

VIACELL INC  
Form 424B4  
January 21, 2005

**Table of Contents**Filed Pursuant to Rule 424(b)4  
Registration No. 333-114209

7,500,000 Shares

**VIACELL****Common Stock**

Prior to the offering, there has been no public market for our common stock. Our common stock has been approved for quotation on the Nasdaq National Market under the symbol VIAC.

The underwriters have an option to purchase a maximum of 1,125,000 additional shares to cover over-allotments of shares.

**Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 8.**

	<u>Price to Public</u>	<u>Underwriting Discounts and Commissions</u>	<u>Proceeds to ViaCell</u>
Per Share	\$ 7.00	\$ 0.49	\$ 6.51
Total	\$52,500,000	\$3,675,000	\$48,825,000

Delivery of the shares of common stock will be made on or about January 26, 2005.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

**Credit Suisse First Boston****UBS Investment Bank****Lazard****Leerink Swann & Company**

The date of this prospectus is January 20, 2005

**TABLE OF CONTENTS**

<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	8
<u>FORWARD-LOOKING STATEMENTS</u>	26
<u>USE OF PROCEEDS</u>	27
<u>DIVIDEND POLICY</u>	27
<u>CAPITALIZATION</u>	28
<u>DILUTION</u>	30
<u>SELECTED CONSOLIDATED FINANCIAL DATA</u>	32
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	35

Edgar Filing: VIACELL INC - Form 424B4

<u>BUSINESS</u>	56
<u>MANAGEMENT</u>	86
<u>CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS</u>	97
<u>PRINCIPAL STOCKHOLDERS</u>	99
<u>DESCRIPTION OF CAPITAL STOCK</u>	103
<u>SHARES ELIGIBLE FOR FUTURE SALE</u>	106
<u>UNDERWRITING</u>	108
<u>NOTICE TO CANADIAN RESIDENTS</u>	111
<u>LEGAL MATTERS</u>	112
<u>EXPERTS</u>	112
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	112
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1

---

**You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document is only accurate as of the date of this document.**

**Dealer Prospectus Delivery Obligations**

**Through and including February 15, 2005 (25 days after commencement of the offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter with respect to unsold allotments or subscriptions.**

---

**Table of Contents**

**PROSPECTUS SUMMARY**

*As used in this prospectus, references to we, our, us and ViaCell refer to ViaCell, Inc. and its subsidiaries, unless the context requires otherwise.*

*You should read the following summary together with the entire prospectus, including the more detailed information in our financial statements and related notes appearing in the back of this prospectus. You should carefully consider, among other things, the matters discussed in Risk Factors.*

**Our Business**

ViaCell is 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 candidates and have recently initiated our first clinical trial for our lead product candidate, CB001. We are developing a pipeline of other proprietary product candidates intended to address cancer, cardiac diseases, and infertility. We also have a commercial business dedicated to the preservation of umbilical cord blood, an abundant source of stem cells for potential therapeutic use. If and when we have successfully developed our product candidates, we intend to manufacture, market and sell these products ourselves or through commercial partners. We currently generate revenue from our cord blood preservation activities, which we market as our Viacord product.

Cellular therapy already plays 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. 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 stem cells to regenerate healthy, functioning bone marrow to maintain the blood and immune systems. 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 cell therapy will only be realized if current limitations are overcome. Current sources of stem cells are difficult to harvest and typically yield a poorly characterized mixture of cells with an insufficient quantity for therapeutic purposes. In addition, compatible donors are often not found. Further, except for diseases currently addressed by hematopoietic stem cell transplants, it has not been proven in clinical trials that stem cell therapy will be an effective treatment for other diseases, including cardiac and non blood-related cancers.

Through our existing commercial activities, we have already begun building an infrastructure and a base of research, sourcing, cell processing and marketing expertise. We believe this infrastructure, combined with strategic partnerships and our proprietary technologies, if proven to be effective, could enable us to overcome current limitations on the development of cellular therapeutics. In December 2003, we entered into a license and collaboration agreement with Amgen under which we received a non-exclusive license to certain Amgen stem cell growth factors, and Amgen made a \$20 million equity investment in us. We also believe we can develop other cellular products to benefit patients, including enabling fertility preservation by preserving oocytes, or human eggs, by freezing them.

**Our Product and Product Candidates**

Our lead cellular therapy product candidate, CB001, is initially being developed by us for use as a substitute for bone marrow and other hematopoietic stem cell transplants. CB001 is a proprietary, highly concentrated and purified population of stem cells. In November 2003, we submitted to the US Food and Drug Administration (FDA) a revised protocol to our Investigational New Drug application, or IND, originally filed in October 2001, relating to CB001, and we are currently enrolling patients in a Phase I clinical trial to assess the safety and preliminary clinical efficacy of CB001. Five patients, out of ten patients planned in total, have received CB001 in the trial thus far. The primary endpoint we hope to achieve is safety as assessed by a lack of toxicity. The secondary endpoint we hope to achieve is rapid neutrophil, or infection-fighting white blood cell, recovery. No other clinical trials involving CB001 have been conducted to date. Although the safety and efficacy of CB001 has not yet been, and may never be,

**Table of Contents**

demonstrated in humans, because of its high concentration and purity relative to conventional sources, we believe that CB001 may provide a more effective treatment with fewer side effects and faster recovery for patients following a hematopoietic stem cell transplant. We are leveraging our infrastructure in cellular therapy to develop a pipeline of product candidates for a range of unmet medical needs, including cardiac disease. We are currently conducting pre-clinical studies for cardiac disease with the expectation of completing an IND and initiating a Phase I clinical trial for this product candidate in 2006, if we successfully complete preclinical development. We are also conducting research with Genzyme Corporation in the area of islet stem cell transplantation for the treatment of diabetes.

We have built our initial commercial organization in the area of reproductive health. We market our Viacord umbilical cord blood preservation product through ViaCell 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, or preserve by freezing, for potential future use by that child or a sibling. We believe that we are one of the leaders in the emerging private, or family, cord blood preservation industry. Based on estimates by the independent organization Parent's Guide to Cord Blood Banks of the cumulative total units stored in family cord blood banks (178,000 as of September 2003), we calculate the units stored by us to approximate 21% of this total. We calculate our estimated share of the market in 2003 to be approximately 25% based on our revenue and estimates of the 2003 annual industry revenue (\$128 million) by an independent market research report published in 2002. To date, we have facilitated collections at over 2,000 birthing centers in the United States and, as of November 2004, we had over 63,000 customers. Over the past three years, the number of customers in this industry has grown significantly, and we believe, based on the demographic profile of our average Viacord customer, that the total available target market could be as large as 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. We and several other defendants have been sued for allegedly infringing two third party patents related to our Viacord product. Although a jury verdict finding infringement has been overturned on both patents, if we are ultimately found to infringe following appeal, we could be required to pay damages and obtain a license or curtail or cease our Viacord business. The same plaintiff has also sued us for infringement of two related patents pertaining to our Viacord business.

We intend to leverage our reproductive health commercial and operational infrastructure by developing a second product which involves the preservation and storage of human oocytes. We have an exclusive license to a proprietary cryopreserving media that allows us to preserve oocytes. 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 are working with *in vitro* fertilization centers to demonstrate additional births using this technology. Subject to our media supplier obtaining FDA 510(k) clearance for the media, we intend to commercialize this product candidate. 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 intends to submit 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. We expect our target markets to include women choosing to extend their fertility and women undergoing cancer treatment who are seeking to preserve their fertility. We estimate that these target markets include approximately 4.3 million women in the United States between the ages of 27 and 36 with, according to US Census data, household income exceeding \$65,000. If FDA-cleared, Viacyte will make use of our existing sales and marketing presence in the reproductive health field and our expertise in the preservation of human cells.

## **Table of Contents**

### **Our Collaborative Partners**

In December 2003, we entered into a license and collaboration agreement with Amgen under which we received a non-exclusive 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 development and commercialization of any product, including CB001, that incorporates an Amgen growth factor or technology. In conjunction with this license and collaboration agreement, Amgen made a \$20 million equity investment in us. In addition, we have an agreement with Genzyme, an equity investor in ViaCell, under which Genzyme provides scientific support in the area of islet stem cell research. We also have entered into relationships with academic institutions and other companies.

### **Our Infrastructure**

We have assembled an organization with an infrastructure and capabilities in all areas necessary for our current operations, including research, cell sourcing, development, clinical development and manufacturing, cell processing and marketing. These capabilities include a 65-person sales and marketing force and a 12,000 square foot cell processing and storage facility. We also have a clinical scale cell manufacturing facility where we are producing CB001 for Phase I clinical trials, and we intend to build out additional manufacturing capabilities for Phase II and III clinical trials and initial commercialization. Our organization is supported by a management team with experience in the development, regulatory approval and commercialization of biologics and an experienced scientific advisory board.

### **Our Technology**

While present applications of stem cell therapy are relatively limited, if the potentially broad development of this therapy is to be realized, a significant impediment to overcome is the current inability to manufacture, in a robust manner, highly pure and potent pharmaceutical grade cells in therapeutic quantities. Our portfolio of technologies seeks to address this bottleneck. Selective Amplification is one of our proprietary technologies and is used in the manufacture of CB001. Selective Amplification enables the expansion of stem cell populations by stimulating their growth while re-purifying them by removing differentiated cells. By repeating these growth and purification cycles, in pre-clinical studies, we have been able to produce a greatly expanded, undifferentiated stem cell product, achieving up to 150-fold expansion, with an average of 35-fold expansion, within a 14-day period. Transplant physicians generally believe that they can substantially reduce the time it takes for transplanted stem cells to engraft, or begin to grow and function following transplantation, by treating patients with a large quantity of stem cells. Furthermore, although the safety and efficacy of stem cells expanded using our Selective Amplification technology have not yet been demonstrated in human clinical trials, we believe that the increased purity and consistency of our expanded stem cell products have the potential to result in a more predictable clinical response, better patient care and the potential to manufacture and distribute cells as a standardized pharmaceutical product. While we believe that our technology is broadly applicable to stem cells from all sources, we currently use umbilical cord blood as our source of cells because it provides us with a rich supply of easily obtainable cells that can be immunologically matched to individual patients, while eliminating many of the limitations inherent to other sources of stem cells.

### **Our Strategy**

We intend to use our existing assets in cell therapy and cell preservation 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;
- leverage our technology to commercialize additional products to effectively treat and potentially cure patients with unmet clinical needs;
- leverage ViaCell Reproductive Health to provide financial stability and create additional value;

**Table of Contents**

continue to develop and grow areas of our business that are complementary to each other;

continue to build strategic business relationships; and

strategically in-license or acquire complementary products, technologies and businesses.

**Risks Related to Our Business**

We are an early stage company and our technology is unproven in human clinical studies. We are in the early stage of clinical development of CB001 and have not applied for or received the regulatory approvals we will need to commercialize this or any other expanded stem cell product. We have incurred substantial losses to date; at September 30, 2004 we had an accumulated deficit of \$151.1 million. While our revenue from umbilical cord blood preservation and storage has shown substantial growth in recent years, our costs in offering this product have also increased along with our therapeutic development costs, which we expect to increase in the near future. We were sued for infringing two patents relating to our Viacord umbilical cord stem cell cryopreservation business after we rejected the plaintiff's initial requests seeking a license arrangement because we believe that we do not infringe these patents and that they are invalid. The court recently overturned an unfavorable jury verdict against us and several other defendants, representing a majority of the family cord blood preservation industry. The court ruled that we did not infringe either of the patents as a matter of law. The same plaintiff has recently sued us, as well as several other defendants in different courts, for infringement of two related patents pertaining to our Viacord business and has filed a motion for preliminary injunction in the federal district court in Massachusetts in connection with this suit, which, if granted, would prevent us from collecting and storing cord blood that had not been collected as of the date the injunction is issued. We can give no assurance as to the ultimate outcome of these proceedings. You should carefully consider these and the other risks described under the heading "Risk Factors" before investing in our common stock.

**Corporate Information**

We were incorporated in Delaware in September 1994 under the name t. Breeders, Inc. In April 2000, we acquired Viacord, Inc. and changed our name to ViaCell, Inc. The address of our principal executive office is 245 First Street, Cambridge, Massachusetts 02142, and our telephone number is (617) 914-3400. Our website address is www.viacellinc.com. We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus.

ViaCell®, Viacord® and Viacyte™ are trademarks of ViaCell, Inc. This prospectus also refers to trademarks and tradenames of other organizations.

**Table of Contents**

**THE OFFERING**

Common stock offered by ViaCell	7,500,000 shares (8,625,000 shares if the underwriters' over-allotment option is fully exercised)
Common stock to be outstanding after the offering	36,072,518 shares (37,197,518 shares if the underwriters' over-allotment option is fully exercised)
Nasdaq National Market symbol	VIAC
Use of proceeds	We expect to use the net proceeds from this offering to fund clinical trial activities, to fund preclinical research and development activities, to repay an outstanding promissory note and for other general corporate purposes, including capital expenditures and working capital. Please refer to the section entitled "Use of Proceeds."

The number of shares to be outstanding immediately after this offering is based on:

2,761,586 shares of common stock outstanding as of November 30, 2004; and

25,810,932 shares of common stock that will be issued upon the automatic conversion of our currently outstanding preferred stock concurrently with the closing of this offering.

The number of shares to be outstanding immediately after this offering excludes:

4,463,136 shares of common stock issuable upon the exercise of stock options outstanding as of November 30, 2004, with a weighted average exercise price of \$2.28 per share;

850,000, 18,750 and 560,000 shares of common stock issuable upon the exercise of warrants outstanding as of November 30, 2004, with exercise prices of \$1.50, \$8.00 and \$12.00 per share, respectively;

2,190,000 shares of common stock issuable upon the exercise of warrants with an exercise price of \$5.00 per share, which warrants are not currently issued or outstanding, but will be issued to certain of our stockholders upon the closing of this offering;

241,481 escrowed shares of common stock and 289,256 contingent shares of common stock releasable and issuable, respectively, to certain former stockholders of Kourion Therapeutics AG if we experience a change of control prior to September 30, 2006;

2,267,248 shares of common stock reserved for future grants under our stock option plan as of November 30, 2004; and

750,000 shares of common stock reserved for future issuance under our employee stock purchase plan.

**Table of Contents****SUMMARY CONSOLIDATED FINANCIAL DATA**

The following summary financial data should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations section included later in this prospectus, and our financial statements and related notes included in the back of this prospectus. We have derived the statements of operations data for the five years ending December 31, 2003 presented below from our audited financial statements, which are included in this prospectus, and other audited financial statements. The consolidated statement of operations data for the nine months ended September 30, 2003 and 2004 and the consolidated balance sheet data as of September 30, 2004 are derived from our unaudited consolidated financial statements included elsewhere in the prospectus.

We have presented pro forma net loss per share information to give effect to the assumed conversion of all outstanding shares of our convertible preferred stock into a total of 25,810,932 shares of common stock as of their original dates of issuance.

	Year Ended December 31,					Nine Months Ended September 30,	
	1999	2000	2001	2002	2003(1)	2003	2004
(in thousands, except share and per share data)							
<b>Consolidated Statement of Operations Data:</b>							
Revenues	\$	\$ 2,394	\$ 7,298	\$ 20,375	\$ 31,880	\$ 22,632	\$ 28,633
Operating expenses:							
Cost of revenues:(2)							
Direct costs		991	3,070	5,877	7,141	5,276	5,514
Royalty expense					3,258		(3,258)
Total cost of revenues		991	3,070	5,877	10,399	5,276	2,256
Research and development	1,193	3,854	6,978	11,429	13,226	9,515	11,698
Sales and marketing		2,177	9,349	16,578	20,959	16,203	15,081
General and administrative	1,034	3,879	7,086	10,920	15,222	10,723	10,400
In-process technology(3)			594	5,889	23,925	22,200	
Stock-based compensation(4)		196	4,490	6,464	3,232	2,545	2,662
Restructuring							1,740
Total operating expenses	2,227	11,097	31,567	57,157	86,963	66,462	43,837
Operating loss	(2,227)	(8,703)	(24,269)	(36,782)	(55,083)	(43,830)	(15,204)
Interest income (expense), net	90	991	2,136	744	(385)	83	(717)
Income taxes							
Net loss	\$ (2,137)	\$ (7,712)	\$ (22,133)	\$ (36,038)	\$ (55,468)	\$ (43,747)	\$ (15,921)
Net loss attributable to common stockholders	\$ (2,692)	\$ (10,262)	\$ (28,753)	\$ (44,182)	\$ (64,884)	\$ (50,448)	\$ (25,865)
Net loss per common share, basic and	\$ (2.05)	\$ (5.55)	\$ (12.22)	\$ (17.60)	\$ (24.63)	\$ (19.21)	\$ (9.62)

Edgar Filing: VIACELL INC - Form 424B4

diluted							
Weighted average shares used in computing net loss per common share, basic and diluted	1,316,352	1,849,073	2,352,468	2,510,632	2,634,096	2,625,618	2,689,866
Pro forma net loss per common share, basic and diluted					\$ (2.32)		\$ (0.56)
Pro forma weighted average shares used in computing net loss per common share, basic and diluted					23,865,902		28,500,798

**Table of Contents**

	As of September 30, 2004		Pro Forma As Adjusted(6)
	Actual	Pro Forma(5)	
	(unaudited) (in thousands)		
<b>Consolidated Balance Sheet Data:</b>			
Cash, cash equivalents and investments	\$ 34,116	\$ 34,116	\$ 65,526
Working capital	12,408	12,408	58,706
Total assets	66,797	66,797	95,680
Long-term debt obligations, including current portion	19,017	19,017	3,897
Redeemable convertible preferred stock	172,086		
Total stockholders' equity (deficit)	(153,405)	18,681	64,979

- (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 expense, 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 its 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:

	Years Ended December 31,					Nine Months Ended September 30,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands)						
Cost of revenues	\$	\$	\$	\$ 20	\$ 7	\$ 6	\$ 25
Research and development		98	2,249	2,489	1,073	803	532
Sales and marketing		30	222	670	414	314	184
General and administrative		68	2,019	3,285	1,738	1,422	1,677
Restructuring							244
Total stock-based compensation	\$	\$ 196	\$ 4,490	\$ 6,464	\$ 3,232	\$ 2,545	\$ 2,662

## Edgar Filing: VIACELL INC - Form 424B4

- (5) Pro forma to give effect to the automatic conversion upon completion of this offering of our outstanding shares of convertible preferred stock into 25,810,932 shares of common stock.
- (6) Pro forma as adjusted to give further effect to the sale of common stock in this offering and our receipt of the net proceeds therefrom and to give effect to the repayment of certain of our indebtedness with a portion of the net proceeds of this offering, as described in Use of Proceeds.

