**2002**
Options	4,222,211	4,374,160	3,824,199
Warrants	1,428,750	1,413,906	1,246,666
Convertible preferred stock	25,810,932	25,810,932	20,544,516

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Instruments with Characteristics of both Liabilities and Equity* (SFAS No. 150). This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of these instruments were previously classified as equity. This statement is effective for new or existing contracts at the beginning of the first interim period beginning after June 15, 2003. The adoption of this statement did not have a material impact on the Company s financial statements.

In December 2003, the FASB issued FASB Interpretation No. 46-R (FIN 46-R) a revised interpretation of FASB Interpretation No. 46 (FIN 46). FIN 46-R requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The provisions of FIN 46-R are effective for all arrangements entered into after January 31, 2003. For all arrangements entered into after January 31, 2003, the Company is required to continue to apply FIN 46-R through the end of the first quarter of fiscal 2004. The Company does not have any equity interests that would change its current reporting or require additional disclosures outlined in FIN 46-R. For arrangements entered into prior to February 1, 2003, the Company is required to adopt the provisions of FIN 46-R in the first quarter of fiscal 2004. The Company does not have any equity interests that would change its current reporting or require additional disclosures outlined in FIN 46-R.

On December 16, 2004, the FASB released SFAS No. 123R. This new accounting standard requires all forms of stock compensation, including stock options, to be reflected as an expense in the Company s financial statements. Public companies must adopt the standard by their first fiscal period beginning after June 15, 2005. The Company

intends to apply the revised standard beginning with the quarter ending September 30, 2005. Although the Company has not finalized its analysis, it expects that the adoption of the revised standard will result in higher operating expenses and loss per share. Note 2 to the consolidated financial statements shows the pro-forma impact on net loss and net loss per common share as if the Company had historically applied the fair value recognition provisions of SFAS No. 123 to stock based employee awards.

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

In December 2004, the FASB issued Statement No. 153 (FAS 153), Exchanges of Nonmonetary Assets Accounting Principles Board Opinion No. 29, Accounting for Nonmonetary Transactions (APB 29). FAS 153 is based on the principle that nonmonetary asset exchanges should be recorded and measured at the fair value of the assets exchanged, with certain exceptions. This standard requires exchanges of productive assets to be accounted for at fair value, rather than at carryover basis, unless (i) neither the asset received nor the asset surrendered has a fair value that is determinable within reasonable limits or (ii) the transactions lack commercial substance (as defined). In addition, the FASB decided to retain the guidance in APB 29 for assessing whether the fair value of a nonmonetary asset is determinable within reasonable limits. The new standard is the result of the convergence project between the FASB and the International Accounting Standards Board (IASB). The Company will adopt this standard for nonmonetary asset exchanges in the event that these types of transactions are entered into by the Company in future periods.

3. Acquisitions

Acquisition of Kourion Therapeutics AG

In September 2003, the Company acquired all the outstanding common shares of Kourion Therapeutics AG (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.

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

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

The fair value of the net assets acquired from Kourion exceeded the total consideration paid by ViaCell, resulting in negative goodwill of approximately $8.2 million. Because the acquisition involves contingent consideration, the Company is required to recognize additional purchase consideration equal to the lesser of the negative goodwill of $8.2 million or the maximum amount of contingent consideration of $16.2 million. Accordingly, contingent purchase price totaling $8.2 million has been included in the Company s determination of the total purchase price. The total contingent consideration consists of the $12.0 million of potential milestone payments to the Kourion shareholders, the 241,481 escrow shares with a face value of $2.0 million and the 289,256 contingent shares with a face value of $2.3 million. The entire contingent consideration of $8.2 million included in purchase price has been included as a non-current liability since the escrowed and contingent shares will only be issued if there is a change of control of the Company prior to September 30, 2006, and the milestone payments are less likely to be paid.

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

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

The aggregate purchase price of $28,705,000 consists of the following:		
Series I convertible preferred stock	$	4,400,000
Note payable to related party		14,000,000
Acquisition costs		2,150,000
Contingent consideration		8,155,000
Total purchase price	$	28,705,000

The aggregate purchase price was allocated as follows:

Cash and cash equivalents	$	4,563,000
Other current assets, net		1,125,000
Property and equipment		1,432,000
Other assets		139,000
Current liabilities		(513,000)
Capital lease obligation		(141,000)
In-process technology		22,100,000
	$	28,705,000

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

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

Pro Forma Results of Operations (Unaudited)

The following unaudited pro forma combined results of operations for the Company assume that the Kourion acquisition was completed as of January 1, 2002.

		2003		2002
Total revenue	$	32,505,000	$	21,441,000
Net loss	$	(36,277,000)	$	(39,654,000)

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

These pro forma amounts represent the historical operating results of Kourion prior to the date of acquisition, combined with those of the Company as adjusted to eliminate the write off of the in-process technology of $22.1 million and include two years interest expense related to the note payable to a related party for pro forma periods ended December 31, 2003 and 2002, respectively. These pro forma results are not necessarily indicative of operating results that would have occurred if Kourion had been operated by current management during the periods presented.

4. Property and Equipment

Property and equipment consisted of:

	December 31, 2004	December 31, 2003
Software	$ 2,700,096	$ 2,714,477
Laboratory equipment	4,674,531	5,647,104
Office and computer equipment	1,867,498	2,147,608
Leasehold improvements	3,129,401	2,310,729
Furniture and fixtures	717,195	358,172
Construction in progress	379,575	274,030
Property and equipment, gross	13,468,296	13,452,120
Less: accumulated depreciation and amortization	(6,730,085)	(5,560,004)
Property and equipment, net	$ 6,738,211	$ 7,892,116

At December 31, 2004 and 2003 the net book value of property and equipment serving as collateral under loan agreements amounted to $3,159,000 and $4,721,000, respectively.