**Table of Contents**

**RISK FACTORS**

*Before you invest in our common stock, you should understand the high degree of risk involved. You should consider carefully the following risks and other information in this prospectus, including the historical financial statements and related notes, before you decide to purchase shares of our common stock. If any of the following risks actually occur, our business, financial condition and operating results could be adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.*

**Risks Related to Our Business**

***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.

## **Table of Contents**

*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. 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.

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

We have generated operating losses since our inception. As of September 30, 2004, we had cumulative net losses of approximately \$151.1 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately \$84.9 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 geographically 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 federal district 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 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. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court's decision. With respect to the patent for which a new trial had been

**Table of Contents**

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.

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. 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 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 \$30.9 million in 2003 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 have filed a motion to consolidate the Massachusetts case with six other actions in a single proceeding in the District of Delaware. We also filed a motion to stay the Massachusetts litigation pending a ruling on our motion to consolidate the cases, which was granted on January 18, 2005. 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 Business Legal Proceedings.

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

As of September 30, 2004, we had approximately \$34.1 million in cash, cash equivalents and investments. 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, together with the net proceeds of this offering, 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;

**Table of Contents**

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;

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;

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

costs associated with expanding our ViaCell Reproductive Health franchise abroad, for which we do not have currently the degree of infrastructure that we have in the United States.

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

## **Table of Contents**

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 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 and Illinois and we believe that we will be able to comply with the license and registration requirements in

## **Table of Contents**

Maryland and Pennsylvania 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.

*Oocyte cryopreservation.* There are no established precedents for US and international regulation of oocyte cryopreservation. We anticipate that in the United 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. 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 intends to address the FDA letter and submit existing, published third party clinical data and to submit 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 five US patents and two international patents. We also own or have exclusive licenses to 13 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

## **Table of Contents**

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.

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

**Table of Contents**

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 September 30, 2004 of \$5.8 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 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 regulatory approval process, harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

## **Table of Contents**

***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 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

## **Table of Contents**

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 and GlaxoSmithKline, with whom we have agreements to supply SCF, Flt-3 and Tpo mimetic 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 StemCell Technologies, Miltenyi Biotec 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. Specifically, we will depend on a single source supplier of cGMP grade antibodies conjugated to a magnetic particle in our Selective Amplification process. In the event that this supplier is 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

## **Table of Contents**

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. We also intend to close our facility in Langenfeld, Germany in 2005 and transfer all manufacturing and development activities currently being 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 \$21.7 million against damage to our property and equipment, and an additional \$21.5 million to cover incremental expenses and loss of profits resulting from such damage.

***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

**Table of Contents**

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 and to commence and expand these activities in Europe and other parts of the world. This expansion could put significant strain on our management, operational and financial resources. Currently, our only facilities abroad are offices and laboratories in Germany and in Singapore, and we intend to close our German operations in 2005 and consolidate our activities there with our US operations. 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 seek clinical trials 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, 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.

As a private company, we have maintained a small finance and accounting staff. Our reporting obligations as a public company, as well as our need to comply with the requirements of the Sarbanes-Oxley Act of 2002, the rules and regulations of the Securities and Exchange Commission and the Nasdaq 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. For instance, in connection with the audit for the year ended December 31, 2003, PricewaterhouseCoopers LLP, our independent auditors, brought to our attention our need to better formalize our procedures for monitoring expense accruals and closing our books, to proactively monitor our network and to better organize our stock ledgers. PricewaterhouseCoopers LLP identified some of these issues as reportable conditions, which are significant deficiencies in the design or operation of the internal controls which could adversely affect the Company's ability to record, process, summarize and report financial information. Although PricewaterhouseCoopers LLP did not conclude that the reportable conditions, either individually or in the aggregate, constituted a material weakness in 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.

## **Table of Contents**

***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, Neuronix, 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 hematopoietic stem cell therapy product candidate similar to CB001. This product is currently being 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, would 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 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

## **Table of Contents**

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.

***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.

## **Table of Contents**

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

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

Most health care providers, including research collaborators from whom we obtain patient information, are subject to privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA ( 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. For a discussion of the HIPAA Privacy Rule and its relation to our business, see the section below entitled Business Government Regulation.

***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 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.

### **Risks Related to This Offering**

***Purchasers in this offering will suffer immediate dilution.***

If you purchase common stock in this offering, the value of your shares based upon our actual book value will immediately be less than the offering price you paid. This reduction in the value of your equity

## **Table of Contents**

is known as dilution. Based upon the net tangible book value of our common stock at September 30, 2004, our shares of common stock outstanding will have a pro forma net tangible book value of \$1.62 per share after this offering. As a result, immediately after you purchase shares in this offering, the net tangible book value of your shares will be \$5.38 less per share than the price you paid in the offering. If options and warrants we have previously granted are exercised, additional dilution would occur. Please refer to the section entitled Dilution. Furthermore, if, after this offering, we raise additional funding by issuing more equity securities, the newly issued shares will further dilute the voting power of your investment on a percentage basis.

***The sale of a substantial number of shares could cause the market price of our common stock to decline.***

If we or our stockholders sell substantial amounts of our common stock in the public market after this offering, including shares issued upon the exercise of outstanding options and warrants, the market price of our common stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. Please refer to the section entitled Shares Eligible for Future Sale.

In addition, if registration rights that we have previously granted are exercised, then our stock price may be negatively affected. We have granted registration rights in connection with the issuance of our securities to a number of our stockholders and warrant holders. As of November 30, 2004, these registration rights covered 13,333 shares of our outstanding common stock, approximately 25.8 million shares of our common stock issuable upon the conversion of our outstanding preferred stock and up to an additional approximately 1.4 million shares of our common stock issuable upon exercise of outstanding warrants. Furthermore, upon the closing of this offering, we will issue warrants to certain existing investors to purchase up to 2,190,000 shares of common stock with registration rights identical to those registration rights to which the above mentioned shareholdings are entitled. Additionally, if we experience a change in control prior to September 30, 2006, we will release and issue 241,481 escrowed shares and 289,256 contingent shares, respectively, of common stock with registration rights to former shareholders of a company that we acquired. If any of these registration rights, or similar registration rights for securities we may issue in the future, are exercised by the holders, it could result in additional sales of our common stock in the market, which may have an adverse effect on our stock price.

All of our securityholders with registration rights have agreed not to exercise their registration rights without the prior written consent of both Credit Suisse First Boston LLC and UBS Securities LLC for a period of 180 days after the date of this prospectus.

We intend to file, shortly after completing this offering, a registration statement on Form S-8 under the Securities Act covering all shares of common stock reserved for issuance under our equity plans and subject to outstanding options under our 1998 equity incentive plan. See Management Employee Benefit Plans. Shares of common stock issued upon exercise of options under the Form S-8 will be available for sale in the public market, subject to Rule 144 volume limitations for our affiliates and restrictions imposed by the 180-day lock-up agreements that substantially all of our existing security holders have entered into with the underwriters. As of November 30, 2004, options to purchase 4,463,136 shares of common stock were outstanding. After expiration of the 180-day lock up period described above, approximately 2.2 million shares issuable upon the exercise of vested stock options will become eligible for sale in the public market, if the options are exercised.

***An active public market for our common stock may not develop or be sustained after this offering, and our common stock may have a volatile public trading price which could fall below the initial public offering price. As a result, you could lose all or part of your investment.***

Prior to this offering, our common stock did not trade in a public market. You may not be able to sell your shares quickly or at the market price if trading in our stock is not active.

We and the underwriters, through negotiations, determine the initial public offering price. The initial public offering price may bear no relationship to the price at which the common stock will trade following completion of this offering. Please refer to the section entitled Underwriting for more information

## **Table of Contents**

regarding our arrangement with the underwriters and the factors considered in setting the initial public offering price.

The market prices for securities of companies comparable to us have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of the individual companies. Many factors may have a significant adverse effect on the market price of the common stock, including:

announcements regarding our product development programs;

actual or anticipated variations in quarterly operating results;

new products or services introduced or announced by us or our competitors;

changes in the market valuations of other similar companies;

sales of substantial amounts of our stock by existing stockholders;

announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments; and

additions or departures of key personnel.

In addition, in the past stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies' stock. In the future, our stockholders may pursue similar litigation against us. In general, decreases in our stock price would reduce the value of our stockholders' investments and could limit our ability to raise necessary capital or make acquisitions of assets or businesses. If a stockholder instituted litigation on this basis, it could result in substantial costs and would divert management's attention and resources.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Upon completion of this offering, our executive officers, directors and beneficial owners of 5% or more of our common stock and their affiliates will, in aggregate, beneficially own approximately 58.2% of our outstanding common stock or 56.6% if the underwriters exercise their over-allotment option in full. These persons, acting together, will be able to exercise significant influence over all matters requiring stockholder approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. This concentration of ownership may harm the market price of our common stock by delaying or preventing a change in control of our company at a premium price even if beneficial to our other stockholders. Please refer to the section entitled "Principal Stockholders" for additional information on the concentration of ownership of our common stock.

***Provisions in our charter documents could prevent or frustrate any attempts to replace our current management by stockholders.***

After the closing of this offering, our corporate charter and bylaws will contain provisions that could make it more difficult for a third party to acquire us without consent of our board of directors. Our charter will provide for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, our charter will permit our board of directors to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. Our issuance of preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our board of directors. Our charter will also provide that our stockholders may not take action by written consent. Our bylaws will require advance notice of stockholder proposals and nominations, and permit only our chief executive officer, chairman, president or a majority of our board of directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering any attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the

**Table of Contents**

holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. The board may use this provision to prevent changes in our management. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future. Please also refer to the section entitled Description of Capital Stock.

***Our management has broad discretion over the use of proceeds from this offering and may invest or spend the proceeds in ways with which you may not agree and in ways that may not yield a return.***

Our management will have broad discretion over the use of proceeds from this offering. You may not agree with management's decisions, and our use of the proceeds may not yield any return on your investment in us. The failure of our management to apply the net proceeds of this offering effectively could harm our business and financial condition.

***We do not intend to pay cash dividends on our common stock in the foreseeable future.***

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may become subject to contractual restrictions or prohibitions on the payment of dividends.

***Changes in accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and would also negatively impact our results of operations.***

The Financial Accounting Standards Board has issued Statement No. 123(R), Share-Based Payments, FAS 123(R), which requires all companies to treat the fair value of stock options granted to employees as an expense beginning July 1, 2005. Currently, we are generally not required to record compensation expense in connection with stock option grants. Because we will be required to expense the fair value of stock option grants, it reduces the attractiveness of granting stock options because of the additional expense associated with these grants, which will negatively impact our results of operations. For example, had we been required to expense stock option grants by applying the measurement provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation, our recorded net loss of \$64.9 million would have been increased by \$1.3 million, to a net loss of \$66.2 million for the year ended December 31, 2003. Nevertheless, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, after FAS 123(R) becomes effective, our results of operations will be negatively impacted if we continue to use stock options as an employee recruitment and retention tool.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements, principally in the sections entitled Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business. Generally, these statements can be identified by the use of phrases like believe, expect, anticipate, plan, may, will, could, estimate, potential, opportunity, future, project, and similar statements about:

the implementation of our corporate strategy;

our financial performance, including expectations for revenue growth from our cord blood preservation activities;

our ability to enter into future collaborations with pharmaceutical and biotechnology companies, academic institutions and others;

our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for CB001 and other product candidates;

our spending of the proceeds from this offering;

our cash needs;

expected market sizes and growth;

the ability of our potential products to treat disease;

our plans for sales and marketing, including plans to expand our ViaCell Reproductive Health franchise in the United States and begin establishing these activities abroad;

the types of regulatory frameworks we expect will be applicable to our potential products, including cell therapy products and cord blood and oocyte collection and storage products and services;

timing of regulatory approvals;

results of our scientific research; and

the potential outcome and consequences of the PharmaStem litigations.

These forward-looking statements involve risks and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Risk Factors. You should carefully consider that information before you make an investment decision. You should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date of this document, and we undertake no obligation to update or revise these statements.

**Table of Contents**

**USE OF PROCEEDS**

We estimate that we will receive net proceeds of approximately \$46.3 million from the sale of the 7,500,000 shares offered by us in this offering, or \$53.6 million if the underwriters exercise their over-allotment option in full. Those net proceed amounts are what we expect to receive after paying underwriting discounts and commissions and our estimated offering expenses. We intend to use the net proceeds of this offering to fund the growth of our business, including:

approximately \$15.0 million for conducting a Phase II clinical trial for CB001, assuming successful completion of the Phase I clinical trial for CB001 currently underway;

approximately \$5.0 million for preclinical research and development activities relating to our product candidates;

approximately \$15.5 million for repayment of principal and interest on a \$14.0 million note issued as partial consideration in our acquisition of Kourion Therapeutics in 2003; and

approximately \$10.8 million for general corporate purposes, including working capital needs, and potential acquisitions of technologies or businesses or the establishment of partnerships and collaborations complementary to our business.

The above-referenced promissory note matures on September 30, 2007, but under its terms we must repay the outstanding principal and accrued and unpaid interest concurrently with closing this offering. The full \$14.0 million of principal currently remains outstanding, and since its issuance on September 30, 2003, the note has accrued interest at a rate of 8% per annum. The note is held by several of our stockholders, which are funds affiliated with MPM Asset Management LLC, two affiliates of which are members of our board of directors.

Other than the immediate prepayment of the note, we are not obligated to use the net proceeds from this offering for any particular purpose and the amounts and timing of our actual use of proceeds will depend upon numerous factors, including cash flows from operations, the growth of our business and other factors described under Risk Factors. Also, although we periodically evaluate acquisition and licensing opportunities, we currently have no commitments or agreements with respect to any specific acquisition or license. As a result, we cannot specify with certainty the amounts that we may allocate to the particular uses of the net proceeds of this offering. Our management will have significant flexibility and discretion in applying the net proceeds of this offering. Pending any use, we will invest the net proceeds of this offering generally in short-term, investment grade, interest bearing securities but cannot predict that these investments will yield a favorable return.

**DIVIDEND POLICY**

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

**Table of Contents****CAPITALIZATION**

The following table presents our cash, cash equivalents and short-term investments and our capitalization as of September 30, 2004:

on an actual basis; and

on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our preferred stock into 25,810,932 shares of common stock; and

on a pro forma as adjusted basis to adjust the pro forma information to give effect to:

our sale of 7,500,000 shares of common stock in this offering at the initial public offering price of \$7.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us; and

repayment of our outstanding promissory note, consisting of \$14.0 million in principal and an aggregate of \$1.1 million in interest payments, assuming 12 months of accruing interest since the issuance of the note on September 30, 2003.

You should read this table together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus.

	As of September 30, 2004		
	Actual	Pro Forma	Pro Forma as Adjusted
	(in thousands, except share data)		
Cash, cash equivalents and investments	\$ 34,116	\$ 34,116	\$ 65,526
Long-term debt obligations, including current portion	\$ 19,017	\$ 19,017	3,897
Redeemable convertible preferred stock, \$0.01 par value; 30,396,809 shares authorized; 25,628,075 shares issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	172,086		
Stockholders' (deficit) equity:			
Convertible preferred stock, \$0.01 par value; 428,191 shares authorized; 182,857 shares issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	2		
Common stock, \$0.01 par value; 80,000,000 shares authorized, actual; 2,708,644 shares issued and outstanding, actual; 28,519,576 shares issued and outstanding, pro forma, and 36,019,576 shares issued and outstanding, pro forma as adjusted	27	285	360
Additional paid-in capital		171,829	218,053
Deferred compensation	(2,690)	(2,690)	(2,690)
Accumulated deficit	(151,106)	(151,106)	(151,106)
Accumulated other comprehensive income	362	362	362
<b>Total stockholders' equity (deficit)</b>	<b>(153,405)</b>	<b>18,681</b>	<b>64,979</b>
<b>Total capitalization</b>	<b>\$ 37,698</b>	<b>\$ 37,698</b>	<b>\$ 68,876</b>

The share data in the table above does not include:

Edgar Filing: VIACELL INC - Form 424B4

4,339,227 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2004 at a weighted average exercise price of \$2.17 per share;

**Table of Contents**

850,000 and 560,000 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2004, with exercise prices of \$1.50 and \$12.00 per share, respectively;

18,750 shares of our Series J preferred stock issuable upon the exercise of warrants outstanding as of September 30, 2004, each with an exercise price of \$8.00 per share;

2,190,000 shares of common stock that will be issuable under warrants with a \$5.00 per share exercise price, which warrants are not currently outstanding but will be issued immediately following this offering; and

any release of 241,481 escrowed shares or issuance of 289,256 contingent shares of common stock to satisfy a contingent purchase price obligation to former shareholders of Kourion Therapeutics. The escrowed shares will not be released and the contingent shares will not be issued unless there is a change of control of the company prior to September 30, 2006.

**Table of Contents****DILUTION**

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Our net tangible book value as of September 30, 2004 was approximately \$(160.1) million, or \$(59.11) per share of common stock. Our pro forma net tangible book value as of September 30, 2004, after giving effect to the automatic conversion of all of our preferred stock outstanding as of that date into 25,810,932 shares of common stock was approximately \$12.0 million, or \$0.42 per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the number of shares of common stock outstanding at September 30, 2004. Our pro forma net tangible book value after this offering would have been \$58.3 million or \$1.62 per share. This represents an immediate increase in pro forma net tangible book value of \$1.20 per share to existing stockholders and an immediate dilution in pro forma net tangible book value of \$5.38 per share to new investors. Dilution in pro forma net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately afterwards, after giving effect to the sale of 7,500,000 shares in this offering at the public offering price of \$7.00 per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses. The following table illustrates this per share dilution:

Initial public offering price per share		\$7.00
Net tangible book value per share before this offering	(59.11)	
Change attributable to pro forma conversion of preferred stock	59.53	
Pro forma net tangible book value per share before this offering	0.42	
Increase attributable to this offering	1.20	
Pro forma net tangible book value per share after this offering		\$1.62
Dilution per share to new investors		\$5.38

The following table summarizes, on a pro forma basis as of September 30, 2004, after giving effect to this offering, the total number of shares of common stock purchased from us and the total consideration and the average price per share paid by existing shareholders and by new investors, calculated before deduction of underwriting discounts and commissions and estimated offering expenses.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	28,519,576	79%	\$137,200,000	72%	\$4.81
New investors	7,500,000	21	52,500,000	28	7.00
Total	36,019,576	100%	\$189,700,000	100%	

The number of shares of common stock outstanding in the table above is based on the number of shares outstanding as of September 30, 2004 and excludes:

4,339,227 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2004 at a weighted average exercise price of \$2.17 per share;

850,000 and 560,000 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2004, with exercise prices of \$1.50 and \$12.00 per share, respectively;

**Table of Contents**

18,750 shares of our Series J preferred stock issuable upon the exercise of warrants outstanding as of September 30, 2004, each with an exercise price of \$8.00 per share;

2,190,000 shares of common stock that will be issuable under warrants with a \$5.00 per share exercise price, which warrants are not currently outstanding but will be issued immediately following this offering; and

any release of 241,481 escrowed shares or issuance of 289,256 contingent shares of common stock to satisfy a contingent purchase price obligation to former shareholders of Kourion Therapeutics. The escrowed shares will not be released and the contingent shares will not be issued unless there is a change of control of the company prior to September 30, 2006.