At December 31, 2004 and 2003, equipment held under capital leases totaled $474,776 and $584,374, and accumulated depreciation related to this leased equipment totaled approximately $250,909 and $224,430, respectively.

Depreciation and amortization expense on property and equipment totaled approximately $2,413,000, $2,256,000, and $1,616,000 in the years ended December 31, 2004, 2003, and 2002.

5. Long-Lived Assets and Goodwill

Intangible assets consist of trade names, customer base, assembled workforce 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.

Effective January 1, 2002, the Company adopted SFAS No. 142, *Goodwill and Other Intangible Assets.* This Statement requires, among other things, that goodwill and certain other intangibles no longer be amortized, but instead tested for impairment at least annually. The Company has completed the transitional and annual impairment tests as required by SFAS No. 142 upon adoption at January 1, 2002 and again on December 31, 2004, 2003 and 2002. Based on the results of these analyses, no impairment of goodwill was identified.

Amortization of intangible assets was approximately $250,000, $261,000, and $372,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

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

At December 31, 2004 and 2003, ViaCell s goodwill and intangible assets consisted of the following:

	December 31, 2004	December 31, 2003
Goodwill	$ 3,620,750	$ 3,620,750
Intangible assets		
Trademark	$ 4,400,000	$ 4,400,000
Employment agreements	288,338	288,338
Less: accumulated amortization	(1,663,341)	(1,413,617)
Intangible assets, net	$ 3,024,997	$ 3,274,721

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

6. Accrued Expenses

At December 31, 2004 and 2003, accrued expenses consisted of the following:

	December 31, 2004	December 31, 2003
Accrued patent royalties	$	$ 3,257,639
Payroll and payroll related	1,016,375	1,487,932
Management incentive	722,915	481,209
Professional fees	2,026,540	2,766,042
Accrued marketing	911,843	865,455
Accrued restructuring	907,296	
Other	1,904,826	1,152,745
	$ 7,489,795	$ 10,011,022

7. Income Taxes

Loss before income taxes is as follows at December 31:

	2004	2003	2002
Domestic	$ (16,018,802)	$ (52,299,065)	$ (35,667,790)
Foreign	(5,078,494)	(3,169,185)	(370,238)
Total Income Before Taxes	$ (21,097,296)	$ (55,468,250)	$ (36,038,028)

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

Our benefit for income taxes were at rates other than the US federal statutory tax rate for the following reasons:

	For the Years Ended December 31,		
	2004	**2003**	**2002**
US Statutory rate	34.0%	34.0%	34.0%
State taxes, net	3.7%	2.0%	6.9%
Foreign rate differential	1.8%	0.4%	(0.1)%
Benefit of tax credits	2.6%	1.3%	1.6%
Change in valuation allowance	(36.8)%	(14.8)%	(41.5)%
Stock based compensation	(5.1)%	(8.1)%	0.0%
In process R&D	0%	(14.7)%	0.0%
Other	(0.2)%	(0.1)%	(0.9)%
Effective tax rate	0.0%	0.0%	0.0%

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

	2004	**2003**
Deferred tax assets		
Operating loss carryforwards	$ 35,435,742	$ 31,159,658
Tax credit carryforwards	3,484,494	2,542,262
Stock based compensation	3,790,367	3,782,964
Temporary differences	8,509,660	6,151,824
	51,220,263	43,636,708
Less: valuation allowance	(50,002,096)	(42,233,874)
Net deferred tax assets	1,218,167	1,402,834
Deferred tax liabilities		
Intangible assets	(1,218,167)	(1,402,834)
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 in the near future. At December 31, 2004, the Company has federal and state net operating loss carryforwards of approximately $73,062,215 and $71,919,828, respectively, which begin to expire in 2009 and 2005, respectively.

The Company has federal and state credit carryforwards of approximately $2,639,477 and $1,280,328 which begin to expire in 2009 and 2013, respectively. The Company also has foreign net operating loss carryforwards of $13,165,922. The carryforwards expire through 2024 and are subject to review and possible adjustment by the Internal Revenue Service. Ownership changes, as defined in the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income.

Of the $49 million valuation allowance, $3.8 million relates to nonqualified stock option deductions, the benefit of which will be credited to additional paid in capital if and when realized.

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

At December 31, the Company s valuation allowance consisted of the following:

Description	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
2004	$ 42,233,874	7,768,222		$ 50,002,096
2003	$ 28,965,573	13,268,301		$ 42,233,874
2002	$ 13,520,000	15,445,573		$ 28,965,573

8. Long-Term Obligations

The Company had the following long-term debt outstanding as of December 31, 2004 and 2003:

	December 31, 2004	2003
Debt facility loans	$ 3,135,512	$ 4,668,690
Related party note payable	15,422,400	14,280,000
Capital lease obligations	178,975	289,586
Total long-term debt	18,736,887	19,238,276
Less: current portion	(17,164,847)	(15,891,604)
Total long-term debt, net of current portion	$ 1,572,040	$ 3,346,672

The American Jobs Creation Act of 2004 (the Act) was signed into law on October 22, 2004. The Act contains numerous amendments and additions to the U.S. corporate income tax rules. While the Company continues to analyze these new provisions in order to determine their impact to its financial statements, none of these changes, either individually or in the aggregate, is expected to have a significant effect on the Company s income tax liability.

Debt facility

During 2002, 2001 and 2000, the Company entered into several equipment term loans with the same financial institution. Outstanding borrowings under these agreements amounted to $5,172,000 at December 31, 2002. These borrowings bore an interest rate of 4.25%-4.75% per annum, were collateralized by equipment purchased and letters of credit of $1,350,000 and certificates of deposit of $4,425,788. Letters of credit were collateralized by a $650,000 certificate of deposit. These borrowings were repaid in 2003.

In October 2003, the Company entered into a $5,000,000 loan agreement with a financial institution. Borrowings under this agreement bear interest at 6.9 percent per annum and are collateralized by the fixed assets of the Company. Monthly payments of interest and principal are due through October 2006. Approximately $3,136,000 was outstanding under this loan as of December 31, 2004. The Company was also required to make a $1,750,000 cash deposit with the lender as additional collateral for this loan. As of December 31, 2004 and 2003, the net book value of the fixed assets which are collateralized under this agreement was $3,159,000 and $4,721,000, respectively.

During 2004, $403,000 of the deposit was returned based on the repayment schedule of the loan agreement. As of December 31, 2004, the remaining deposit was $1,347,000 and is included with other non-current assets in the accompanying consolidated balance sheet.

The Company also issued a warrant, in connection with the above financing, for the purchase of 18,750 shares of Series J preferred stock with an exercise price of $8 per share with a life of ten years.

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

The Company valued the warrant under a Black-Scholes model deriving a fair market value of approximately $57,000. This amount was recorded as a deferred financing cost and is being amortized over the term of the note. Total warrant amortization was approximately $29,000 for the period ended December 31, 2004.

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

Note Payable to Related Party

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

Capital Lease Obligations

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

At December 31, 2004, payments of principal and interest on existing debt were due as follows:

Year Ending December 31,		
2005	$	17,334,137
2006		1,573,035
2007		36,652
2008		12,217
Thereafter		
Total payment		18,956,041
Less: interest		(219,154)
Total debt		18,736,887
Less: current portion		(17,164,847)
Total long-term debt	$	1,572,040

9. Commitments and Contingencies

Leases

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

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

Future minimum rental payments under the operating leases are approximately as follows:

Year Ending December 31,		
2005	$	2,022,015
2006		1,889,384
2007		1,931,998
2008		1,758,897
2009		1,704,181
Thereafter		8,041,094
Total lease payments	$	17,347,569

Rent expense was approximately $2,212,000, $1,797,000, and $1,566,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

In connection with the above commitments, the Company has issued letters of credit totaling approximately $1,865,000 as collateral against these leases. These letters of credit are collateralized by certificates of deposit that are classified as restricted cash on the accompanying balance sheets.

In 2004 the Company received approximately $1.0 million as a tenant improvement allowance to offset the fixed asset costs of our corporate office space.

Agreements

In December 2004, the Company entered into a Research Agreement with Genzyme. Under the Research Agreement, the Company provides islet stem cells to Genzyme, and Genzyme is obligated to conduct specified research using the islet stem cells. The Company has granted Genzyme a right of first negotiation to enter into an agreement with it 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 no agreement is reached in such negotiations, the Company cannot, for a period of 12 months following such negotiations, enter into an agreement with another party on terms more favorable than those last offered to Genzyme without first offering such terms to Genzyme.

In January 2002, the Company executed two sponsored research agreements with MGH, one relating to amyotrophic lateral sclerosis (ALS) research and the other relating to muscular dystrophy research. Pursuant to these two agreements, the Company funded Dr. Robert Brown s work in these areas for 12 months, complementing its internal development efforts in ALS and muscular dystrophy and potentially providing it with new intellectual property. Under the agreements the Company paid approximately $200,000 to MGH, and provided cord blood stem cell populations expanded through Selective Amplification to Dr. Brown for experiments in mouse models of ALS and muscular dystrophy. These two agreements expired in January 2003. The Company incurred $120,000 in related expenses associated with this agreement for the period ended December 31, 2004. The Company will not be continuing this relationship after December 31, 2004.

In March 2002, the Company entered into a license agreement with MGH under which the Company received exclusive, worldwide rights to make, have made, use, sell, offer for sale, and import products based on patents (currently pending) covering inventions of Dr. Joel Habener pertaining to pancreatic stem cells for treatment of diabetes. In exchange for these rights, as part of this agreement, the Company committed to spend up to $2,000,000 in the first 18 months of the agreement to achieve a defined set of research objectives which support pre-clinical development of a pancreatic stem cell product for the treatment of diabetes. As of December 31, 2003, the Company had spent approximately $1,400,000 on this project, and no further financial obligation relating to this commitment will be incurred.

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

Under this agreement, the Company is also obligated to reimburse MGH for patent related costs and an annual license fee of $30,000 per year until the patents expire in December 2020. In addition, the Company shall pay certain amounts to MGH, contingent upon the achievement of certain milestones as defined in the agreement, totaling a minimum of $900,000 and shall pay royalties to MGH upon commercial sale of products covered under the license. No royalties were paid in connection with this agreement.

In August 2002, the Company entered into a license agreement with Massachusetts Institute of Technology (MIT) under which the Company receives exclusive, worldwide rights to make, have made, use, sell, offer for sale and import products based on patents (currently pending) pertaining to a novel molecule invented by Dr. Ram Sasisekharan for treatment of neurological disorders, including stroke. In exchange for these rights, the Company has paid an upfront fee of $50,000 and an annual license fee of $20,000 for the life of the patents. In addition, the Company shall pay certain amounts to MIT upon the achievement of certain milestones defined in the agreement totaling a maximum of $500,000 for each licensed product or process and shall pay royalties to MIT upon commercial sale of products covered under the license. No milestone payments were made under this agreement.