To the extent warrants and outstanding options are exercised and the underlying shares are issued, there will be further dilution to new investors. If all outstanding options and warrants had been exercised as of September 30, 2004, net tangible book value per share after this offering would be \$1.84 and total dilution per share to new investors would be \$5.16. The above table assumes no exercise of the underwriters over-allotment option.

**Table of Contents****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, 2003 and the nine months ended September 30, 2003 and September 30, 2004. The financial statements for the three years ended December 31, 2001, 2002 and 2003 have been audited by PricewaterhouseCoopers LLP, independent accountants. The financial statements for the two years ended December 31, 1999 and 2000 have been audited by Arthur Andersen LLP, independent public accountants. The consolidated statement of operations data for the nine months ended September 30, 2003 and 2004 and the consolidated balance sheet data as of September 30, 2004 are derived from our unaudited consolidated financial statements included elsewhere in the prospectus. The unaudited consolidated financial statements include, in the opinion of management, all adjustments, consisting only of normal, recurring results for those periods. The results for the nine months ended September 30, 2004 should not be considered indicative of results expected for the full fiscal year.

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 prospectus 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.

We have presented pro forma net loss per share information to give effect to the assumed conversion of all outstanding shares of our convertible preferred stock into a total of 25,810,932 shares of common stock as of their original dates of issuance.

	Year Ended December 31,					Nine Months Ended September 30,	
	1999	2000	2001	2002	2003(1)	2003	2004
(in thousands, except share and per share data)							
<b>Consolidated Statement of Operations Data:</b>							
Revenues	\$	\$ 2,394	\$ 7,298	\$ 20,375	\$ 31,880	\$ 22,632	\$ 28,633
Operating expenses:							
Cost of revenues:(2)							
Direct costs		991	3,070	5,877	7,141	5,276	5,514
Royalty expense					3,258		(3,258)
Total cost of revenues		991	3,070	5,877	10,399	5,276	2,256
Research and development	1,193	3,854	6,978	11,429	13,226	9,515	11,698
Sales and marketing		2,177	9,349	16,578	20,959	16,203	15,081
General and administrative	1,034	3,879	7,086	10,920	15,222	10,723	10,400
In-process technology(3)			594	5,889	23,925	22,200	
Stock-based compensation(4)		196	4,490	6,464	3,232	2,545	2,662
Restructuring							1,740
Total operating expenses	2,227	11,097	31,567	57,157	86,963	66,462	43,837
Operating loss	(2,227)	(8,703)	(24,269)	(36,782)	(55,083)	(43,830)	(15,204)
	90	991	2,136	744	(385)	83	(717)

Edgar Filing: VIACELL INC - Form 424B4

Interest income (expense), net							
Income taxes							
Net loss	\$ (2,137)	\$ (7,712)	\$ (22,133)	\$ (36,038)	\$ (55,468)	\$ (43,747)	\$ (15,921)
Net loss attributable to common stockholders	\$ (2,692)	\$ (10,262)	\$ (28,753)	\$ (44,182)	\$ (64,884)	\$ (50,448)	\$ (25,865)
Net loss per common share, basic and diluted	\$ (2.05)	\$ (5.55)	\$ (12.22)	\$ (17.60)	\$ (24.63)	\$ (19.21)	\$ (9.62)
Weighted average shares used in computing net loss per common share, basic and diluted	1,316,352	1,849,073	2,352,468	2,510,632	2,634,096	2,625,618	2,689,866
Pro forma net loss per common share, basic and diluted					\$ (2.32)		\$ (0.56)
Pro forma weighted average shares used in computing net loss per common share, basic and diluted					23,865,902		28,500,798

**Table of Contents**

	As of December 31,					September 30,
	1999	2000	2001	2002	2003	2004
(in thousands)						
<b>Consolidated Balance Sheet</b>						
<b>Data:</b>						
Cash, cash equivalents and investments	\$ 4,615	\$ 55,287	\$ 53,787	\$ 29,188	\$ 46,832	\$ 34,116
Working capital	3,640	53,144	46,062	25,407	22,857	12,408
Total assets	4,974	67,775	70,981	56,119	78,161	66,797
Long-term debt obligations, including current portion	312	656	1,586	5,173	19,238	19,017
Redeemable convertible preferred stock	9,947	79,727	101,268	110,912	162,141	172,806
Total stockholders equity (deficit)	(5,484)	(15,376)	(38,749)	(70,487)	(130,151)	(153,405)

- (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 expense, 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 its 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.

**Table of Contents**

- (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:

	Years Ended December 31,					Nine Months Ended September 30,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands)						
Cost of revenues	\$	\$	\$	\$ 20	\$ 7	\$ 6	\$ 25
Research and development		98	2,249	2,489	1,073	803	532
Sales and marketing		30	222	670	414	314	184
General and administrative		68	2,019	3,285	1,738	1,422	1,677
Restructuring							244
Total stock-based compensation	\$	\$ 196	\$ 4,490	\$ 6,464	\$ 3,232	\$ 2,545	\$ 2,662

**Table of Contents**

**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 included elsewhere in this prospectus. This discussion and other parts of this prospectus 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 Risk Factors.*

**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 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 September 30, 2004, our accumulated deficit was approximately \$151.1 million. From inception through September 30, 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 and Europe;

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.

## **Table of Contents**

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, 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 September 30, 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 expect to close our German facility in 2005 and transition its research activities to the United States, and revenue from grants in Germany will cease once that facility is closed.

### ***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

## **Table of Contents**

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 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.

## **Table of Contents**

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 becoming a publicly-traded company.

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 severance, contract termination costs and disposal of excess equipment. We expect to complete final activities associated with the restructuring in 2004. At September 30, 2004, restructuring charges of \$0.1 million were paid out, the net book value of fixed assets was written down by \$0.2 million and the accrued liability relating to the restructuring was \$1.4 million.

### ***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. If neither event occurs prior to September 30, 2006, the escrow shares would 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. Immediately prior to the offering made by this prospectus, the escrow shares will convert automatically into shares of common stock along with all other outstanding shares of Series I convertible preferred stock.

The results of operations of Kourion Therapeutics are included in our consolidated financial statements from the date of acquisition. We have also included a pro forma consolidated statement of operations showing the effect of Kourion Therapeutics had we acquired it on January 1, 2003. In addition, the financial statements of Kourion Therapeutics for the year ended December 31, 2002 and the nine months ended September 30, 2003 are included in this prospectus.

**Table of Contents**

In December 2004, our board of directors approved a plan to close the facility in Germany in 2005 and transfer these operations to the United States. The Company expects to record a restructuring charge of approximately \$0.6 million in the fourth quarter of 2004.

**Results of Operations**

*Nine Months Ended September 30, 2004 and 2003 (table amounts in millions, year over year changes based on rounded amounts in millions)*

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
Processing revenues	\$20.0	\$24.0	\$4.0	20%
Storage revenues	2.0	3.4	1.4	70%
<b>Total</b>	<b>22.0</b>	<b>27.4</b>	<b>5.4</b>	<b>25%</b>
Grant and contract revenues	0.6	1.2	0.6	100%
<b>Total revenues</b>	<b>\$22.6</b>	<b>\$28.6</b>	<b>\$6.0</b>	<b>27%</b>

The increase in processing and storage revenues of \$5.4 million or 25% was due primarily to an increase in the number of cords processed for new customers, as well as an increase in the number of cords stored. The increase in grant and contract revenues of \$0.6 million or 100% was primarily due to grant revenue of \$0.8 million from Kourion Therapeutics, which was acquired on September 30, 2003, offset by a decrease in contract revenue of \$0.2 million.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
Cost of revenues:				
Direct costs	\$5.3	\$ 5.6	\$ 0.3	6%
Royalty expense		(3.3)	(3.3)	100%
<b>Total cost of revenues</b>	<b>\$5.3</b>	<b>\$ 2.3</b>	<b>\$(3.0)</b>	<b>(57%)</b>

The increase in direct costs of \$0.3 million or 6% was due to increased variable expenses relating to transportation of, materials for collecting, and testing of the cord blood due to an increase in cords processed.

The decrease in royalty expense of \$3.3 million or 100% 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. While PharmaStem has filed a Notice of Appeal and a Motion to Expedite the 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.

	Nine Months Ended September 30,	
	\$ Change	% Change

Edgar Filing: VIACELL INC - Form 424B4

	<u>2003</u>	<u>2004</u>	<u>2003 to 2004</u>	<u>2003 to 2004</u>
Clinical development	\$5.5	\$ 6.1	\$ 0.6	11%
Pre-clinical programs	1.1	2.9	1.8	164%
Basic research	2.4	2.2	(0.2)	(8%)
Other research and development	<u>0.5</u>	<u>0.5</u>	<u>—</u>	<u>—</u>
Total research and development	\$9.5	\$11.7	\$ 2.2	23%

**Table of Contents**

Clinical development expense is related primarily to outside services and clinical trial expenses for CB001, and the increase reflected the cost of conducting the human clinical trials that commenced in late 2003. The increase in pre-clinical expenses was due to expenses of \$2.2 million related to Kourion Therapeutics, which was acquired in September 2003. These expenses related primarily to the cardiac disease program, and were offset by a decrease of \$0.4 million in pre-clinical costs incurred on other programs.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
Sales & marketing	\$ 16.2	\$ 15.1	\$ (1.1)	(7%)

The decrease in sales and marketing expenses of \$1.1 million or 7% was due primarily to cost savings attributed to the restructuring of our call center in the first quarter of 2004. We were able to reduce the number of employees in our call center by implementing call center automation technology.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
General & administrative	\$ 10.7	\$ 10.4	\$ (0.3)	(3%)

The decrease in general and administrative expenses of \$0.3 million or 3% was due primarily to the decrease in litigation expenses of \$1.7 million, relating to the PharmaStem lawsuit, a decrease in transaction costs of \$0.9 million relating to the acquisition of Kourion Therapeutics, our German subsidiary, in September 2003, and a reduction in bad debt expense of \$0.4 million due to continued improvements in our collection efforts in 2004. These decreases were offset by additional expense of \$0.7 million at Kourion Therapeutics, consulting costs related to our oocyte program of \$0.2 million, increase in general legal costs of \$0.6 million, and increased employee related costs of \$0.8 million, primarily due to employee severance and payroll increases related to existing employees.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
In-process technology	\$ 22.2		\$ (22.2)	(100%)

No in-process technology expenses were incurred for the nine months ended September 30, 2004. The \$22.2 million of expenses incurred for the nine months ended September 30, 2003 consisted primarily of \$22.1 million representing the portion of the Kourion Therapeutics purchase price allocated to acquired in-process technology, and \$0.1 million related to technology acquired from GlaxoSmithKline.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
Stock-based compensation	\$ 2.5	\$ 2.7	\$ 0.2	8%

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 expense for the nine months ended September 30, 2004 amounted to \$2.7 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

## Edgar Filing: VIACELL INC - Form 424B4

accelerated amortization expense related to their vested 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.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
Restructuring		\$ 1.7	\$ 1.7	100%

**Table of Contents**

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 severance, contract termination costs and the write-down of excess equipment. We expect to complete final activities associated with the restructuring in 2004. At September 30, 2004, restructuring charges of \$0.1 million were paid out, fixed assets were written down by \$0.2 million and the accrued liability relating to the restructuring was \$1.4 million.

	Nine Months Ended September 30,			
	2003	2004	\$ Change 2003 to 2004	% Change 2003 to 2004
Interest income	\$ 0.2	\$ 0.4	\$ 0.2	100%
Interest expense	(0.1)	(1.1)	(1.0)	(1,000)%
Total interest income (expense), net	\$ 0.1	\$(0.7)	\$(0.8)	(800)%

Interest income is earned from the investment of our cash in short and long term securities and money market funds. Interest expense relates to interest payable on our credit facility and in 2004, \$0.8 million of interest on the \$14.0 million note we issued in connection with the acquisition of Kourion.

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

	2002	2003	\$ Change 2002 to 2003	% Change 2002 to 2003
Processing revenues	\$ 18.5	\$ 27.8	\$ 9.3	50%
Storage revenues	1.6	3.1	1.5	94%
Total	20.1	30.9	10.8	54%
Grant and contract revenues	0.3	1.0	0.7	233%
Total revenues	\$ 20.4	\$ 31.9	\$ 11.5	56%

The increase in processing and storage revenues of \$10.8 million or 54% 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 \$0.7 million or 233% was primarily due to grant and contract revenue of \$0.4 million from Kourion Therapeutics, which was acquired on September 30, 2003, \$0.1 million from the receipt of a grant from the Government of Singapore covering the whole of 2003 compared with half the year in 2002, and \$0.2 million from contract revenue derived from research activities in the United States.

	2002	2003	\$ Change 2002 to 2003	% Change 2002 to 2003
Cost of revenues:				
Direct costs	\$ 5.9	\$ 7.1	\$ 1.2	20%
Royalty expense		3.3	3.3	100%
Total cost of revenues	\$ 5.9	\$ 10.4	\$ 4.5	76%

The increase in direct costs of \$1.2 million or 20% was due to an increase in expenses of \$2.0 million directly related to our processing and storage facility in Kentucky. The increased costs were offset by a decrease of \$0.8 million relating to third party vendors.

## Edgar Filing: VIACELL INC - Form 424B4

The increase in royalty expense of \$3.3 million or 100% was due to our accrual of \$3.3 million in 2003 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.

**Table of Contents**

While PharmaStem has filed a Notice of Appeal and a Motion to Expedite the Appeal, we continue to believe that the lawsuit is without merit and that the judge's decision will be upheld on appeal.

	<u>2002</u>	<u>2003</u>	<u>\$ Change 2002 to 2003</u>	<u>% Change 2002 to 2003</u>
Clinical development	\$ 6.8	\$ 7.3	\$0.5	7%
Pre-clinical programs	1.5	2.1	0.6	40%
Basic research	2.5	3.1	0.6	24%
Other research & development	0.6	0.7	0.1	17%
<b>Total research &amp; development</b>	<b>\$ 11.4</b>	<b>\$ 13.2</b>	<b>\$ 1.8</b>	<b>16%</b>

Clinical development expenses related primarily to CB001 and the increase in spending reflected the start of human clinical trials during fiscal year 2003 and increased spending on quality assurance testing. Expenses for our pre-clinical programs were primarily in connection with our muscular dystrophy program, which we are not currently pursuing, and our cardiac repair program, and the increase in expenses was due primarily to the acquisition of Kourion Therapeutics in September 2003 and the inclusion of their expenses of \$0.7 million for the three months ended December 31, 2003. Basic research expense increased primarily due to increased activity at our Singapore research center. Other research and development expense related primarily to our umbilical cord blood processing and storage business. We anticipate that research and development expenses in future periods will increase at an equal or higher percentage than in fiscal year 2003 as our product candidates progress into later stage clinical trial programs.

	<u>2002</u>	<u>2003</u>	<u>\$ Change 2002 to 2003</u>	<u>% Change 2002 to 2003</u>
Sales & marketing	\$ 16.6	\$ 21.0	\$ 4.4	27%

The increase in expenses of \$4.4 million or 27% 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. However, in 2004 we reduced the number of call center employees following the implementation of call center automation technology. Additionally, the employee related costs in 2003 increased over 2002 due to general payroll increases for existing employees. For both years, these expenses related primarily to our cord blood preservation business. 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. We believe that the level of spending reached in 2003 is sufficient to enable us to achieve future sales growth and that future increases in sales and marketing expense will be at a more modest rate than in 2003.

	<u>2002</u>	<u>2003</u>	<u>\$ Change 2002 to 2003</u>	<u>% Change 2002 to 2003</u>
General & administrative	\$ 10.9	\$ 15.2	\$ 4.3	39%

General and administrative expenses increased by \$4.3 million or 39% over 2002. 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. We expect that legal fees in 2004 will be lower than in 2003 and that as a result general and administrative expenses will increase at a lower rate in 2004 than in 2003.

**Table of Contents**

	<u>2002</u>	<u>2003</u>	<u>\$ Change 2002 to 2003</u>	<u>% Change 2002 to 2003</u>
In-process technology	\$5.9	\$23.9	\$18.0	305%

The expense for the year ended December 31, 2003 consisted primarily of \$22.1 million, representing the portion of the Kourion Therapeutics purchase price allocated to acquired in-process technology. 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.

	<u>2002</u>	<u>2003</u>	<u>\$ Change 2002 to 2003</u>	<u>% Change 2002 to 2003</u>
Stock-based compensation	\$6.5	\$3.2	\$(3.3)	(51%)

Stock-based compensation expense decreased by \$3.3 million, or 51% due 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 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 unamortized portion of stock-based compensation at December 31, 2003 amounted to \$3.4 million. 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.

	<u>2002</u>	<u>2003</u>	<u>\$ Change 2002 to 2003</u>	<u>% Change 2002 to 2003</u>
Interest income	\$ 0.9	\$ 0.3	\$(0.6)	(67%)
Interest expense	(0.2)	(0.7)	(0.5)	250%
Total interest income (expense), net	\$ 0.7	\$(0.4)	\$(1.1)	157%

Interest income is earned from the investment of our cash in short-term securities and money market funds. Interest expense relates to interest payable on our credit facility and interest on the \$14.0 million note we issued in connection with the acquisition of Kourion.

**Years Ended December 31, 2002 and 2001 (table amounts in millions, year over year changes based on rounded amounts in millions)**

	<u>2001</u>	<u>2002</u>	<u>\$ Change 2001 to 2002</u>	<u>% Change 2001 to 2002</u>
Processing revenues	\$6.8	\$18.5	\$11.7	172%
Storage revenues	0.3	1.6	1.3	433%
Total	7.1	20.1	13.0	183%
Grant and contract revenues	0.2	0.3	0.1	50%
Total revenues	\$7.3	\$20.4	\$13.1	179%

The increase in processing and storage revenues of \$13.0 million or 183% was due primarily to an increase in the number of units processed for customers, as well as an increase in the number of units stored. Our remaining revenues came from research contracts and grants.

	<u>2001</u>	<u>2002</u>	<u>\$ Change 2001 to 2002</u>	<u>% Change 2001 to 2002</u>
--	-------------	-------------	-----------------------------------	----------------------------------

Edgar Filing: VIACELL INC - Form 424B4

Cost of revenues:				
Direct costs	\$3.1	\$5.9	\$2.8	90%
Royalty expense	—	—	—	—
Total cost of revenues	\$3.1	\$5.9	\$2.8	90%

**Table of Contents**

The increase in direct costs of \$2.8 million or 90% was primarily due to expenses of \$1.4 million directly related to our processing and storage facility in Kentucky, and an increase of \$1.4 million relating to costs from third party vendors.

	<u>2001</u>	<u>2002</u>	<u>\$ Change 2001 to 2002</u>	<u>% Change 2001 to 2002</u>
Clinical development	\$5.7	\$ 6.8	\$ 1.1	19%
Pre-clinical programs	0.6	1.5	0.9	150%
Basic research	0.7	2.5	1.8	257%
Other research and development		0.6	0.6	100%
	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>
Total research and development	\$7.0	\$ 11.4	\$ 4.4	63%

Clinical development expenses related primarily to the development of CB001 and our Selective Amplification technology. Pre-clinical expenses related to our diabetes and neuro-sciences programs increased by \$0.9 million over 2002, and basic research expenses increased by \$1.8 million following the establishment of our Singapore research center in April 2002 and our Cambridge research center in November 2001. Other research and development expenses of \$0.6 million related to our umbilical cord blood processing and storage business.

	<u>2001</u>	<u>2002</u>	<u>\$ Change 2001 to 2002</u>	<u>% Change 2001 to 2002</u>
Sales & marketing	\$9.3	\$ 16.6	\$ 7.3	78%

Sales and marketing expenses increased by \$7.3 million or 78%. For both years, these expenses related primarily to our cord blood preservation business. The increase in expenses was due primarily to expansion of our call center of \$0.8 million, direct to consumer marketing of \$3.0 million, professional marketing of \$0.5 million and employee related costs of \$2.8 million. The increase in employee related costs was due primarily to the increase in salary and commission expenses related to the expansion of the number of employees in our call center in the middle of 2002. Additionally, employee related costs increased due to payroll increases for existing employees.

	<u>2001</u>	<u>2002</u>	<u>\$ Change 2001 to 2002</u>	<u>% Change 2001 to 2002</u>
General & administrative	\$ 7.1	\$ 10.9	\$ 3.8	54%

General and administrative expenses increased by \$3.8 million or 54%. The increase in expenses was due primarily to an increase in legal fees associated with the PharmaStem lawsuit of \$1.7 million, a charge of \$1.6 million in 2002 relating to the preparation of our previous registration statement, and employee related costs of approximately \$1.8 million to support our growing business. The increase in employee related costs was due primarily to the increase in the number of employees in our customer service, finance and information technology departments. Additionally, employee related costs increased due to payroll increases for existing employees. The increases in 2002 were offset by a reduction in amortization charges of \$0.6 million.

	<u>2001</u>	<u>2002</u>	<u>\$ Change 2001 to 2002</u>	<u>% Change 2001 to 2002</u>
In-process technology	\$0.6	\$ 5.9	\$ 5.3	883%

In-process technology expense increased by \$5.3 million. The expense for the year ended December 31, 2002 represented the value of warrants relating to technology licensed from Amgen and the expense for the year ended December 31, 2001 related to stock options granted to Genzyme for a research collaboration.

**\$ Change**                      **% Change**

Edgar Filing: VIACELL INC - Form 424B4

	<u>2001</u>	<u>2002</u>	<u>2001 to 2002</u>	<u>2001 to 2002</u>
Stock-based compensation	\$4.5	\$6.5	\$2.0	44%

44

---

**Table of Contents**

Stock-based compensation expense increased by \$2.0 million or 44% due to more options granted below fair market value. 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. The amortization is based on the vesting period of the related options. The unamortized portion of stock-based compensation at December 31, 2002 amounted to \$6.1 million. 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.

	2001	2002	\$ Change 2001 to 2002	% Change 2001 to 2002
Interest income	\$ 2.2	\$ 0.9	\$(1.3)	(59%)
Interest expense	(0.1)	(0.2)	(0.1)	(100%)
Total interest income (expense), net	\$ 2.1	\$ 0.7	\$(1.4)	(67%)

Interest income is derived from investing our cash balances, and decreased by \$1.3 million or 59% due primarily to lower interest rates. Interest expense represents interest payable on our credit facility.

**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 September 30, 2004. As of September 30, 2004, we had approximately \$34.1 million in cash, cash equivalents and investments, which we believe is, together with the net proceeds from this offering, sufficient to meet our anticipated liquidity needs for at least the next twelve months.

	Years Ended December 31,			\$ Change 2001 to 2002	\$ Change 2002 to 2003	Nine Months Ended September 30, 2004
	2001	2002	2003			
	(in thousands)					
Net cash used in operating activities	\$(14.2)	\$(21.1)	\$(22.5)	\$ (6.9)	\$ (1.4)	\$(11.2)
Net cash provided by (used in) investing activities	(39.2)	18.5	6.3	57.7	(12.2)	(15.2)
Net cash provided by financing activities	15.3	1.4	39.6	(13.9)	38.2	(0.5)
Cash & cash equivalents, end of period	\$ 16.4	\$ 15.2	\$ 39.0	\$ (1.2)	\$ 23.8	\$ 12.1

Net cash used in operating activities was \$11.2 million for the nine months ended September 30, 2004, and increased to \$22.5 million in 2003 from \$21.1 million in 2002 and \$14.2 million in 2001. For the nine months ended September 30, 2004 the cash used by operations was due to our net loss of \$15.9 million and an increase in working capital of \$0.9 million for the period, offset by \$5.6 million in non-cash expenses. 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 related to the PharmaStem litigation and the preclinical efforts in the muscular dystrophy, cardiac disease and other programs, but were partially offset by increased revenues from our cord blood preservation business and increases in accrued expenses.

Net cash used in investing activities for the nine months ended September 30, 2004 was \$15.2 million. Net cash provided by investing activities was \$6.3 million in 2003, compared to net cash provided of \$18.5 million in 2002 and net cash used of \$39.2 million in 2001. During 2001, we invested \$39.6 million of the proceeds from the November 2000 issuance of redeemable convertible preferred stock in US government and highly-rated corporate securities. Of these investments, \$39.0 million matured during 2002 and \$15.6 million was reinvested in similar securities. In 2003, \$15.8 million of these securities matured and \$9.7 million was reinvested in similar securities. During the nine months ended September 30, 2004, \$15.1 million of these securities matured and \$9.3 million was reinvested in similar



**Table of Contents**

securities. In addition, in 2004, we invested \$20.0 million of the proceeds from the December 2003 issuance of redeemable convertible preferred stock. In addition, we acquired approximately \$2.4 million, \$4.8 million and \$1.8 million in property and equipment in 2001, 2002 and 2003, respectively and acquired approximately \$1.2 million in property and equipment in the nine months ended September 30, 2004. 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 \$1.9 million, \$1.6 million and \$0.1 million in laboratory equipment in the years ended December 31, 2003, 2002 and 2001, respectively. The remaining investments in property and equipment consisted of computer equipment, software and furniture and fixtures. We expect to incur approximately \$4.0 million in capital expenditures during 2004 and 2005 in order to complete the build out of our laboratory and office space in Cambridge, of which approximately \$3.5 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 increased by approximately \$1.8 million in the year ended December 31, 2003 primarily related to the deposit in connection with the credit facility that was entered into in October 2003 with General Electric Capital Corporation.

Net cash provided by financing activities amounted to \$15.3 million in 2001, \$1.4 million in 2002 and \$39.6 million in 2003, excluding the effect of the change in exchange rates. Net cash used in financing activities for the nine months ended September 30, 2004 was \$0.4 million, excluding the effect of the change in exchange rates of \$0.1 million. This includes the proceeds from the issuance of redeemable convertible preferred stock of \$14.9 million, \$1.5 million and \$36.9 million in the years ended December 31, 2001, 2002 and 2003, respectively. Of the \$14.9 million received from the issuance of redeemable convertible preferred stock in October 2001, we are committed to investing no more than \$4.0 million over a five-year period in research and development programs to be conducted in, and a research facility located in, Singapore. 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. For the nine months ended September 30, 2004 no additional financing occurred, however we repaid \$1.2 million on our credit facility.

We anticipate that our current cash, cash equivalents and investments, together with the net proceeds from this offering, will be sufficient to fund our operations for at least the next twelve months. However, our forecast for the period of time through 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.

We currently anticipate that we will use the net proceeds from this offering to fund our clinical trial activities, pre-clinical research and development activities, repayment of a \$14.0 million note issued as partial consideration in our acquisition of Kourion 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.

**Table of Contents****Commitments and Contingencies**

The table below summarizes our commitments and contingencies at December 31, 2003 (in millions and does not include our accounts payable and accrued expenses):

Contractual Obligations	Total	Payments by Due Period			
		Less than One Year	One to Three Years	Four to Five Years	After Five Years
Operating lease obligations	\$ 19.3	\$ 1.7	\$ 5.9	\$ 3.5	\$ 8.2
Capital lease obligations	0.5	0.1	0.2	0.1	0.1
Short and long-term debt	5.2	1.8	3.4		
Notes payable(1)	14.3	14.3			
Consulting agreements	0.3	0.2	0.1		
License agreements(2)	11.2	1.5	1.8	1.4	6.5
<b>Total contractual obligations</b>	<b>\$ 50.8</b>	<b>\$ 19.6</b>	<b>\$ 11.4</b>	<b>\$ 5.0</b>	<b>\$ 14.8</b>

- (1) These notes related 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, the sale of the Company, or September 2007. Based on the intent of the offering under this prospectus, we are considering the full amount of the note payable in 2004.
- (2) We have included several patent license agreements for technologies that are in early stages of development. While we are currently making license payments under some of these agreements, we can cancel any of these agreements at any time without further financial obligation. Of the \$11.2 million payable under license agreements, \$9.8 million relates to these cancelable agreements. The remaining \$1.4 million, which is all due in less than one year, relates to one non-cancelable agreement.

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 its 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 is 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). As of September 30, 2004, very few physicians had enrolled in this recently launched program. We may record additional charges if more physicians participate in this program.

## **Table of Contents**

### ***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 \$4.7 million remained outstanding under this loan as of December 31, 2003. In accordance with the terms of the loan, we are required to maintain a cash deposit of approximately \$1.8 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 \$4.0 million in capital expenditures for leasehold and other improvements associated with our move to this new location. Our lease agreement provides for an allowance from our landlord of approximately \$3.5 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. The facility has both laboratory and office space to support our research efforts in Germany. This lease has a term of five years, with a right to one-year extensions each year for an additional five years, with an annual rent of approximately \$0.3 million per year. We intend to close our German operations in 2005 and transfer them to the United States. We are currently in discussions with a third party to sublease the facility in Langenfeld for the remaining initial lease term.

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 totalling \$14.0 million in aggregate principal amount to entities affiliated with MPM Asset Management LLC, that mature on September 30, 2007, but are subject to mandatory repayment upon the earlier to occur of an initial public offering of our common stock (including the offering under this prospectus) and the sale of the Company. The notes bear 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.

*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 achieved. See Management's Discussion and Analysis of Financial Condition and Results of Operation - Recent Acquisition. The milestone payments are payable in cash or stock valued at its fair market value

## **Table of Contents**

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 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. If such an offering occurs, 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, will have automatically converted immediately prior to the offering made by this prospectus). On September 30, 2006, the escrowed shares will be returned to us, and the 289,256 contingent shares will never be issued, if either a qualified public offering or a change in control of our company has not occurred by that date.

### ***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 Year 1 and \$225,000 in Year 2 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. In connection with this investment, we entered into an agreement with Amgen under which Amgen may require us to redeem up to 1,250,000 shares of the Series K preferred stock owned by Amgen at a price of \$8.00 per share if there is a final judgment against us in, or a settlement of, the PharmaStem litigation, for a total amount exceeding \$30 million (including the initial judgement amount as well as certain royalties, if any, that we become obligated to pay PharmaStem), or if PharmaStem is granted an injunction against us that is not stayed or vacated. Amgen's right will terminate upon the closing of this offering.

***Warrants.*** In November 1997, in connection with the issuance of our Series D preferred stock, we issued to those investors warrants to purchase 750,000 shares of our common stock at a price per share of \$1.50. These warrants vested in full 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 our Series E preferred stock, we issued to one of those investors a warrant to purchase 100,000 shares of our common stock at a price per share of \$1.50. The warrant vested in full on the date of grant and is

## **Table of Contents**

exercisable through May 21, 2009. The value ascribed to this warrant was not material. In February 2000, we issued a warrant to purchase 13,333 shares of our common stock at an exercise price of \$3.00 per share to a landlord. The warrant vested in full on the date of grant and was exercised in January 2002. The value ascribed to this warrant was not material.

In April 2002, we entered into an agreement with Amgen under which we received a nonexclusive license to patent rights covering Amgen's Stem Cell Factor. In connection with the agreement, we issued to Amgen a warrant to purchase 560,000 shares of our common stock at an exercise price of \$12.00 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. Using the Black-Scholes pricing model, the warrant had a fair value of approximately \$5.9 million at the date of issuance. The Stem Cell Factor technology licensed from Amgen, which is being used in the production process for CB001, our lead stem cell product candidate, had not achieved technological feasibility and had no alternative future use at that time, therefore we charged the purchase price of \$5.9 million to in-process technology expense.

In connection with our credit facility, we issued a warrant to the lender for the purchase of 18,750 shares of our Series J convertible preferred stock with an exercise price of \$8.00 per share and a term of ten years. We valued the warrant using the Black-Scholes model deriving a fair market value of approximately \$57,000. The warrant is being amortized under the effective interest method over the term of the note. There are no financial covenants associated with this loan agreement.

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.

### **Net Operating Loss Carryforwards**

At December 31, 2003, we had federal and state net operating loss carryforwards of approximately \$67.5 million and \$68.2 million, respectively. These carryforwards begin to expire in 2009 and 2004, respectively. We also had federal and state credit carryforwards of approximately \$1.9 million and \$1.0 million, respectively, which begin to expire 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.

### **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

## **Table of Contents**

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.

### **Critical Accounting Policies**

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



**Table of Contents**

\$3.3 million in 2003 following a jury verdict in October 2003 which found infringement. This expense included a royalty of approximately \$2.9 million on revenues from cord blood preservation through October 29, 2003, plus an accrual of 6.125% of subsequent revenues through December 31, 2003. We also recorded an expense of \$0.5 million for the three months ended March 31, 2004, also based on 6.125% of revenues. In 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 this category. 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.

**Table of Contents**

*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.

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 \$66,000 as of December 31, 2002, 2003, and as of September 30, 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 the quarter ended September 30, 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

**Table of Contents**

September 30, 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 September 30, 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. Because the program was launched during September 2004, only a small number of physicians had enrolled in the program by September 30, 2004. We expect the number of physicians enrolled to increase in the fourth quarter and, as a result, we may record additional reserves for this indemnification program.

**Stock-Based Compensation**

In connection with the grant of stock options to employees in 2000, 2001, 2002, and 2003, we recorded an aggregate amount of \$14.4 million in deferred stock-based compensation within stockholders' deficit. These options were considered compensatory because the deemed fair value, as subsequently determined, was greater than the exercise price on the date of grant. As of December 31, 2003, we had an aggregate of \$3.4 million of deferred stock compensation remaining to be amortized. We are amortizing the deferred compensation over the vesting period of the related options, under the provisions of Financial Accounting Standards Board Interpretation No. 28. 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.

Stock-based compensation related to options granted to employees where the fair market value was above the strike price at the date of grant, will be recognized in the following periods, ending December 31,

2004	\$2,270,000
2005	840,000
2006	180,000
2007	80,000
2008	50,000
	\$3,420,000

We have attached either milestones or vesting accelerators to option grants to some of our employees as performance incentives. Under these arrangements, the employee has to meet a specific performance milestone in order to accelerate vesting. In addition, certain of our key employees have employment agreements that provide for the acceleration of vesting of stock options under certain circumstances, including upon termination and/or change in control. The acceleration of vesting under such circumstances, as well as the acceleration which will occur should the applicable specific performance milestones be achieved, could potentially give rise to an increase in stock-based compensation expense in a future period. Further details of the provisions contained in these agreements are discussed in this prospectus in the section entitled "Management" under the heading "Employment and Severance Arrangements".

**Recent Accounting Pronouncements**

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, certain financial instruments

**Table of Contents**

that embody obligations for the issuer are required to be classified as liabilities. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise will be effective at the beginning of the first interim period beginning after June 15, 2003. We do not expect the provisions of this statement to have a significant impact on our statement of financial position.

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, 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.

**Table of Contents**

**BUSINESS**

**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 candidates, and we are developing a pipeline of proprietary product candidates intended to address cancer, cardiac diseases, 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. Current sources of stem cells are difficult to harvest and compatible donors are often not found.

We have already begun to build an infrastructure and a base of research, sourcing, cell processing and marketing expertise, 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 assembled an organization with research, cell sourcing, clinical development and manufacturing, cell processing and marketing capabilities. 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 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. In conjunction with this license and collaboration agreement, Amgen made a \$20 million equity investment in us. 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

**Table of Contents**

the emerging private cord blood preservation industry. 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 estimates by an independent market research report published in 2002 of industry revenue (\$128 million in 2003), we estimate that our share of the market is approximately 21% based on total units stored and 25% based on revenue. We generated \$30.9 million in sales in 2003 from cord blood processing and storage, an increase of 54% over 2002. Our direct cost of revenues during the same period increased from \$5.9 million to \$7.1 million, or 20%, and our net loss during the same period increased from \$36.0 million in 2002 to \$55.5 million in 2003. We offer our customers, who have preserved their child's own cord blood, a higher probability of obtaining suitable stem cells for transplant. 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 intends to submit 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 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

**Table of Contents**

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).

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.

## **Table of Contents**

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.

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

## **Table of Contents**

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.

We are focusing our initial clinical efforts on developing CB001, a hematopoietic stem cell therapeutic comprised of expanded cord blood stem cell population. 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

## **Table of Contents**

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.

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.

## **Table of Contents**

### ***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 54% in 2003 over 2002, while direct costs of revenues increased 20% over the same period. We intend to continue to invest in the reproductive health area, expand our obstetrician and consumer-directed education and marketing programs and build a presence in Europe and potentially other markets. 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 the 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 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. The acquisition of Kourion Therapeutics also enabled us to establish a presence in Europe, which we intend to leverage as we establish our reproductive health products in Europe. Also in 2004, we exclusively in-licensed an oocyte preservation technology that is highly complementary to our presence in cord blood

## **Table of Contents**

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.

**Table of Contents**

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.

**Table of Contents**

***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.

***High Choline Media Our Method to Cryopreserve Oocytes***

We have exclusively in-licensed technology that we believe will allow the successful cryopreservation of human oocytes using a cryopreserving media. Because of the disruptive effects of ions, particularly sodium ions during cell freezing, this technology uses a choline ion in place of a sodium ion in the media, which apparently alleviates the damaging effects of sodium transport across cell membranes and/or sodium loading of the cell. 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.