The Company has entered into an agreement to provide no more than $4,000,000 to fund stem cell research and development programs conducted in Singapore. Under this agreement, the government of Singapore reimburses a portion of these expenses under a grant. The Company funded $1,045,000, $968,000, and $527,000 of research and development in Singapore during the years ended December 31, 2004, 2003, and 2002, respectively, and recorded grant revenue of $287,000, $252,000 and $130,000 during the years ended December 31, 2004, 2003, and 2002, respectively.

Effective January 1, 2003, the Company entered into a license agreement with GlaxoSmithKline and Glaxo Group Limited for a nonexclusive license to four specific forms of thrombopoietin mimetics for certain ex vivo uses. In consideration for the license, the Company issued 12,500 shares of its Series I preferred stock as of March 31, 2003 and paid a fee of $115,000 and $50,000 license fee in 2004. The value of the Series I preferred stock of $100,000 was charged to in-process technology. In addition, the Company will be required to make certain milestone payments relating to the clinical development of products that incorporate the technology provided under this license agreement. The Company will be required to pay royalties on the sale of commercial products incorporating the licensed technology. The Company had paid no royalties under this agreement and has accrued $50,000 in annual license fees as of December 31, 2004.

On July 15, 2003, the Company entered into a license agreement with Gamete Technology, Inc. for the exclusive rights to utilize intellectual property developed by Gamete and MGH in the field of human oocyte cryopreservation and storage. In exchange for these rights, the Company is required to pay certain royalties on preservation and storage revenues from products that incorporate the licensed technology. The Company is also required to spend at least $2,500,000 to develop this technology during the first eighteen months of the agreement, including fees of approximately $810,000 payable directly to Gamete under a consulting agreement. As of December 31, 2004, the Company had paid Gamete $782,000 for consulting services. For the period ended December 31, 2004 the Company expensed $1,115,000 in the development of human oocyte cryopreservation. No amounts were paid under the royalty provision. As a component of the restructuring charge in September 2004, (see note 14) the Company terminated its agreement with Gamete Technology by paying a termination fee of $175,000. All monies have been paid and there are no ongoing commitments under this agreement as of December 31, 2004.

In December 2003, the Company entered into a license and collaboration agreement with Amgen Inc., under which it licensed certain stem cell growth factors from Amgen for use in developing and manufacturing cell therapy products, and granted Amgen an option to collaborate on any product or products that incorporate any of those growth factors. There is no limit on the number of such products

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

for which Amgen can exercise its option. Each time Amgen exercises its option, it must partially reimburse the Company for its past development costs on the optioned product (Collaboration Product), share in the future development costs and take primary responsibility for clinical development, regulatory matters, marketing and commercialization of the product through a joint venture with the Company. Amgen must also pay ViaCell a one-time payment for each Collaboration Product following the achievement of the first regulatory approval of the first indication in the United States. Profits and losses arising from the commercialization of Collaboration Products will be shared by Amgen and the Company. The agreement terminates on the later of expiration of the licensed Amgen patents or when no products are being co-developed or jointly commercialized between us and Amgen.

Pursuant to this license and collaboration agreement, Amgen purchased 2,500,000 shares of the Company s Series K convertible preferred stock for proceeds of $20,000,000, less issuance costs of $127,000 (see Note 10).

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, typically with business partners, licensors and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. Certain indemnification provisions survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2004 and 2003.

Litigation

PharmaStem Therapeutics, Inc. filed a complaint on February 22, 2002 and an amended complaint on March 25, 2002, against the Company and seven other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 (681 patent) and No. 5,192,553 (553 patent), which relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. The Company counterclaimed that the patents are invalid and unenforceable, and for violation of the antitrust laws resulting from patent misuse, and sought a declaration of non-infringement.

In October 2003, the jury ruled against the Company and the other defendants, and a judgment was entered against the Company for approximately $2,900,000, based on 6.125% royalties on its revenue from the storage of umbilical cord blood since April 2000. The jury also found that the infringement was willful. The Company placed the amount of the award in an escrow account pending final disposition of this case. The Company also recorded an accrued liability for the amount of the award and an additional $361,000 related to revenues from October 2003 through December 31, 2003.

On September 15, 2004, the Delaware Court overturned the earlier judgment against ViaCell. The Court ruled that the Company did not infringe the 553 method patent as a matter of law, and ordered a new trial on infringement and damages, if any, related to the 681 composition patent. PharmaStem s motions for an injunction against the Company and the other defendants and for prejudgment and postjudgment interest, as well as enhanced damages and attorneys fees based upon the jury s finding of willful infringement, were denied. The judge also denied the Company s motion challenging the validity and enforceability of the patents. On September 24, 2004, the Company s $2.9 million escrow payment was released to the Company. On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004

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

decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent. In August 2004, the U.S. Patent and Trademark Office (US PTO) ordered the re-examination of both patents based on the prior art submitted, with a ruling expected in 2005. With respect to the 681 patent for which a new trial was granted, PharmaStem filed a motion on October 5, 2004 with the court for a preliminary injunction. Also on October 5, 2004, the Company filed a complaint with the Delaware court, alleging antitrust and trade violations by PharmaStem concerning misuse of its patents and other deceptive business practices. The court held a hearing on these motions on November 3, 2004, and denied PharmaStem s motion for a preliminary injunction on December 14, 2004 when it overturned the jury verdict on that patent. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005 PharmStem s motion to expedite the appeal was denied. PharmaStem s appeal brief was filed on March 22, 2005.