**Table of Contents****Our Product and Product Candidates**

The following table summarizes our product and pipeline of programs:

<b>Product/Program</b>	<b>Intended Use</b>	<b>Status</b>
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

***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

**Table of Contents**

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 ten patients. The patient population eligible for participation in this trial includes adolescent (over 12 years old) and adult patients with acute leukemia and myelodysplastic syndrome. 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 mid-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 five patients in this clinical trial. We are currently optimizing the CB001 manufacturing process with Amgen cGMP grade growth factors, and we may add 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.

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 long-term 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. 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, we will consider filling an Accelerated Approval application with the FDA based on the Phase II data. 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

## **Table of Contents**

hospitals in the United States. We currently store over 63,000 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.

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

experience in providing banked umbilical cord blood for stem cell transplantation, with thirteen 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 who are of certain income levels 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.



## **Table of Contents**

*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 and would be substantially delayed if our media supplier is required to conduct a clinical study that produces pregnancy and birth rates data to support the application, as the FDA is currently requesting. 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 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. 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.

## **Table of Contents**

*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 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.

## **Table of Contents**

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.

### **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 superseded 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

## **Table of Contents**

not incur any royalties and recognized \$165,000 of expenses in connection with the annual license 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

**Table of Contents**

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. Kourion Therapeutics currently has a staff of 9 (including 4 PhDs) engaged in research and development of USSCs and has active collaborations with academic institutions and investigators to evaluate USSCs in animal models of heart disease and bone fractures. 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. Kourion Therapeutics has provided us with our program in cardiac repair, and provides a location from which to build our Viacord product in Europe.

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. We agreed that the escrowed shares would be released, and the contingent shares would be issued, immediately following 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 million or more. Since the price per share in this offering is less than \$9.70, 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. Immediately prior to the offering made by this prospectus, the escrow shares will automatically convert, 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 must be repaid by ViaCell upon the earliest to occur of an initial public offering of our common stock (including the offering under this prospectus), a change in control of the company or September 2007.

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

**Table of Contents**

Discussion and Analysis of Financial Condition and Results of Operations Recent Acquisitions . The results of operations of Kourion Therapeutics are included in our consolidated financial statements from the date of acquisition. In addition, the financial statements of Kourion Therapeutics for the year ended December 31, 2002 and the nine months ended September 30, 2003 are included in this prospectus.

In December 2004, our board of directors approved a plan to close the facility in Germany in 2005 and transfer these operations to the United States. We expect to record a restructuring charge of approximately \$0.6 million in the fourth quarter of 2004.

**Intellectual Property**

The protection of our intellectual property is a strategic part of our business. We currently own or have exclusively in-licensed the five 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

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.

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 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

## **Table of Contents**

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 hematopoietic 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 is currently being 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. Osiris has publicly stated that it intends to file an IND to begin clinical studies in 2004. 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

## **Table of Contents**

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.

## **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.

## **Table of Contents**

### ***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 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

## **Table of Contents**

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;

fining, 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

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

## **Table of Contents**

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.

### ***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

## **Table of Contents**

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 will 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 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

## **Table of Contents**

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 intends to address the FDA letter and submit existing, published third party clinical data and to submit 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 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 will 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.

## **Facilities**

We currently lease and occupy three facilities in Massachusetts, with development and clinical trial-scale manufacturing operations in Worcester and our corporate headquarters and a separate research facility in Cambridge, Massachusetts. Our operations in Worcester and the research facility in Cambridge total approximately 21,700 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 currently building out the laboratory space and expect to also move our operations currently in Worcester and the research facility in Cambridge 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; both leases expire in 2007, 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. We are currently in discussions with a third party to sub-lease the facility in Langenfeld for the remaining initial 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.

## **Table of Contents**

### **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.

### **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 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. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court's decision. In response, we may appeal the jury's verdict regarding the validity and enforceability of the patents. On September 24, 2004, our \$2.9 million escrow payment was released to the Company. In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both patents based on the prior art submitted, with a ruling on patentability 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, 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.

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

**Table of Contents**

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. 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. We have filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. We also filed a motion to stay the Massachusetts litigation pending a ruling on our motion to consolidate the cases, and the motion was granted on January 18, 2005.

In light of a relationship between the patents asserted in Delaware and Massachusetts, the Massachusetts litigation may be delayed if an appeal is taken in the Delaware case. Regardless of whether an appeal is taken, the Massachusetts litigation may be transferred or consolidated with one or more of PharmaStem's cases pending against other defendants in other jurisdictions. Thus, 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.

## **Table of Contents**

### **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.

*Hal Broxmeyer, Ph.D.* Dr. Broxmeyer is Chairman and the Mary Margaret Walther Professor of Microbiology and Immunology, Professor of Medicine, and Scientific Director of the Walther Oncology Center at the University of Indiana School of Medicine. He is known for his studies on the positive and negative regulation of blood cell production, which since the 1970s have resulted in over 500 publications, and for his extensive research on umbilical cord blood since the 1980s. Dr. Broxmeyer is a founder of the field of cord blood transplantation. His laboratory studies on cord blood stem and progenitor cells and the cryopreservation and storage of cord blood for transplantation helped lead to the first five cord blood transplants. Dr. Broxmeyer has a B.S. from Brooklyn College, City University of New York, a Master's of Science from Long Island University, Brooklyn Campus, a Ph.D. from New York University and completed post doctoral work at Queens University, Kingston, Ontario.

*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

**Table of Contents**

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 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.

**Table of Contents****MANAGEMENT****Executive Officers, Key Employees and Directors**

Set forth below is information regarding our executive officers, key employees and directors, as of December 31, 2004.

Name	Age	Positions
<b>Executive Officers:</b>		
Marc D. Beer	40	President, Chief Executive Officer and Director
Stephen G. Dance	53	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
Stephan Wnendt, Ph.D.	42	Senior Vice President, Research and Development
<b>Key Employees:</b>		
Morey Kraus	46	Vice President and Chief Technical Officer
Mary Larson-Marlowe	38	Vice President, Therapeutic Development Operations
Mary T. Thistle	45	General Manager, ViaCell Reproductive Health
<b>Directors:</b>		
Vaughn M. Kailian	60	Chairman of the Board
George Daley, M.D., Ph.D.	44	Director
Ansbert Gadicke, M.D.	46	Director
Paul Hastings	44	Director
Denise Pollard-Knight, Ph.D.	44	Director
James L.L. Tullis	57	Director
Jan van Heek	54	Director

**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.

## **Table of Contents**

*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 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.

### ***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 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.

*Mary T. Thistle.* Ms. Thistle has served as our 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

**Table of Contents**

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.

***Board of Directors***

*Vaughn M. Kailian.* Mr. Kailian has served as a director and chairman of our board since January 2004. Mr. Kailian serves on the board of NicOx, S.A., and on the boards of Elixir Pharmaceuticals, Inc. and Windhover Information, Inc., both private companies. He also serves on the Pharmaceutical Advisory Council at the University of Texas at Austin. From 2002 until 2004, Mr. Kailian served as vice chairperson of Millennium Pharmaceuticals, Inc., where he was head of the Millennium commercial organization. Mr. Kailian was CEO, President, and director of COR Therapeutics, Inc. from 1990 until its acquisition by Millennium in 2002. Mr. Kailian has a B.A. degree from Tufts University.

*George Daley, M.D., Ph.D.* Dr. Daley has served as a director since April 2000. Since January 2004, he has been 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 is a venture partner at MPM Asset Management LLC. He has also been one of our scientific consultants since 1998 and is Co-Chairman of our medical and scientific advisory board. 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.

*Ansbert Gadicke, M.D.* Dr. Gadicke has served as a director since January 1998. Dr. Gadicke is President, Chairman and Founding General Partner of MPM Asset Management LLC and a manager of MPM BioVentures I LLC and MPM Asset Management II LLC. Dr. Gadicke founded MPM in 1992. MPM and the MPM BioVentures funds invest private equity in early stage startups, as well as large capitalization companies. Prior to MPM, Dr. Gadicke was employed by The Boston Consulting Group, a consulting firm. He has held research positions at the Whitehead Institute at MIT, Harvard University and the German Cancer Research Center. Dr. Gadicke currently serves as a director on management boards of several private companies. Dr. Gadicke has an M.D. from J.W. Goethe University in Frankfurt.

*Paul Hastings.* Mr. Hastings has served as a director since November 2000. Mr. Hastings is President and Chief Executive Officer of QLT, Inc., a biotechnology company. Prior to that, from 2001 until January 2002, he served as President and Chief Executive Officer of Axys Pharmaceuticals Inc. prior to Axys' merger with Celera Genomics, an Applera company. From April 1999 until January 2001, he was President of Chiron Corporation's BioPharmaceuticals Division. Prior to that, he was President and Chief Executive Officer of LXR Biotechnology and President of Genzyme Therapeutics Worldwide. Mr. Hastings has a B.S. degree in pharmacy from the University of Rhode Island.

*Denise Pollard-Knight, Ph.D.* Dr. Pollard-Knight has served as a director since October 2003. Dr. Pollard-Knight is the head of Nomura Phase4 Ventures, a subsidiary of Nomura International plc, a leading Japanese financial institution. Prior to joining Nomura in January 1999, Dr. Pollard-Knight was a member of Rothschild Asset Management Ltd., an investment management firm, from January 1997 to January 1999. Dr. Pollard-Knight held several research and development management positions at Amersham-Pharmacia and Fisons plc. Dr. Pollard-Knight holds a Ph.D. and B.Sc. (Hons) from the University of Birmingham in England. Dr. Pollard-Knight completed postdoctoral work as a Fulbright Scholar at the University of California, Berkeley.

## **Table of Contents**

*James L.L. Tullis.* Mr. Tullis has served as a director since September 2002. Mr. Tullis is the Founder and Chief Executive Officer of Tullis-Dickerson & Co., Inc., a health care-focused private equity firm which he founded in 1986. From 1983 to 1986, Mr. Tullis was Senior Vice President and led healthcare investment banking efforts at E.F. Hutton. Prior to that, Mr. Tullis was a Principal at Morgan Stanley and led that firm's investment research in health care from 1974 through 1983. Mr. Tullis was a research analyst at Putnam Funds from 1972 to 1974. Mr. Tullis is a graduate of Stanford University and earned an MBA from Harvard Business School. Mr. Tullis also serves on the board of directors of Crane Co.

*Jan van Heek.* Jan van Heek has served as director since September 2002. He has served at various positions at Genzyme since 1991, including Executive Vice President, Therapeutics and Genzyme Tissue Repair, and Executive Vice President, Therapeutics and Genetics. From August 2003 through the end of March 2004, Mr. van Heek was responsible for Genzyme's Biosurgery, Genetics and Pharmaceuticals business unit and global manufacturing of therapeutic and biosurgery products, and he currently serves in a part-time capacity as an advisor to Genzyme's Chief Executive Officer. Mr. van Heek established Genzyme's European offices and has played a key role in developing the company's strategic vision. Prior to joining Genzyme, Mr. van Heek held various senior management positions at Baxter Healthcare Corporation, including vice president and general manager of its Fenwal Division. Mr. van Heek received his MBA from St. Gallen University in Switzerland and holds an executive degree in business from Stanford University.

## **Board Composition**

Our board currently has eight members, who we expect to remain the members of our board immediately following this offering. Following this offering, our charter and bylaws will divide our board into three classes of directors serving staggered three-year overlapping terms, with one class of directors elected at each annual meeting of stockholders. Each director will serve until his or her successor is elected or until his or her earlier death, resignation or removal as provided by our bylaws.

Our directors will be divided among the three classes as follows:

the Class I directors will be Dr. Gadicke, Dr. Pollard-Knight and Mr. Tullis, and their terms will expire at the annual meeting of stockholders to be held in 2005;

the Class II directors will be Messrs. Daley, Hastings and van Heek, and their terms will expire at the annual meeting of stockholders to be held in 2006; and

the Class III directors will be Messrs. Beer and Kailian, and their terms will expire at the annual meeting of stockholders to be held in 2007.

Following this offering, our charter and bylaws will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

## **Committees of the Board of Directors**

Upon the close of this offering, our Board of Directors will have the following standing committees:

### ***Audit Committee***

The members of our board's audit committee are Mr. Kailian, Dr. Pollard-Knight and Mr. van Heek; Mr. Kailian is the chairman of the committee, and our board has identified him as our audit committee financial expert. The audit committee assists our Board of Directors with its oversight responsibilities regarding the integrity of our financial statements; our compliance with legal and regulatory requirements; the independent auditors' qualifications and independence; and the performance of our internal audit function, if any, and independent auditors. We believe that the composition of our audit committee meets the requirements for independence under the current requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq National Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

## **Table of Contents**

### ***Compensation Committee***

The members of our board's compensation committee are Mr. Hastings, Mr. Tullis and Mr. van Heek; Mr. Hastings is the chairman of the committee. The compensation committee provides assistance to the Board of Directors by designing and recommending to the Board of Directors for approval and evaluating the compensation plans, policies and programs of ViaCell, especially those regarding executive compensation; reviewing and approving the compensation of our Chief Executive Officer and other officers and directors; and will assist the Board of Directors in producing an annual report on executive compensation for inclusion in our proxy materials in accordance with applicable rules and regulations. We believe that the composition of our compensation committee meets the requirements for independence under, and the functioning of our compensation committee complies with, any applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq National Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

### ***Nominating and Corporate Governance Committee***

The members of our nominating and corporate governance committee are Mr. Kailian and Mr. Hastings; Mr. Kailian will be the chairman of the committee. The nominating and corporate governance committee will assist the Board of Directors with its responsibilities regarding the identification of individuals qualified to become Board members; the selection of the director nominees for the next annual meeting of stockholders; and the selection of director candidates to fill any vacancies on the Board of Directors. In addition, the committee will examine the composition of the Board of Directors following the closing of the initial public offering and may propose changes to the Board composition based on this review. The committee will also assist the Board of Directors in addressing matters regarding corporate governance. We intend for the composition of our nominating and corporate governance committee to meet the requirements for independence under, and the committee's functions will comply with, any applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq National Market and SEC rules and regulations.

### **Director Compensation**

Upon the closing of our initial public offering, each director who is not an employee will be eligible to receive compensation from us for his or her services as a member of our board or any of its standing committees. Each such non-employee director will be entitled to receive an option to purchase 20,000 shares of our common stock upon such director's initial election to our Board of Directors (such options vesting as to 25% on the issuance thereof and 25% on every anniversary thereafter), an annual retainer of \$10,000, and an option to purchase 10,000 shares of our common stock following each annual stockholders meeting. Each non-employee director will also receive \$2,000 for each board meeting attended (or \$1,000 for each such meeting attended by telephone conference call) and \$1,000 for each committee meeting attended (\$2,000, if chairperson of the committee). A non-employee, non-stockholder affiliated board member who serves as chairperson of our board, receives an annual retainer of between \$62,000 and \$112,000 in cash, and options to purchase 160,000 shares of common stock, vesting quarterly at 6.25% over four years. As chairman of the board, the chairman also receives \$2,000 for each board meeting attended. We reimburse all of our board members for expenses incurred in attending board and committee meetings.

Mr. Hastings and Mr. Tullis were paid \$29,394 and \$19,296 in cash, respectively, for their board services in 2004. Mr. van Heek was paid a total of \$13,500 in cash and was granted options to purchase 15,000 shares of our common stock at \$5.00 per share for his services in 2004. Mr. Kailian was paid \$100,000 for his service as chairman of the board and was granted a stock option to purchase 160,000 shares of common stock at \$5.00 per share vesting quarterly in 16 equal installments. Dr. Pollard-Knight, Dr. Gadicke, Mr. Tullis and Dr. Daley each received in April 2004 options to purchase 20,000 shares of our common stock at \$5.00 per share (such options vested as to 25% on the issuance thereof and will vest an additional 25% on every anniversary thereafter) for their service in 2004.

**Table of Contents**

In addition, in connection with his work as a member of our medical and scientific advisory board, in August 2003, we continued Dr. Daley's consulting arrangement with us. Under this arrangement, we have agreed to pay him a \$20,000 per year annual retainer, plus \$5,000 for every full advisory board meeting attended (\$500 if attended by telephone). He also receives options to purchase 30,000 shares of our common stock at an exercise price per share of \$5.00, all of which are vested fully. In 2004, Dr. Daley was paid \$23,000.

**Compensation Committee Interlocks and Insider Participation**

During 2004, our compensation committee consisted of Mr. Hastings, Dr. Gadick and Mr. Tullis, with Mr. van Heek replacing Dr. Gadick in April 2004. None of these individuals has been an officer or employee of ours at any time. Also, none of our executive officers serves, nor served in 2004, on the board of directors or compensation committee of a company with an executive officer serving on our board of directors or compensation committee. Please also refer to the section entitled Certain Relationships and Related Party Transactions.

**Executive Compensation**

The table below summarizes the compensation paid to or earned by our chief executive officer and our six other most highly compensated executive officers during 2003 and 2004. We refer to these seven people as the named executive officers.

**Summary Compensation Table**

Name And Principal Position	Year	Annual Compensation(1)			Long-term Compensation	
		Salary	Bonus(2)	Other Annual Compensation(3)	Securities Underlying Options	All Other Compensation
Marc D. Beer	2004	\$340,000				
<i>President and Chief Executive Officer</i>	2003	325,000	\$87,750			
Christoph M. Adams, Ph.D.	2004	219,828				
<i>Senior Vice President, Business Development</i>	2003	209,535	39,255			
Grant Bogle(4)	2004	64,904				\$167,228
<i>President, ViaCell Commercial Operations</i>	2003	249,953				
Stephen G. Dance(5)	2004	235,000			225,000	30,000(8)
<i>Senior Vice President, Finance and Chief Financial Officer</i>						
Kurt Gunter, M.D.	2004	224,065				
<i>Senior Vice President, Clinical and Regulatory Affairs and Government Relations</i>	2003	218,599	21,000			
Jeffrey A. Sacher(6)	2004	35,335				185,769
<i>Chief Financial Officer</i>	2003	204,346			200,000	115,179
Stephan Wnendt, Ph.D.(7)	2004	223,172			80,000	
<i>Senior Vice President, Research and Development</i>						

(1) Includes amounts earned but deferred at the election of the executive, such as salary deferrals under our 401(k) Plan.

(2) Bonuses earned for the year 2004 have not yet been determined. We intend to finalize the bonus amounts for our named executive officers in the first quarter of 2005, to be determined by our board of directors and to be based on our corporate performance and the individual performances of these individuals.