Should the US PTO find the claims of these patents to be unpatentable, then the litigation proceedings between ViaCell and PharmaStem with respect to the unpatentable claims would cease. If the Court s judgment as to non-infringement of the 553 or 681 patent is reversed on appeal, and if the Company is subsequently enjoined from further engaging in its umbilical cord stem cell cryopreservation business, it will not be able to conduct this business unless PharmaStem grants it a license, which PharmaStem previously informed the Company that it would not do after October 15, 2004. While the Company does not believe this outcome is likely, if, in the event of an injunction, it is not able to obtain a license under the disputed patents or operate under an equitable doctrine known as intervening rights, it will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products.

PharmaStem also filed a complaint against the Company on July 28, 2004 in the United States District Court for the District of Massachusetts, alleging infringement of US Patents No. 6,461,645 and 6,569,427, which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. By agreement of the parties, ViaCell responded to the complaint on December 16, 2004. The Company continues to believe that the patents in this new Massachusetts action are invalid and that it does not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. If this Motion is granted, the Company could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if the Company loses the case. The Company believes that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, the Company believes that PharmaStem s Motion will be denied. If the Company is ultimately found to infringe, it could have a significant damages award entered against it, and it could also face injunctive relief which could prohibit the Company from further engaging in the umbilical cord stem cell business absent a license from PharmaStem on the disputed patents. The Company believes the issues presented in this case are substantially the same as the issues presented in the 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 timing and order of the litigations involving ViaCell and PharmaStem are not presently known. Decisions in the re-examination proceedings, now pending before the US PTO, of the 681 and 553 patents may also affect these factors.

Although it is impossible to predict the final outcome, the Company has substantive defenses to all of PharmaStem s claims, and it intends to continue conducting a vigorous defense. It is possible that the final outcome of these litigations could result in damages payable at a higher or lower amount than previously

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

awarded by the Delaware jury. The Company believes that it is not probable at this time that it will be obligated to pay PharmaStem damages as a result of this litigation.

In addition, the Company may enter into settlement negotiations with PharmaStem regarding its litigation with PharmaStem. If a settlement agreement were entered into, it is not known whether it would provide for a payment by the Company of an ongoing royalty or payment of other amounts by the Company to PharmaStem, or what those amounts might be.

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

On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against the Company in the United States District Court for the Northern District of California alleging false and misleading advertising by the Company in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. The Company is evaluating Cbr s allegations and intends to vigorously defend itself in this action.

The Company periodically becomes subject to legal proceedings and claims arising in connection with its business. With the exception of the PharmaStem complaint noted above, the Company does not believe that there were any asserted claims against it as of December 31, 2004 which, if adversely decided, would have a material adverse effect on results of operations, financial position or cash flow.

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, 2004. The reserve is equal to the estimated fair value of the indemnifications in place at 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*

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(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, 2004. The Company may record additional reserves as more physicians enroll in this program.

Viacord Guarantee Program

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

The following table summarizes the activities in the accrued product guarantee reserve for the years ended December 31, 2004, and 2003:

	For the Years Ended December 31,	
	2004	**2003**
Balance at the beginning of the period	$ 43,000	$ 5,000
Accrual for additional units sold during the period	30,000	38,000
Balance at the end of the period	$ 73,000	$ 43,000

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ViaCell, Inc.
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10. Redeemable Convertible Preferred Stock, Preferred Stock, and Stockholders Deficit

The Company s redeemable convertible preferred stock is accreted to redemption value through the redemption date and consists of the following as of December 31, 2004 and 2003, respectively:

	Carrying Value at December 31,	
	2004	**2003**
Series C, $0.01 par value		
Authorized, issued and outstanding; 919,220 shares	$ 1,587,467	$ 1,469,871
Series D, $0.01 par value		
Authorized, issued and outstanding; 1,500,000 shares	3,885,686	3,597,857
Series E, $0.01 par value		
Authorized, issued and outstanding; 1,983,334 shares	9,171,726	8,492,339
Series F, $0.01 par value		
Authorized, issued and outstanding; 2,666,666 shares	11,513,685	10,660,819
Series G, $0.01 par value		
Authorized, issued and outstanding; 3,666,667 shares	15,831,322	14,658,631
Series H, $0.01 par value		
Authorized, issued and outstanding; 7,577,334 shares	66,459,697	61,515,916
Series I, $0.01 par value		
Authorized, 5,575,000 shares; issued and outstanding; 2,062,500, 2,624,854, and 2,624,854 shares at December 31, 2002, 2003 and 2004, respectively	25,975,325	24,074,390
Series J, $0.01 par value		
Authorized, 3,750,000 shares; issued and outstanding; 2,190,000, and 2,190,000 shares at December 31, 2003 and 2004, respectively	17,958,127	16,073,828
Series K, $0.01 par value		
Authorized, issued and outstanding; 2,500,000, and 2,500,000 shares at December 31, 2003, and 2004, respectively	22,789,840	21,597,786
Total redeemable convertible preferred stock	$ 175,172,875	$ 162,141,437

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The Company s redeemable convertible preferred stock activity for year to date periods ended December 31, 2002, 2003 and 2004, respectively, consisted of the following:

	Series C		Series D		Series E		Series F		Series G	
	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amo
ber 31, 2001	919,220	$ 1,242,271	1,500,000	$ 3,040,740	1,983,334	$ 7,268,522	2,666,666	$ 9,146,877	3,666,667	$ 12,5
e of Shares										
on to ption Value		118,726		290,609		594,755		697,585		9
ber 31, 2002	919,220	1,360,997	1,500,000	3,331,349	1,983,334	7,863,277	2,666,666	9,844,462	3,666,667	13,5
e of Shares										
on to ption Value		108,874		266,508		629,062		816,357		1,0
ber 31, 2003	919,220	1,469,871	1,500,000	3,597,857	1,983,334	8,492,339	2,666,666	10,660,819	3,666,667	14,6
e of Shares										
on to ption Value		117,596		287,829		679,387		852,866		1,1
ber 31, 2004	919,220	$ 1,587,467	1,500,000	$ 3,885,686	1,983,334	$ 9,171,726	2,666,666	$ 11,513,685	3,666,667	$ 15,8

	Series H		Series I		Series J		Series K		
	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts	Total
nce mber 31, 2001	7,577,334	$ 52,849,978	1,875,000	$ 15,162,722					$ 101,288
nce of Shares			187,500	1,500,000					1,500
etion to mption Value		4,099,367		1,326,718					8,123
nce mber 31, 2002	7,577,334	56,949,345	2,062,500	17,989,440					110,911
nce of Shares			562,354	4,498,832	2,190,000	15,622,160	2,500,000	21,597,786	41,718
etion to mption Value		4,566,571		1,586,118		451,668			9,510

nce									
mber 31, 2003	7,577,334	61,515,916	2,624,854	24,074,390	2,190,000	16,073,828	2,500,000	21,597,786	162,141
nce of Shares									
etion to									
mption Value		4,943,781		1,900,935		1,884,299		1,192,054	13,031
nce									
mber 31, 2004	7,577,334	$ 66,459,697	2,624,854	$ 25,975,325	2,190,000	$ 17,958,127	2,500,000	$ 22,789,840	$ 175,172

The Company s convertible preferred stock consists of the following as of December 31, 2004 and 2003, respectively:

	2004	2003
Series A, $0.01 par value		
Authorized, issued and outstanding 100,000 shares (liquidation preference of $100,000 at December 31, 2004 and 2003)	$ 1,000	$ 1,000
Series B, $0.01 par value		
Authorized, issued and outstanding 82,857 shares (liquidation preference of $145,000 at December 31, 2004 and 2003	829	829
Total convertible preferred stock	$ 1,829	$ 1,829

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

On June 1, 1999, the Company issued 1,983,334 shares of its Series E convertible preferred stock at $3.00 per share for total gross proceeds to the Company of approximately $5,950,000. In connection with

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Notes to Consolidated Financial Statements (Continued)

the sale, the Company issued warrants to investors to purchase up to 100,000 shares of the Company s common stock at an exercise price of $1.50 per share.

In connection with the April 2000 merger with Viacord, the Company authorized and issued 2,666,666 shares of $0.01 par value Series F convertible preferred stock. Upon closing, the Company also issued 3,666,667 shares of $0.01 par value Series G convertible preferred stock at $3.00 per share to three venture capital investors in exchange for a total of $11,000,000.

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

On October 25, 2001, the Company issued 1,875,000 shares of Series I convertible preferred stock for gross proceeds of approximately $15,000,000, excluding $79,000 of issuance costs. In addition, the Company may sell and issue an additional 375,000 shares of Series I stock for $8 per share pursuant to an option agreement dated October 25, 2001.

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

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

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

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

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

In connection with the shares of Series K convertible preferred stock issued to Amgen and the current PharmaStem litigation, the Company has a side agreement under which Amgen has a one-time option to require the Company to redeem up to 1,250,000 of its Series K shares at a price of $8.00 per share. This option is triggered upon the occurrence of the earliest of June 23, 2007, a settlement or final judgment against the Company for a total amount exceeding $30 million (including the initial judgement amount as well as certain royalties, if any, that the Company becomes obligated to pay PharmaStem), or an injunction enjoining the Company s cord blood preservation operations that has not been stayed or vacated. This option expires upon the earliest of the second anniversary of the triggering event, a settlement or final judgment against the Company for a total amount less than or equal to $30 million (provided that an injunction is not currently in effect at the time), or a public offering of the Company s common stock in which all outstanding shares of convertible preferred stock of the Company automatically convert into common stock. All preferred stock immediately converted to common stock upon the completion of the Company s initial public offering. (see note 16).

The rights and privileges of Series A, B, C, D, E, F, G, H, I, J and K convertible preferred stock are as follows:

Dividends

The holders of Series H, I, J and K convertible preferred stock are entitled to receive cumulative dividends at a rate of 8 percent per year if, when and as declared by the Company s Board of Directors or upon liquidation, dissolution, or winding-up of the corporation before any dividends can be paid to the common stockholders or any other preferred stock holder.

The holders of Series C, D, E, F and G convertible preferred stock are entitled to receive cumulative dividends declared at a rate of 8 percent per year if, when and as declared by the Company s Board of Directors or upon redemption, dissolution, or winding-up of the corporation before any dividends can be paid to the common stockholders.