**Table of Contents**

- (3) The value of perquisites and benefits for each named officer does not exceed the lesser of \$50,000 and 10% of his total annual salary and bonus.
- (4) Mr. Bogle's employment with us terminated on March 31, 2004. All other compensation reflects loan forgiveness of \$55,418 and severance payments of \$111,635.
- (5) Mr. Dance joined us on January 1, 2004.
- (6) Mr. Sacher's employment with us terminated on February 2, 2004. Mr. Sacher's salary for 2004 includes vacation payout of \$11,104. All other compensation for the years 2003 and 2004 reflects payments made to Mr. Sacher to reimburse his relocation expenses and severance payments, respectively.
- (7) Dr. Wnendt joined us in September 2003 as our Senior Vice President, European Operations and became Senior Vice President, Research and Development in October 2004.
- (8) Reflects payment made to Mr. Dance to reimburse his relocation expenses.

**Stock Options**

The table below provides information regarding stock option grants by us to Mr. Dance and Dr. Wnendt, who were the only named executive officers in 2004 to receive such grants. All options were granted under our equity incentive plan. These options were granted at exercise prices at least equal to the fair market value of our common stock as determined by the compensation committee or by our board of directors on the dates of grant. The percentage of options granted is based on options to purchase an aggregate of 891,000 shares of our common stock granted by us in 2004 to our employees, including the named executive officers.

**Option Grants in Fiscal Year 2004**

Name	Individual Grants				Potential Realizable Value Assumed Annual Rates of Stock Price Appreciation for Option Terms(1)	
	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees in 2004	Exercise Price Per Share	Expiration Date	5%	10%
Stephen G. Dance	225,000	25.3%	\$5.00	January 1, 2014	\$1,440,509	\$2,960,144
Stephan Wnendt, Ph.D.	80,000	9.0%	\$5.00	October 13, 2014	\$ 512,181	\$1,052,496

- (1) The dollar amounts under these columns are the result of calculations at the 5% and 10% rates set by the SEC and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying common stock. The potential realizable values are calculated using a base value equal to the initial public offering price of \$7.00 per share and assuming that the market price appreciates from this price at the indicated rate for the entire term of each option and that each option is exercised and sold on the last day of its term at the appreciated price.

**Table of Contents**

The table below provides information regarding unexercised stock options held on December 31, 2004 by each of the named executive officers. No stock options were exercised by named executive officers during our last fiscal year. As our common stock is not publicly traded, a readily ascertainable market value for these options is not available.

**Option Exercises And Year-End Option Values**

Name	Number of Securities Underlying Unexercised Options at December 31, 2004		Value of Unexercised In-the-Money Options at December 31, 2004(1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Marc D. Beer	600,000	900,000	\$4,020,000	\$5,010,000
Christoph M. Adams	81,250	48,750	491,563	263,438
Grant Bogle				
Stephen G. Dance	23,437	201,563	46,874	403,126
Kurt Gunter	97,500	62,500	589,875	378,125
Jeffrey A. Sacher	62,500	137,500	125,000	275,000
Stephan Wnendt, Ph.D.	42,500	157,500	85,000	315,000

(1) Based on the difference between the option exercise price and the initial public offering price of \$7.00 per share of common stock.

**Employment and Severance Arrangements**

All of our current employees have entered into agreements with us which contain restrictions and covenants. These provisions include covenants relating to the protection of our confidential information, the assignment of inventions and restrictions on soliciting our clients, employees or independent contractors. None of our employees are employed for a specified term, and each employee's employment with us is subject to termination at any time by either party for any reason, with or without cause. We have entered into employment agreements with Mr. Beer and letter agreements with our other named executive officers.

Under Mr. Beer's employment agreement, dated May 2, 2000, he serves as our Chief Executive Officer for automatically renewed one-year terms each June 1st, until terminated by either party upon three months' notice. His agreement provides for a base salary of \$250,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the board of directors in its discretion. Under the agreement, we granted Mr. Beer at commencement of his employment an option to purchase 900,000 shares of our common stock at \$0.30 per share, two-thirds of which began vesting in 48 equal, monthly installments on the grant date, with the remaining one-third to vest in equal annual installments on each of the eighth, ninth and tenth anniversary dates of the grant date. If we terminate Mr. Beer without cause or if he terminates his employment for good reason, he is entitled to his then current base salary plus benefits for twelve months following the date of termination.

Under Dr. Adams' letter agreement, dated June 7, 2001, he serves as our Senior Vice President, Business Development with a base salary of \$200,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the board of directors in its discretion. Under the agreement, we granted Dr. Adams an option to purchase 100,000 shares of our common stock at \$0.95 per share, vesting quarterly over four years. If we terminate Dr. Adams without cause or if he terminates his employment for good reason, he is entitled to his then current base salary for six months following the date of the termination.

Mr. Bogle's letter agreement, dated July 1, 2002, provided for his employment as our President, ViaCell Commercial Operations with a base salary of \$225,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the board of directors in its discretion. Under the agreement, we granted Mr. Bogle an option to purchase 250,000 shares of our common stock at \$5.00 per share, vesting quarterly over four years, and an option to purchase 50,000 shares of our common

**Table of Contents**

stock at \$5.00 per share, vesting upon the achievement of certain milestones. Mr. Bogle's employment with us terminated on March 31, 2004, and under the terms of a mutual release and early separation agreement entered into on February 18, 2004, we made severance payments to Mr. Bogle for a six month period, at the Company's regular payment periods, in amounts equal to his base rate of pay at the time of his termination, and during such six-month period his stock options remained exercisable. Our obligation to make further severance payments, and his right to exercise his stock options, has expired.

Under Dr. Wnendt's letter agreement, dated December 29, 2004, he serves as our Senior Vice President, Research & Development, at an annual base salary of \$230,000, plus potential performance-based bonuses of up to \$75,000 annually based on the achievement of corporate and individual goals. Prior to his assuming this position in October 2004, we employed Dr. Wnendt in our German office as Senior Vice President, European Operations and Executive Officer, and his letter agreement confirms that he remains entitled to his 2004 guaranteed bonus of \$30,625. Dr. Wnendt received an option to purchase 80,000 shares of our common stock at \$5.00 per share, vesting quarterly over four years. Dr. Wnendt is also entitled to a relocation package, sponsorship and payment of all costs associated with his visa and immigration matters and a full payment for his US individual plan health insurance while his family remains in Germany. If we terminate Mr. Wnendt without cause or if he terminates his employment for good reason, each as defined in the letter agreement, he is entitled to his then current base salary plus benefits for twelve months following the date of termination.

Under Dr. Gunter's letter agreement, dated May 14, 2001, he serves as our Senior Vice President, Clinical and Regulatory Affairs/Government Relations, with a base salary of \$210,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the board of directors in its discretion. Under the agreement, we granted Dr. Gunter an option to purchase 120,000 shares of our common stock at \$0.95 per share, vesting quarterly over four years, and an option to purchase up to an additional 40,000 shares of our common stock at \$0.95 per share, vesting upon the achievement of certain milestones. If we terminate Dr. Gunter without cause or if he terminates his employment for good reason, he is entitled to his then current base salary for six months following the date of the termination.

Mr. Sacher's employment agreement, dated October 26, 2002, provided for his employment as our Chief Financial Officer with a base salary of \$210,000 per year, subject to yearly adjustment, and performance-based bonuses to be granted in amounts in our board of directors' discretion. Under the agreement, we granted Mr. Sacher options to purchase 125,000 shares of our common stock at \$5.00 per share vesting quarterly over four years. We also granted Mr. Sacher options to purchase 75,000 shares of our common stock at \$5.00 per share, vesting on the grant date's fourth, fifth, sixth and seventh anniversaries, subject to accelerated vesting of up to 55,000 of such shares upon achievement of certain milestones. Mr. Sacher's employment with us terminated on February 2, 2004, and under the terms of a mutual release and early separation agreement dated January 2, 2004, we will make severance payments to Mr. Sacher for a 12-month period commencing February 2, 2004 at the Company's regular payroll periods in an amount equal to his base salary at the time of his termination, and during such 12-month period his options will continue to vest as if he were employed with us. All of Mr. Sacher's unexercised options (whether vested or unvested) will terminate at the end of such 12-month period.

Under Mr. Dance's letter agreement, dated March 11, 2004, he serves as our Senior Vice President, Finance and Chief Financial Officer at an annual starting base salary of \$235,000, plus potential bonuses at a target of \$50,000 payable annually based on achievement of both corporate and individual goals. The letter agreement provides for a lump sum bonus towards relocation expenses of \$30,000. Under the letter agreement, Mr. Dance is entitled to an option to purchase 125,000 shares of our common stock at \$5.00 per share, vesting quarterly over four years beginning on the last day of the first quarter after Mr. Dance's effective date of employment. In addition, Mr. Dance is entitled to a performance based option to purchase 100,000 shares of common stock at \$5.00 per share, 25% of which will vest in equal annual installments on each of the fourth, fifth, sixth and seventh anniversary dates of the date of grant, provided, however, that 25,000 of such shares will become fully vested on each of the first and second anniversaries of an initial public offering. If at any time within 24 months after the lock up period imposed by the

## **Table of Contents**

underwriters in connection with an initial public offering, the average closing price of our common stock over a period of 30 consecutive trading days as reported by any exchange on which our common stock is traded equals or exceeds \$26.00 per share, or if at any time within 36 months after the expiration of such lock up period such average closing price equals or exceeds \$34.00 per share, then 50,000 of the 100,000 shares under the performance based option will fully vest and become exercisable. If we terminate Mr. Dance without cause or if he terminates his employment for good reason, he is entitled to his then current base salary plus benefits for twelve months following the date of termination. If we terminate Mr. Dance within twelve months of a change in control without cause or if Mr. Dance voluntarily resigns for good reason, in addition to being entitled to his base salary and benefits for a period of twelve months, all options granted to Mr. Dance as of that date will become fully vested and exercisable. In the event of a change of control, 100,000 shares of common stock under the performance based option granted to Mr. Dance will fully vest and become exercisable.

### **Employee Benefits Plans**

#### ***Amended and Restated 1998 Equity Incentive Plan***

Our board of directors initially adopted our current equity incentive plan in 1998. It has been subsequently amended and restated several times, with the most recent amendment and restatement to the plan having been adopted by the Board in March 2004 and approved by the stockholders on December 30, 2004, to become effective upon the effectiveness of the registration statement of which this prospectus forms a part. Our equity incentive plan provides for the grant of incentive stock options, as defined under section 422 of the US Internal Revenue Code, nonstatutory stock options, restricted and unrestricted stock awards, stock appreciation rights, and stock units. Under the plan, incentive stock options may be granted to employees, including officers. All other awards may be granted to employees, including officers, non-employee directors and consultants.

We have reserved 7,200,000 shares of common stock for issuance under the plan. Of that number, as of November 30, 2004, a total of 4,463,136 shares are reserved for issuance under outstanding awards, leaving 2,267,248 shares available for issuance for future grants. No awards can be granted under the plan after 2008 or such earlier date designated by our board of directors.

Our board of directors administers our equity incentive plan, although it may delegate any of its functions as plan administrator to the board's compensation committee. The plan administrator determines recipients, grant dates, the numbers and types of equity awards to be granted and the terms and conditions of the equity awards, including the period of their exercisability and vesting. The plan administrator also determines the exercise price of options granted, the purchase price for rights to purchase restricted stock and the strike price for stock appreciation rights. The plan administrator may also amend the terms of any outstanding equity awards, subject to the award holder's consent unless the plan administrator determines the holder would not be materially and adversely affected. Our board may amend, suspend or terminate the plan at any time.

In the event of a change in control of our company, or a sale of substantially all of our assets, the compensation committee or the board may, in its discretion, and either at the time of grant, or afterwards, provide for the manner in which an award may be affected by such transaction, including assumption of the award by the acquiring party in the change in control or asset sale, acceleration of any vesting or release of restrictions, termination of the award or otherwise.

#### ***2004 Employee Stock Purchase Plan***

Our board of directors adopted in March 2004, and our stockholders approved on December 30, 2004, our employee stock purchase plan, to become effective upon the effectiveness of the registration statement of which this prospectus forms a part. The purchase plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the US Internal Revenue Code. Under the purchase plan, employees may purchase shares of common stock at a discount from fair market value.

**Table of Contents**

We have reserved 750,000 shares of common stock for issuance under the purchase plan. We have not, and will not prior to the initial public offering of our common stock, issue any shares of common stock under the purchase plan. Once the first offering period begins under the purchase plan, we can continue to grant purchase rights under the plan through the end of 2014, unless the purchase plan is earlier terminated by our board.

We expect that our compensation committee will grant rights under the purchase plan, although our board may also exercise that function. Also, the compensation committee, or a duly appointed administrator, will determine the frequency and duration of individual offerings under the plan and the dates when employees may purchase stock. Eligible employees participate voluntarily and may withdraw from any offering at any time before they purchase stock. Participation terminates automatically upon termination of employment. The purchase price per share of common stock in an offering will not be less than 85% of the lesser of its fair market value at the beginning of the offering period or on the applicable exercise date and employees may pay through payroll deductions, periodic lump sum payments or a combination of both. The compensation committee may amend, modify or terminate the purchase plan at any time

***401(k) Plan***

We have a 401(k) defined contribution retirement plan covering substantially all full-time employees. Our 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees and by us to our 401(k) plan and income earned on plan contributions are not taxable to employees until withdrawn or distributed from the plan, and so that contributions, including employee salary deferral contributions, will be deductible by us when made.

**Table of Contents**

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

**Sales of Securities**

Since January 1, 2001, several of our executive officers, directors and 5% stockholders purchased our securities as described below.

Dr. Gadicke, a member of our board of directors, is a manager of MPM BioVentures I LLC and MPM Asset Management II LLC. In September 2003, we issued to five funds affiliated with these entities an aggregate total of 235,274 shares of our Series I preferred stock when we purchased from those funds and other sellers all of the outstanding capital shares of Kourion Therapeutics. We have an obligation to issue those funds an additional 289,256 shares of our Series I preferred stock (contingent shares) if, prior to September 30, 2006, we experience a change in control. If the contingent shares issue upon a change in control, we will issue to the funds an additional number of contingent shares equaling 8% of the initial 289,256 of contingent shares compounded annually from the Kourion Therapeutics acquisition date up to the date of issuance. Also in connection with our acquisition of Kourion Therapeutics, we issued to four of those funds promissory notes for a total of \$14.0 million, which accrue interest at a rate of 8.0% per annum and mature in September 2007, but are to be mandatorily prepaid by us upon closing of the offering made by this prospectus. Under the Kourion Therapeutics acquisition agreement, we are obligated to pay the five funds, and the other sellers of Kourion Therapeutics, future payments if and when the programs acquired in the transaction meet certain clinical trial milestones; the funds' share of these potential payments equals approximately \$3.3 million. The payments can be satisfied in cash or Series I preferred stock (or, after we are publicly traded, common stock) at the recipient's election. Also in 2003, three other MPM-affiliated funds purchased from us 125,000 shares of our Series J preferred stock, and rights to contingent warrants to purchase an additional 125,000 shares of our common stock, at a price of \$8.00 per combined share and contingent warrant, for an aggregate purchase price of \$1.0 million. The contingent warrants will be issued to the rights holders following this offering pursuant to our obligation to issue those warrants if the public offering price of our common stock in this offering is less than \$9.70. The warrants will have an exercise price of \$5 per share. Also, under our current agreement with our preferred stockholders, one of the MPM-affiliated funds is entitled to appoint two members to our board of directors presently, Dr. Gadicke and Dr. Daley, a venture partner at MPM, occupy those board positions; this right terminates upon the closing of the offering being made in this prospectus.

Amgen Inc., one of our stockholders, is party to a license and collaboration agreement with us described above under Business Collaborations, Licenses and Strategic Relationships - Amgen. We issued to Amgen a warrant to purchase 560,000 shares of our common stock at \$12.00 per share in April 2002 in connection with our initial license from them. In December 2003, when we expanded that arrangement through our current license and collaboration agreement with Amgen, they purchased 2,500,000 shares of our Series K preferred stock for \$20 million in cash.

James L.L. Tullis, a member of our board of directors, is the Chief Executive Officer of Tullis-Dickerson & Co., Inc. In 2001, investment funds affiliated with Tullis-Dickerson & Co. paid an aggregate price of \$3.0 million to purchase from us 375,000 shares of our Series I preferred stock at a \$8.00 per share. Tullis-Dickerson is entitled to appoint one member to our board of directors and has appointed Jim Tullis as this member. This right will expire upon the closing of the offering being made by this prospectus.

Funds affiliated with Zero Stage Capital, in 2001, purchased from us 250,000 shares of our Series I preferred stock at a price of \$8.00 per share, for an aggregate purchase price of \$2.0 million.

Cynthia A. Fisher, a co-founder of ViaCell and founder of Viacord, and a former officer of both companies, in 2001 exercised an option to purchase 250,000 shares of our common stock at an aggregate purchase price of \$82,500.

## **Table of Contents**

Denise Pollard-Knight, a member of our board of directors, is the head of Nomura Phase4 Ventures, a subsidiary of Nomura International plc. In 2001, Nomura International purchased from us 125,000 shares of our Series I preferred stock at a price of \$8.00 per share, for an aggregate purchase price of \$1.0 million. Nomura International is entitled to appoint one member to our board of directors and has appointed Ms. Pollard-Knight as this member. This right will expire upon the closing of this offering.

All purchases of our Series I preferred stock by Zero Stage Capital and the several entities affiliated with our directors, as described above, were made at prices negotiated between us and groups of investors that included third parties unaffiliated with us. Specifically, in our acquisition of Kourion, the shares of Series I preferred stock issued, and to be issued as contingent payments, for the outstanding capital stock of Kourion, were priced at a share-for-share ratio agreed to by us and the shareholders of Kourion, which included the MPM entities as well as unaffiliated third parties. Similarly, the price of \$8 per share paid by Zero Stage Capital and the entities affiliated with Mr. Tullis and Ms. Denise Pollard-Knight is the price that was paid by all investors, which included unaffiliated third parties, that purchased our Series I preferred stock in that financing. The Board approved the offering value of \$8 per share for the Series I preferred stock in both transactions based on its consideration of the Company's assets and future prospects, the price negotiations with the third parties, and market conditions. We believe that at the time of the sale of that stock, the stock's fair market value was not greater than \$8 per share.

The shares of our Series J preferred stock, with contingent warrant rights, purchased by the MPM entities, as described above, were purchased at an \$8 per share price that was agreed to with the MPM entities as well as with a group of other third-party investors not affiliated with us that also participated in that financing and that represented 75% of the shares sold in that offering. The Board approved the purchase price of \$8 per share based on its consideration of the Company's assets and future prospects, the price negotiations with the third parties, and market conditions. We believe that at the time of the sale of that stock, the stock's fair market value was not greater than \$8 per share.

Shares of our Series K preferred stock have been sold only to Amgen. In approving the purchase price of \$8 per share, the Board considered that the terms of the Series K shares were similar to the terms of the Series J shares, except that the Series K shares were senior to the Series J shares and had more investor favorable anti-dilution protection. That was counterbalanced against the fact that Amgen was purchasing shares alone, without accompanying contingent purchase rights received by the investors in the Series J shares. We believe that at the time of the sale of that stock, the stock's fair market value was not greater than \$8 per share. We believe that the sale of our Series K shares to Amgen were on terms as favorable as could have been obtained from unrelated third parties.

Upon the closing of this offering, each share of preferred stock described above will convert into one share of our common stock.

## **Employment, Consulting and Director Agreements**

In December 2000, we entered into a consulting agreement with Dr. Daley, one of our directors, regarding his service on our Medical and Scientific Advisory Board. Please refer to the section above entitled "Management - Director Compensation."

We have entered into an employment agreement with Mr. Beer and letter agreements with our other executive officers. For information regarding these agreements, please refer to the section entitled "Management - Employment and Severance Arrangements."

We compensate non-employee directors, who are not affiliates of an institutional stockholder, for their services on our board and its committees. Please refer to the section above entitled "Management - Director Compensation."

**Table of Contents****PRINCIPAL STOCKHOLDERS**

The table below provides information about the beneficial ownership of our capital stock as of January 17, 2005 by (1) each person we know to beneficially own more than five percent of our outstanding capital stock, including preferred stock that will be automatically converted with common stock upon the closing of this offering, (2) each of our directors, (3) each of the named executive officers and (4) all directors and executive officers as a group. Except as indicated in the table or footnotes and pursuant to community property laws, each stockholders named in the table has sole voting and investment power with respect to the shares opposite that stockholder's name. Beneficial ownership is determined in accordance with the rules of the SEC; the information does not necessarily indicate beneficial ownership for any other purpose.

The Percentage of Shares Outstanding column below is based on 28,576,418 shares outstanding as of January 17, 2005, including shares of preferred stock on an as-converted basis and excluding 241,481 shares issued in escrow which will be released to certain former stockholders of Kourion Therapeutics AG if there is a change of control of our company prior to September 30, 2006. The Percentage of Shares Outstanding also lists applicable percentage ownership based on 36,076,418 shares of common stock to be outstanding after the closing of the offering. Options and warrants to purchase shares of our common or preferred stock that are currently exercisable or exercisable within 60 days after January 17, 2005, are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing that person's percentage ownership, but are not treated as outstanding for the purpose of computing any other person's percentage ownership.

Name and Address of Beneficial Owners(1)	Number of Shares Beneficially Owned	Percentage of Shares Outstanding	
		Before Offering	After Offering
MPM Asset Management LLC affiliated funds(2) 111 Huntington Avenue Boston, MA 02199	5,597,096	19.3%	15.6%
Amgen Inc.(3) One Amgen Center Drive Thousand Oaks, California 91320-1799	3,060,000	10.5	8.4
Tullis-Dickerson & Co., Inc. affiliated funds(4) 2 Greenwich Plaza, 4th Floor Greenwich, CT 06830	2,761,822	9.6	7.6
Zero Stage Capital affiliated funds(5) 101 Main Street, 17th Floor Cambridge, MA 02142	2,576,499	9.0	7.1
DWS Investment GmbH(6) Feldberg Strasse 35 60612 Frankfurt am Main, Germany	2,350,776	8.2	6.5
Cynthia A. Fisher 186 Park Street Newton, MA 02458	1,889,934	6.6	5.2
Nomura International plc(7) 1 St. Martin's le Grand London, EC1A 4NP, United Kingdom	1,692,184	5.9	4.7
Cynthia A. Fisher 1999 Family Trust(8) c/o Jonathan Goldstein TA Associates, Inc. 125 High Street, Suite 2500 Boston, MA 02110	1,556,408	5.4	4.3

**Table of Contents**

Name and Address of Beneficial Owners(1)	Number of Shares Beneficially Owned	Percentage of Shares Outstanding	
		Before Offering	After Offering
Ansbert Gadicke, M.D.(9) c/o MPM Asset Management 111 Huntington Avenue Boston, MA 02199	5,602,096	19.3	15.6
James Tullis(10) c/o Tullis-Dickerson & Co., Inc. 2 Greenwich Plaza, 4th Floor Greenwich, CT 06830	2,766,822	9.6	7.6
Denise Pollard-Knight(11) c/o Nomura International plc 1 St. Martin s le Grand London, EC1A 4NP, United Kingdom	1,697,184	5.9	4.7
Marc D. Beer(12)	600,000	2.1	1.6
George Q. Daley, M.D., Ph.D.(13) Childrens Hospital Division of Hematology/Oncology 1 Blackfan Circle Boston, MA 02114	181,198	*	*
Kurt C. Gunter, M.D.(14)	105,000	*	*
Christoph M. Adams, Ph.D.(15)	87,500	*	*
Jeff Sacher(16) 12 Chanticleer Road Sudbury, MA 01776	79,500	*	*
Vaughn Kailian(17)	40,000	*	*
Paul Hastings(18) QLT Inc. 887 Great Northern Way Vancouver, BC Canada V5T 4T5	28,291	*	*
Jan van Heek(19) Genzyme Corporation One Kendall Square Cambridge, MA 02139	20,875	*	*
Grant Bogle		*	*
Stephen Dance(20)	31,249	*	*
Stephan Wnendt(21)	53,750	*	*
All executive officers and directors as a group (12 persons)(22)	11,213,965	36.9%	29.8%

\* Indicates less than 1%.

- (1) Unless otherwise indicated, the address of each shareholder is ViaCell, Inc., 245 First Street, Cambridge, Massachusetts 02142.
- (2) Consists solely of 4,568,835 shares owned by BB BioVentures, L.P., 334,481 shares owned by MPM BioVentures Parallel Fund, L.P., 25,173 shares owned by MPM Asset Management Investors 2000A LLC, 130,880 shares owned by MPM BioVentures II-QP, L.P., 46,089 shares owned by MPM BioVentures GmbH & Co. Parallel-Beteiligungs KG, 14,444 shares owned by MPM BioVentures II, L.P., 2,715 shares owned by MPM Asset Management Investors 2001 LLC, 41,146 shares owned by MPM Founders LLC, a fully-exercisable warrant to purchase 433,333 shares of common stock owned by BB BioVentures, L.P., and warrants to purchase up to a total of 125,000 shares of

**Table of Contents**

common stock to be issued upon the closing of this offering to several MPM affiliated funds, as follows: warrants for 111,167 shares to BB BioVentures, L.P., for 12,620 shares to MPM BioVentures Parallel Fund, L.P., and for 1,213 shares to MPM Asset Management Investors 2000A LLC.

BAB BioVentures L.P., BAB BioVentures N.V. and MPM BioVentures I LLC are direct and indirect general partners/equity owners of BB BioVentures L.P. MPM BioVentures I L.P. and MPM BioVentures I LLC are the direct and indirect general partners of MPM BioVentures Parallel Fund, L.P. Luke Evnin, Ansbert Gadicke, and Michael Steinmetz are managers of MPM BioVentures I LLC and MPM Asset Management Investors 2000 A LLC. Each member of the group disclaims beneficial ownership of the securities except to the extent of their pecuniary interest therein.

MPM Asset Management II, L.P. and MPM Asset Management II LLC are the direct and indirect general partners of MPM BioVentures II, L.P., MPM BioVentures II-QP, L.P. and MPM BioVentures GmbH & Co. Parallel-Beteiligungs KG. Luke Evnin, Ansbert Gadicke, Nicholas Galakatos, Michael Steinmetz and Kurt Wheeler are investment managers of MPM Asset Management II LLC and MPM Asset Management Investors 2001 LLC. Each member of the group disclaims beneficial ownership of the securities except to the extent of their pecuniary interest therein.

- (3) Includes a fully-exercisable warrant to purchase 560,000 shares of common stock.
- (4) Consists solely of 921,667 shares owned by TD Javelin Capital Fund, L.P., 681,838 shares owned by TD Javelin Capital Fund II, L.P., 558,317 shares owned by TD Lighthouse Capital Fund, L.P., 175,000 shares owned by TD Origen Capital Fund, L.P., 175,000 shares owned by Tullis-Dickerson Capital Focus II, L.P., and a fully-exercisable warrant to purchase 250,000 shares of common stock owned by TD Javelin Capital Fund, L.P. James L.L. Tullis, Thomas P. Dickerson, Joan P. Neuscheler, Timothy M. Buono and Lyle A. Hohnke have the voting and/or dispositive power over such shares. These individuals disclaim beneficial ownership of the shares owned by the above entities except to the extent of their proportionate pecuniary interests therein. All these funds are under common management of Tullis-Dickerson & Co., Inc., of which James L. Tullis, one of our directors, is chief executive officer.
- (5) Consists solely of 1,073,010 shares owned by Zero Stage Capital V L.P., 666,667 shares owned by Zero Stage Capital VI L.P., 526,271 shares owned by Zero Stage Capital VII L.P., 162,284 shares owned by Zero Stage Capital (Cayman) VII, L.P., 31,600 shares owned by Zero Stage Capital SBIC VII, L.P., and a fully-exercisable warrant to purchase 116,667 shares of common stock owned by Zero Stage Capital V L.P. Mr. Paul M. Kelley is a general partner of each of these funds.

**Table of Contents**

Mr. Kelley has voting and dispositive power of such shares. Mr. Kelley disclaims beneficial ownership of the shares owned by the above entities except to the extent of their proportionate pecuniary interest therein.

- (6) Mr. Thomas Buchner has voting power over such shares and has dispositive power over such shares.
- (7) Dr. Pollard-Knight, one of our directors, is the head of Nomura Phase4 Ventures, a subsidiary of Nomura International plc, and has voting and dispositive power of these shares.
- (8) The beneficiaries of this trust are Ms. Cynthia A. Fisher's children. The trustees of this trust are Kirstin Lynde and Jonathan Goldstein and they disclaim beneficial ownership of these shares.
- (9) Includes 5,163,763 shares owned by MPM Asset Management affiliated funds and fully-exercisable warrants to purchase 433,333 shares of common stock owned by BB BioVentures, LP. See footnote 2 to this table. Dr. Gadicke is a manager of MPM Asset Management Investors 2000 A LLC and MPM Asset Management Investors 2001 LLC, as well as of MPM BioVentures I LLC and MPM Asset Management II LLC which are the direct and indirect general partners of several of the MPM-affiliated funds. Dr. Gadicke beneficially owns 20,573 shares through MPM Founders LLC. Dr. Gadicke shares voting and dispositive power with respect to the remaining shares held by, directly or indirectly, each of MPM-affiliated funds and disclaims beneficial ownership except to the extent of his pecuniary interest therein.

Also includes 5,000 options currently exercisable or exercisable within 60 days of January 17, 2005.

- (10) Includes 2,511,822 shares owned by Tullis-Dickerson & Co., Inc. affiliated funds and a fully-exercisable warrant to purchase 250,000 shares of common stock owned by TD Javelin Capital Fund, L.P. All these funds are under common management of Tullis-Dickerson & Co., Inc., of which Mr. Tullis is a chief executive officer. See footnote 4 to this table.

Also includes 5,000 options currently exercisable or exercisable within 60 days of January 17, 2005.

- (11) Includes 1,692,184 shares owned by Nomura International plc. Dr. Pollard-Knight is the head of Biopharma Private Equity at Nomura International plc. See footnote 7 to this table.

Also includes 5,000 options currently exercisable or exercisable within 60 days of January 17, 2005.

- (12) Consists solely of options currently exercisable or exercisable within 60 days of January 17, 2005.
- (13) Includes 136,875 options currently exercisable or exercisable within 60 days of January 17, 2005.
- (14) Consists solely of options currently exercisable or exercisable within 60 days of January 17, 2005.
- (15) Consists solely of options currently exercisable or exercisable within 60 days of January 17, 2005.
- (16) Includes 62,500 options currently exercisable or exercisable within 60 days of January 17, 2005.
- (17) Consists solely of options currently exercisable or exercisable within 60 days of January 17, 2005.
- (18) Includes 25,000 options currently exercisable or exercisable within 60 days of January 17, 2005.
- (19) Includes 20,000 options currently exercisable or exercisable within 60 days of January 17, 2005.
- (20) Consists solely of options currently exercisable or exercisable within 60 days of January 17, 2005.
- (21) Consists solely of options currently exercisable or exercisable within 60 days of January 17, 2005.
- (22) Includes 1,114,374 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days of January 17, 2005 fully-exercisable warrants to purchase 683,333 shares of stock and warrants to purchase up to a total of 125,000 shares of common stock to be issued upon the closing of this offering.



**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

Our authorized capital stock consists of 80,000,000 shares of common stock and 30,825,000 shares of preferred stock. As of November 30, 2004, there were outstanding 2,761,586 shares of common stock held of record by a total of 107 stockholders and 25,810,932 shares of preferred stock.

Upon the closing of this offering:

Our corporate charter will be amended and restated to provide for total authorized capital consisting of 100,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock;

All outstanding shares of preferred stock will convert into 25,810,932 shares of common stock, and no shares of preferred stock will be outstanding; and

Based on the number of shares outstanding as of November 30, 2004, a total of 36,072,518 shares of common stock will be outstanding after giving effect to the sale of common stock we are offering hereunder, which does not include any exercise of the underwriters over-allotment option or of any options or warrants.

Additionally, we issued 241,481 escrowed shares of common stock and reserved 289,256 contingent shares of common stock for possible issuance in the future to certain former stockholders of Kourion Therapeutics AG. These shares are releasable and issuable, respectively, if there is a change in control of our company prior to September 30, 2006.

**Common Stock**

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive dividends out of assets legally available therefor as the board may from time to time determine. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Cumulative voting for the election of directors is not provided for in our certificate of incorporation, which means that the holders of a majority of the shares voted can elect all of the directors then standing for election. The common stock is not entitled to preemptive rights and is not subject to conversion or redemption. Each outstanding share of common stock is, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

**Preferred Stock**

Under our corporate charter, as amended and restated upon the closing of this offering, a total of 5,000,000 shares of preferred stock will be authorized for issuance, none of which will be designated in any series. Our board of directors is authorized, without further stockholder action, to authorize and issue any of the 5,000,000 undesignated shares of preferred stock in one or more series and to fix the voting rights, liquidation preferences, dividend rights, repurchase rights, conversion rights, preemption rights, redemption rights, and terms, including sinking fund provisions and certain other rights and preferences of such shares of our preferred stock. The issuance of any class or series of preferred stock could adversely affect the rights of the holders of common stock by restricting dividends on, diluting the power of, impairing the liquidation rights of common stock, or delaying, deferring, or preventing a change in control of our company.

**Warrants**

As of November 30, 2004, we had outstanding warrants to purchase 850,000 and 560,000 shares of common stock, with exercise prices of \$1.50 and \$12.00 per share, respectively. We also had an

**Table of Contents**

outstanding warrant to purchase 18,750 shares of Series J preferred stock convertible into common stock with an exercise price of \$8.00 per share. Of these warrants, warrants to purchase:

750,000 shares of common stock expire on November 12, 2007,

100,000 shares of common stock expire on May 21, 2009,

560,000 shares of common stock expire on April 9, 2009, and

18,750 shares of Series J preferred stock convertible into common stock expire on October 6, 2013.

The warrants contain anti-dilution provisions providing for adjustments of the exercise price and the number of shares underlying the warrants upon the occurrence of events, including any recapitalization, reclassification, stock dividend, stock split, stock combination or similar transaction.

In addition, we will be required to issue warrants to purchase 2,190,000 shares of our common stock to certain existing investors immediately following this offering under our obligation to issue such warrants if the public offering price per share in this offering is less than \$9.70.

**Anti-Takeover Provisions of Delaware Law and our Charter and Bylaw Provisions**

Section 203 of the Delaware General Corporation Law is applicable to corporate takeovers of Delaware corporations. Subject to exceptions enumerated therein, Section 203 provides that a corporation shall not engage in any business combination with any interested stockholder for a three-year period following the date that the stockholder becomes an interested stockholder unless:

prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, though some shares may be excluded from the calculation; or

on or subsequent to that date, the business combination is approved by the board of directors of the corporation and by the affirmative votes of holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Except as specified in Section 203, an interested stockholder is generally defined to include any person who, together with any affiliates or associates of that person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation, any time within three years immediately prior to the relevant date. Under certain circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may elect not to be governed by this section by adopting an amendment to the certificate of incorporation or by-laws, effective 12 months after adoption. Our certificate of incorporation and by-laws do not exclude us from the restrictions imposed under Section 203. We expect that the provisions of Section 203 may encourage companies interested in acquiring us to negotiate in advance with our board of directors. These provisions may have the effect of deterring hostile takeovers or delaying a change in control, which could depress the market price of the common stock and which could deprive stockholders of opportunities to realize a premium on shares of the common stock held by them.

In addition, provisions of our certificate of incorporation and bylaws, which will be in effect upon the closing of this offering and are summarized below, may have an anti-takeover effect and may delay, defer or prevent a tender offer or takeover attempt and make more difficult attempts by stockholders to change management.

## **Table of Contents**

The certificate of incorporation includes provisions classifying the board of directors into three classes with staggered three-year terms. Under the certificate of incorporation and by-laws, the board of directors may enlarge the size of the board and fill any vacancies on the board.

Our certificate of incorporation provides that stockholders may not take action by written consent but may only act at a stockholders meeting. The certificate of incorporation also provides that special meetings of our stockholders may only be called by the Chairman of the Board, the CEO (or President if there is no CEO), or the board of directors. Stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. Our bylaws contain the specific requirements as to the timing, form and content of a stockholder's notice.

## **Registration Rights**

After this offering, the following shareholdings will be entitled to registration rights under the Securities Act: 13,333 shares of our outstanding common stock, approximately 25.8 million shares of our common stock issuable upon the conversion of our outstanding preferred stock and up to an additional approximately 1.4 million shares of our common stock issuable upon exercise of outstanding warrants. Furthermore, upon the closing of this offering, we will issue warrants to certain existing investors to purchase up to 2,190,000 shares of common stock with registration rights identical to those registration rights to which the above mentioned shareholdings are entitled. Additionally, if we experience a change in control prior to September 30, 2006, we will release and issue 241,481 escrowed shares and 289,256 contingent shares, respectively, of common stock with registration rights to former shareholders of a company that we acquired. Under the terms of the agreements between us and the holders of all registrable shares, at any time following the 180th day after the effective date of the registration statement of which this prospectus is a part, the holders of at least 50% of the registrable shares held by the holders of our Series C through Series K preferred stock and the holders of our warrants may require on two occasions that we file a registration statement under the Securities Act with respect to their registrable shares. Also, all holders of registrable shares may require that we register their shares for public resale on Form S-3 or similar short-form registration, if we are eligible to use Form S-3 or similar short-form registration, and the aggregate price to the public of the shares to be registered exceeds \$1,000,000. There is no limit on the number of occasions on which the holders of registrable shares may require these Form S-3 registrations. Also, if we propose to register any of our securities under the Securities Act, other than in connection with registrations requested by the holders of registrable shares and registrations on Form S-8, all holders of registrable shares are entitled to notice of and to include in the registration shares of common stock owned by, or issuable to, them. The holders of these registration rights have waived their rights with respect to this offering. All of these registration rights are subject to various conditions and limitations, among them certain rights of the underwriters of an offering to limit the number of shares included in a registration. We will bear all of the expenses incurred in connection with all exercises of these registration rights, other than underwriting discounts and selling commissions.