Liquidation, Distribution, or Winding-Up

In the event of voluntary or involuntary liquidation, dissolution, or winding-up, the holders of Series A, B, C, D, E, F, G, H, I, J and K convertible preferred stock are entitled to be paid out of the assets available for distribution, in preference to holders of common stock, the greater of (i) an amount equal to $1.00, $1.75, $1.00, $1.50, $3.00, $3.00, $3.00, $6.38, $8.00, $8.00 and $8.00 per share, respectively, plus any unpaid dividends declared or (ii) amount per share as would have been payable had each share been convertible into common stock immediately prior to such liquidation, dissolution or winding-up, plus any dividends declared or accrued but unpaid on such common stock. If assets of the Company available for distribution are insufficient for payment, the holders of Series H, I, J and K convertible preferred stock shall be paid first, with Series K holders being fully paid first, the Series J holders being fully paid second, and Series H and I holders being fully paid third. After payment is made in full to the holders of Series H, I, J and K, the holders of Series C, D, E, F and G shall share in distribution ratably in proportion to their aggregate liquidation preference amounts. Remaining funds will be distributed to the Series A and B preferred stockholders before distribution is made to common stockholders.

Voting Rights

Each holder of preferred stock is entitled to the number of votes equal to the number of common stock shares into which such holder s shares of preferred stock are then convertible.

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Notes to Consolidated Financial Statements (Continued)

Conversion

All shares of preferred stock are convertible at the option of the holder into common stock on a one-for-one basis, adjustable for certain dilutive events, as defined in the Company s Certificate of Incorporation. All outstanding shares of preferred stock will automatically be converted into common stock upon the closing of the sale of shares of common stock at a price per share of at least $7.00 in a public offering in which the Company receives aggregate gross proceeds of at least $50,000,000.

Redemption

At the written request of at least 60 percent of the then outstanding shares of Series C, D, E, F, G, H, I, J and K convertible preferred stock made any time on or after November 26, 2007, the Company will redeem each then outstanding share of Series C, D, E, F, G, H, I, J and K convertible preferred stock for an amount equal to the original issue price plus all accumulated and unpaid dividends accrued with respect to each such share since the original issue date of the share. If the funds of the Company available for redemption are insufficient to redeem the total number of shares, the holders of Series H, I, J and K convertible preferred stock shall be paid first; thereafter, the holders of the Series C, D, E, F, and G convertible preferred stock shall share ratably according to the respective amounts they would have been paid.

Common Stock

As of December 31, 2004, the Company has authorized 80,000,000 shares of common stock with a $0.01 par value each. Each holder of a share of common stock is entitled to one vote for each share held at all meetings of stockholders.

11. Warrants

In November 1997, in connection with the issuance of Series D preferred stock, the Company issued warrants to certain stockholders 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.

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

In February 2000, the Company issued a warrant to purchase 13,333 shares of the Company s common stock at an exercise price of $3.00 per share to a landlord. The warrant vested 100 percent on the date of grant and is exercisable through February 24, 2010. The value ascribed to this warrant was not material.

In April 2002, the Company entered into a license agreement with Amgen Inc. for the nonexclusive license to patent rights covering Amgen s Stem Cell Factor. This agreement was superseded by a license and collaboration agreement entered into by the parties in December 2003. In connection with this agreement, the Company issued a warrant to purchase 560,000 shares of its common stock at an exercise price of $12 per share. The warrant vested on October 9, 2002 and is exercisable in whole or in part at any time prior to April 9, 2009. The warrant had a fair value of approximately $5,888,000 at the date of issuance. The fair value of this warrant was estimated at the time of issuance using the Black-Scholes pricing model and assuming a dividend yield of 0 percent, expected volatility of 110 percent, risk-free rate of 4.6 percent and a contractual term of seven years. The Stem Cell Factor technology licensed from Amgen, which is being used in the production process for CB001, our lead product candidate, had not yet

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Notes to Consolidated Financial Statements (Continued)

achieved technological feasibility and had no alternative future at that time, therefore the Company charged the purchase price of $5,888,000 to in-process technology expense.

As described in Note 10, the Company issued rights to contingent warrants in September and October 2003.

In October 2003, the Company also issued a warrant in connection with debt financing for the purchase of 18,750 shares of Series J preferred stock with an exercise price of $8.00 per share with a life of 10 years. The Company valued the warrant under a Black-Scholes model deriving a fair market value of approximately $57,000. The fair value of the warrants issued in September and October 2003 was estimated at the time of issuance using the Black-Scholes pricing model and assuming a dividend yield of 8%, expected volatility of 100%, risk-free rate of 2% and a contractual term of 10 years. The warrant is being amortized under the effective interest method over the term of the related note (Note 8).

12. Stock Option Plan

The ViaCell, Inc. Amended and Restated 1998 Equity Incentive Plan (the Plan), which was adopted on February 12, 1998, provides for the granting of incentive and nonqualified stock options to purchase an aggregate of 4,000,000 shares of common stock to employees, consultants and directors of the Company. In 2002, 2003 and 2004 the Board of Directors increased the number of shares of common stock available for issuance under the Plan to 5,000,000, 6,000,000 and 7,200,000, respectively. Incentive stock options may only be granted to employees of the Company. The exercise price of each option is determined by the Board of Directors. The exercise price of each incentive stock option, however, may not be less than the fair market value of the stock on the date of grant, as determined by the Board of Directors.

Options granted under the Plan vest over a period of four years and expire ten years from the grant date. At December 31, 2004, there were 2,245,824 shares available for future grant under the Plan.

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Notes to Consolidated Financial Statements (Continued)

Information with respect to option activity is as follows:

	Number of Options Authorized	Number of Options Outstanding	Exercise Price	Aggregate Exercise Price	Weighted Average Exercise Price
Outstanding, December 31, 2001	4,000,000	3,561,008	$ 0.10-2.00	$ 3,066,894	$ 0.86
Authorized	1,000,000				
Granted		1,383,468	2.00-5.00	5,407,790	3.91
Exercised		(102,362)	0.10-2.00	(31,343)	0.31
Canceled		(466,362)	0.30-5.00	(816,272)	1.75
Outstanding, December 31, 2002	5,000,000	4,375,752	0.10-5.00	7,627,069	1.74
Authorized	1,000,000				
Granted		713,436	5.00	3,567,180	5.00
Exercised		(101,280)	0.15-5.00	(54,009)	0.53
Canceled		(282,572)	0.30-5.00	(1,096,129)	3.88
Outstanding, December 31, 2003	6,000,000	4,705,336	0.10-5.00	10,044,111	2.13
Authorized	1,200,000				
Granted		903,500	5.00	4,517,500	5.00
Exercised		(89,915)	0.30-5.00	(108,568)	1.21
Cancelled		(1,063,383)	0.30-5.00	(4,308,492)	4.03
Outstanding, December 31, 2004	7,200,000	4,455,538	$ 0.30-5.00	$ 10,144,551	$ 2.28
Exercisable, December 31, 2002		1,233,069	$ 0.15-5.00	$ 719,246	$ 0.58
Exercisable, December 31, 2003		1,806,628	$ 0.30-5.00	$ 1,784,266	$ 0.99
Exercisable, December 31, 2004		2,228,710	$ 0.30-5.00	$ 3,161,845	$ 1.42

Options Outstanding at December 31, 2004			Options Exercisable at December 31, 2004	
		Weighted Average		

Exercise Price	Number of Shares	Remaining Contractual Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.30	1,471,000	5.39	$ 0.30	1,171,000	$ 0.30
0.75	48,950	6.08	0.75	37,775	0.75
0.95	624,092	6.50	0.95	512,758	0.95
2.00	792,588	6.97	2.00	62,590	2.00
4.00	73,175	7.25	4.00	53,021	4.00
5.00	1,445,733	8.89	5.00	391,566	5.00
	4,455,538	7.00	$ 2.28	2,228,710	$ 1.42

The weighted average fair value of options granted in 2004, 2003 and 2002 was $7.23, $6.18 and $6.31, respectively.

In October 2001, ViaCell granted a shareholder, Genzyme, an option, issued outside the Plan, to acquire up to an aggregate of $3,000,000 of shares of Series I preferred stock or such other series of preferred stock most recently issued by the Company at the time of exercise of the option. One half of the option was exercisable at any time after issuance of the option but prior to its expiration. During 2002,

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Genzyme exercised the vested portion of this option and purchased 187,500 shares of Series I preferred stock. The Company and Genzyme mutually agreed to terminate the remaining unvested portion of the option.

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

13. Employee Benefit Plan

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

14. Restructuring

In September 2004, the Company restructured its operations to reduce operating expenses and concentrate its resources on four key products and product candidates, and related business initiatives. These products and product candidates consist of Viacord, Viacyte, CB001 and the cardiac development program. As a result, the Company recorded a $1.7 million restructuring charge in the third quarter of 2004 related to employee severance, contract termination costs and the write-down of excess equipment. The majority of the contract termination costs relate to the Company exercising the termination provision in its agreement with Gamete Technologies, under which the Company is required to pay $175,000 to Gamete Technologies. In December 2004, the Company s Board voted to restructure the Company s German operations and sub-let its laboratory facility in Germany to a third party effective January 1, 2005. As a result the Company recorded an additional restructuring charge of $1.2 million in the fourth quarter of 2004, including facility related costs of $1.1 million and $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 the Company s German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future lease payments receivable from the sub-lessee. At December 31, 2004, restructuring charges of $1.2 million were paid out, the net book value of fixed assets was written down by $0.9 million and the accrued liability relating to the restructurings was $0.9 million.

FOOTNOTE DISCLOSURE

	Balance as of December 31, 2003	Additions	Writedowns	Payments	Balance as of December 31, 2004
Severance related	$	$ 1,315,604	$	$ (894,841)	$ 420,763
Contractual terminations		295,833		(290,292)	5,541
Facility related		1,333,823	(852,831)		480,992
	$	$ 2,945,260	$ (852,831)	$ (1,185,133)	$ 907,296

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15. Unaudited Quarterly Financial Information

Selected Quarterly Consolidated Financial Data:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands, except per share data)			
Year ended December 31, 2004				
Total revenues	$ 9,019	$ 9,676	$ 9,938	$ 9,641
Gross profit	$ 6,675	$ 11,604	$ 8,099	$ 7,790
Net loss attributable to common stockholders	$ (10,761)	$ (5,650)	$ (9,454)	$ (8,303)
Net loss per share (basic and diluted)	$ (4.03)	$ (2.10)	$ (3.50)	$ (3.06)
Year ended December 31, 2003				
Total revenues	$ 6,365	$ 7,196	$ 9,071	$ 9,248
Gross profit	$ 4,755	$ 5,361	$ 7,240	$ 4,125
Net loss attributable to common stockholders	$ (10,175)	$ (9,735)	$ (30,538)	$ (14,436)
Net loss per share (basic and diluted)	$ (3.92)	$ (3.74)	$ (11.69)	$ (5.52)

16. Subsequent Event

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 $53,600,000 after underwriters discounts and offering expenses. As a result of the IPO, all shares of the Company s preferred stock immediately converted into 28,510,952 shares of common stock. On January 26, 2005, the Company paid in full the related party note of $15,509,760, which included all outstanding principal and interest owed at that date.