## **Transfer Agent And Registrar**

The transfer agent and registrar for our common stock is Equiserve, Inc.

## **NASDAQ National Market Listing**

Our common stock has been approved for quotation on the Nasdaq National Market under the symbol VIAC.

**Table of Contents**

**SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of common stock, including shares issued upon exercise of outstanding options and warrants, in the public market after this offering or the anticipation of those sales could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

After the closing of this offering, we will have outstanding approximately 36.1 million shares of common stock, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options or warrants. Of these shares, the shares sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by any of our affiliates as that term is defined in Rule 144 under the Securities Act. The remaining shares of common stock outstanding held by existing stockholders are restricted shares as that term is defined in Rule 144 and approximately 27.5 million of these restricted shares are also subject to the lock-up agreements described in Underwriting. Though these restricted shares subject to lock-up agreements may be eligible for earlier sale under the provisions of the Securities Act, absent a waiver of the lock-up agreements with Credit Suisse First Boston LLC and UBS Securities LLC, none of these locked-up shares may be sold until 181 days after the date of this prospectus.

Immediately after the date of the prospectus, approximately 34,000 restricted shares will be eligible for resale. Beginning 91 days after the date of this prospectus, approximately 900,000 additional restricted shares will be eligible for resale. Beginning 181 days after the date of this prospectus, all of the approximately 27.5 million restricted shares that are subject to the lock-up agreements will be eligible for sale in the US public market, subject to the limitations imposed by Rule 144. In addition, as of January 17, 2005, there were outstanding options to purchase approximately 4.4 million shares of common stock and warrants to purchase approximately 1.4 million shares of common stock. Approximately 90% of the shares issued upon exercise of these options and warrants will be subject to lock-up agreements.

In general, under Rule 144 as currently in effect, a person, or persons whose shares are aggregated, who has beneficially owned restricted shares for at least one year is entitled to sell within any three-month period up to that number of shares that does not exceed the greater of: (1) 1% of the number of shares of common stock then outstanding, which immediately following this offering is expected to equal approximately 361,000 shares, or (2) the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a Form 144 with respect to the sale. Sales under Rule 144 are also subject to certain manner of sale provisions and notice requirements and to the requirement that current public information about the issuer be available. Under Rule 144(k), a person who is not deemed to have been an affiliate of the issuer at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner except an affiliate, is entitled to sell those shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

Rule 701 under the Securities Act permits resales of qualified shares held by some affiliates in reliance upon Rule 144 but without compliance with some restrictions, including the holding period requirement, of Rule 144. Rule 701 further provides that non-affiliates may sell shares in reliance on Rule 144 without having to comply with the holding period, public information, volume limitation or notice provisions of Rule 144. Any of our employees, officers, directors or consultants who purchased his or her shares pursuant to a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701. All holders of Rule 701 shares of common stock are required to wait until 90 days after the date of this prospectus before selling shares. The holders of approximately 300,000 outstanding shares of our common stock will be eligible to sell these shares 90 days after the date of this prospectus in reliance on Rule 701. Approximately 836,000 shares issued pursuant to Rule 701 are subject to the lock-up agreements referred to above and absent a waiver of the lock-up agreements with Credit Suisse First Boston LLC and UBS Securities LLC, will only become eligible for sale upon the expiration of the 180-day lock-up.

**Table of Contents**

We intend to file, shortly after the effectiveness of this offering, a registration statement on Form S-8 under the Securities Act covering all shares of common stock reserved for issuance under our equity incentive plan. Shares of common stock issued upon exercise of options under the Form S-8 will be available for sale in the public market, subject to limitations under Rule 144 applicable to our affiliates and subject to the lock-up agreements described above. Following this offering, the holders of approximately 2.5 million shares of our common stock (including shares issued upon the conversion of our preferred stock upon completion of this offering) and up to an additional approximately 1.4 million shares of our common stock issuable upon exercise of outstanding warrants have the right to require us to register their shares for sale in the public market upon meeting specific requirements set forth in our agreements with such holders, as described in Description of Capital Stock Registration Rights.

**Table of Contents****UNDERWRITING**

Credit Suisse First Boston LLC and UBS Securities LLC are acting as joint book-running managers for this offering.

Under the terms and subject to the conditions contained in an underwriting agreement dated January 20, 2005, we have agreed to sell to the underwriters named below the following respective number of shares of common stock:

Underwriters	Number of Shares
Credit Suisse First Boston LLC	3,375,000
UBS Securities LLC	2,625,000
Lazard Frères & Co. LLC	1,125,000
Leerink Swann & Company	375,000
Total	7,500,000

The underwriting agreement provides that the underwriters are obligated to purchase all of the shares of common stock in the offering if any are purchased, other than those shares covered by the over-allotment option described below. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of the non-defaulting underwriters may be increased or this offering may be terminated.

We have granted to the underwriters a 30-day option to purchase on a pro rata basis up to 1,125,000 additional shares from us at the initial public offering price less the underwriting discounts and commissions. The option may be exercised only to cover any over-allotments of common stock.

The underwriters propose to offer the shares of common stock initially at the public offering price on the cover page of this prospectus, and to selling group members at that price less a selling concession of \$0.294 per share on sales to other broker/ dealers. The underwriters and selling group members may allow a discount of \$0.100 per share on sales to other broker/ dealers. After the initial public offering, the underwriters may change the public offering price, selling concession or discount to broker/ dealers.

The following table summarizes the compensation and estimated expenses we will pay:

	Per Share		Total	
	Without Over-allotment	With Over-allotment	Without Over-allotment	With Over-allotment
Underwriting discounts and commissions paid by us	\$0.490	\$0.490	\$3,675,000	\$4,226,250
Expenses payable by us	\$0.337	\$0.293	\$2,527,000	\$2,527,000

The underwriters have informed us that the underwriters do not expect sales to accounts over which the underwriters have discretionary authority to exceed 5% of the shares of common stock being offered.

We have agreed that we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended (the Securities Act), relating to, any additional shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any such offer, sale, pledge, disposition or filing without the prior written consent of both Credit Suisse First Boston LLC and UBS Securities LLC for a period of 180 days after the date of this prospectus, except issuances of common stock pursuant to the exercise of warrants, options or other rights to acquire securities, in each case outstanding on the date hereof or issued under equity plans or written contracts existing on the date hereof (including our obligation to issue contingent warrants to purchase 2.19 million common shares),

grants of stock-based awards pursuant to the terms of a plan in effect on the date hereof, issuances of shares in connection with strategic licensings or acquisitions of intellectual property, technologies or businesses or establishment of strategic partnerships or collaborations complementary to our business (provided that, in each such case,

**Table of Contents**

such shares are subject to restrictions on transfer for the remainder of the aforementioned 180-day period) and registration on Form S-8 of securities issuable under currently outstanding options or existing equity plans.

Holders of approximately 94% of our securities, assuming exercise and conversion of all outstanding options and warrants, including our executive officers, directors and other senior management, are each a party to agreements by which they have agreed that they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, enter into a transaction that would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any of these transactions are to be settled by delivery of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement, without, in each case, the prior written consent of both Credit Suisse First Boston LLC and UBS Securities LLC for a period of 180 days after the date of this prospectus except in the following circumstances:

by gift, will or intestacy;

to a member or members of the party's immediate family (i.e., any relation by blood, marriage or adoption, not more remote than first cousin);

to charitable organizations; or

if the party is an entity, (a) to corporations, partnerships, limited liability companies or other entities to the extent that such entities are wholly owned by it, or (b) by distribution to its partners, members or stockholders, provided however, that in such circumstances, it shall be a condition that such transfer shall not involve a disposition for value and that the transferee agrees to be bound in writing by the foregoing terms prior to such transfer. In addition, our executive officers, directors, other senior management and securityholders that have registration rights have agreed that, without the prior written consent of Credit Suisse First Boston LLC and UBS Securities LLC, they will not, during the period ending 180 days after the date of this prospectus, make any demand for or exercise any right with respect to, the registration of any common stock or any security convertible into or exercisable or exchangeable for the common stock.

The underwriters have reserved for sale at the initial public offering price up to 375,000 shares of the common stock for employees, directors and other persons associated with us who have expressed an interest in purchasing common stock in the offering. The number of shares available for sale to the general public in the offering will be reduced to the extent these persons purchase the reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares.

We have agreed to indemnify the underwriters against liabilities under the Securities Act or contribute to payments that the underwriters may be required to make in that respect.

Our common stock has been approved for quotation on the Nasdaq National Market under the symbol VIAC.

From time to time in the ordinary course of their respective businesses, certain of the underwriters and their respective affiliates have provided and may in the future provide financial advisory, commercial banking and/or investment banking services for us for which they have received or will receive customary compensation.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined by negotiation between us and the underwriters. The principal factors that were considered in determining the initial public offering price included the following:

the information included in this prospectus and otherwise available to the underwriters;

market conditions for initial public offerings;

**Table of Contents**

the history of and prospects for our business, our past and present operations;

the history and prospects for the industry in which we compete;

our past and present earnings and current financial position;

an assessment of our management;

the market of securities of companies in businesses similar to ours; and

the general condition of the securities markets.

There can be no assurance that the initial public offering price will correspond to the price at which our common stock will trade in the public market subsequent to this offering or that an active trading market will develop and continue after this offering.

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended.

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in this offering.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions. These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the Nasdaq National Market or otherwise and, if commenced, may be discontinued at any time.

A prospectus in electronic format will be made available on the web sites maintained by one or more of the underwriters, or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The underwriters may allocate for sale, and may agree to allocate a number of shares to selling group members for sale, to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations.

**Table of Contents**

**NOTICE TO CANADIAN RESIDENTS**

**Resale Restrictions**

The distribution of our common stock in Canada is being made only on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of common stock are made. Any resale of our common stock in Canada must be made under applicable securities laws which will vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the common stock.

**Representations of Purchasers**

By purchasing common stock in Canada and accepting a purchase confirmation a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

the purchaser is entitled under applicable provincial securities laws to purchase the common stock without the benefit of a prospectus qualified under those securities laws,

where required by law, that the purchaser is purchasing as principal and not as agent, and

the purchaser has reviewed the text above under Resale Restrictions.

**Rights of Action – Ontario Purchasers Only**

Under Ontario securities legislation, a purchaser who purchases a security offered by this prospectus during the period of distribution will have a statutory right of action for damages, or while still the owner of our common stock, for rescission against us in the event that this prospectus contains a misrepresentation. A purchaser will be deemed to have relied on the misrepresentation. The right of action for damages is exercisable not later than the earlier of 180 days from the date the purchaser first had knowledge of the facts giving rise to the cause of action and three years from the date on which payment is made for the common stock. The right of action for rescission is exercisable not later than 180 days from the date on which payment is made for our common stock. If a purchaser elects to exercise the right of action for rescission, the purchaser will have no right of action for damages against us. In no case will the amount recoverable in any action exceed the price at which our common stock were offered to the purchaser and if the purchaser is shown to have purchased the securities with knowledge of the misrepresentation, we will have no liability. In the case of an action for damages, we will not be liable for all or any portion of the damages that are proven to not represent the depreciation in value of the common stock as a result of the misrepresentation relied upon. These rights are in addition to, and without derogation from, any other rights or remedies available at law to an Ontario purchaser. The foregoing is a summary of the rights available to an Ontario purchaser. Ontario purchasers should refer to the complete text of the relevant statutory provisions.

**Enforcement of Legal Rights**

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

**Table of Contents**

**Taxation and Eligibility for Investment**

Canadian purchasers of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the common stock in their particular circumstances and about the eligibility of the common stock for investment by the purchaser under relevant Canadian legislation.

**LEGAL MATTERS**

Our counsel, Ropes & Gray LLP, Boston, Massachusetts, will pass on the validity of the shares of common stock offered by this prospectus. Marc Rubenstein, a partner of Ropes & Gray LLP, is our Secretary. Dewey Ballantine LLP, New York, New York, is counsel to the underwriters in connection with this offering.

**EXPERTS**

The consolidated financial statements for ViaCell, Inc. as of December 31, 2003 and 2002 and for each of the three years in the period ended December 31, 2003 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph related to the change in the method of accounting for goodwill and other intangible assets as described in Note 2) of PricewaterhouseCoopers LLP, independent registered public accountants, given on the authority of said firm as experts in auditing and accounting.

The financial statements of Kourion Therapeutics AG as of September 30, 2003 and December 31, 2002, and for the nine months ended September 30, 2003 and for the year ended December 31, 2002, included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers, GmbH, independent accountants given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1, including the exhibits, schedules and amendments to the registration statement, under the Securities Act of 1933 with respect to the shares of common stock to be sold in this offering. This prospectus does not contain all the information set forth in the registration statement. For further information with respect to ViaCell and the shares of common stock to be sold in this offering, please refer to the registration statement. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete, and in certain instances reference is made to the copy of the contract, agreement or other document filed as an exhibit to the registration statement, each statement being qualified in all respects by this reference.

You may read and copy all or any portion of the registration statement or any other information we file at the SEC's public reference room at 450 Fifth Street, NW, Washington, DC 20549. You can request copies of these documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference room. Our SEC filings, including the registration statement, are also available to you on the SEC's Website (<http://www.sec.gov>).

As a result of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934, and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC.

We intend to provide our stockholders with annual reports containing consolidated financial statements that have been audited by an independent accounting firm, and to file with the SEC quarterly reports containing unaudited combined financial statements for the first three quarters of each year.

**Table of Contents****Index to Financial Statements****ViaCell, Inc.**

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

**Kourion Therapeutics AG**

Report of Independent Auditors	F-41
Balance Sheet	F-42
Income Statement	F-43
Notes to the Financial Statements	F-44

**Pro Forma ViaCell, Inc.**

Unaudited Pro Forma Combined Statement of Operations	F-56
Notes to Unaudited Pro Forma Combined Statements of Operations	F-57

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying consolidated balance sheets and the related statements of operations, comprehensive loss, stockholders equity (deficit) and cash flows present fairly, in all material respects, the financial position of ViaCell, Inc. and its subsidiaries at December 31, 2003 and 2002, and the results of their operations and their cash flows for the three years in the period ended December 31, 2003 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 of America), which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the financial statements, effective January 1, 2002, the Company changed its method of accounting for goodwill and other intangible assets.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 29, 2004, except for the last paragraph of Note 9, as to which the date is June 23, 2004

F-2

---

**Table of Contents**

## ViaCell, Inc.

**Consolidated Balance Sheets**

	As of December 31,		As of	Pro Forma
	2002	2003	September 30, 2004	As of September 30, 2004
			(Unaudited)	(See Note 2) (Unaudited)
<b>ASSETS</b>				
Current assets				
Cash and cash equivalents	\$ 15,239,089	\$ 39,007,880	\$ 12,080,420	\$ 12,080,420
Short-term investments	13,949,264	7,823,852	21,248,061	21,248,061
Accounts receivable, net	6,418,263	7,676,439	9,903,117	9,903,117
Prepaid expenses and other current assets	665,603	4,106,358	3,464,490	3,464,490
Restricted cash			161,818	161,818
Total current assets	36,272,219	58,614,529	46,857,906	46,857,906
Property and equipment, net	6,621,315	7,892,116	8,783,776	8,783,776
Goodwill, net	3,620,750	3,620,750	3,620,750	3,620,750
Intangible assets, net	3,536,055	3,274,721	3,075,414	3,075,414
Long-term investments			787,059	787,059
Restricted cash	5,895,367	2,834,109	1,944,012	1,944,012
Other assets	173,519	1,924,870	1,727,980	1,727,980
Total assets	\$ 56,119,225	\$ 78,161,095	\$ 66,796,897	\$ 66,796,897
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)</b>				
Current liabilities				
Current portion of long-term debt obligations	\$ 2,130,872	\$ 1,611,604	\$ 1,731,667	\$ 1,731,667
Accounts payable	2,760,443	3,363,875	1,566,797	1,566,797
Accrued expenses	3,856,490	10,011,022	8,426,522	8,426,522
Note payable to related party		14,280,000	15,120,000	15,120,000
Contingent purchase price		4,245,896	4,245,896	4,245,896
Deferred revenue	2,117,638	2,244,972	3,359,416	3,359,416
Total current liabilities	10,865,443	35,757,369	34,450,298	34,450,298
Deferred revenue	1,787,220	3,157,884	6,633,493	6,633,493
Deferred rent			958,610	958,610
Contingent purchase price		3,909,104	3,909,104	3,909,104
Long-term debt obligations, net of current portion	3,042,001	3,346,672	2,164,843	2,164,843
Total liabilities	15,694,664	46,171,029	48,116,348	48,116,348
Redeemable convertible preferred stock (at redemption value); authorized 21,696,809 in 2002 and 30,396,809 shares in 2003 and September, 2004 (unaudited), respectively; issued and outstanding 20,375,721,	110,911,677	162,141,437	172,085,660	

Edgar Filing: VIACELL INC - Form 424B4

25,628,075, and 25,628,075 shares in 2002, 2003, and September, 2004 (unaudited) respectively; 0 issued and outstanding pro forma (unaudited)

Commitments and contingencies (Notes 8 and 9)				
Stockholders' (deficit), equity:				
Convertible preferred stock, \$0.01 par value; authorized 428,191 shares; issued and outstanding 182,857 shares (liquidation preference of \$245,000) in 2002, 2003 and September 30, 2004; 0 issued and outstanding pro forma (unaudited)	1,829	1,829	1,829	
Common stock, \$0.01 par value; authorized 35,000,000, 80,000,000, and 80,000,000 shares in 2002, 2003, and September 30, 2004 (unaudited) respectively; issued and outstanding 2,558,574, 2,659,854, 2,708,644 and 28,519,576 shares in 2002, 2003, September 30, 2004 (unaudited) and pro forma September 30, 2004 (unaudited)	25,586	26,599	27,087	285,197
Additional paid-in capital	8,821,678	1,437,260		171,829,379
Deferred compensation	(6,125,680)	(3,422,375)	(2,689,983)	(2,689,983)
Accumulated deficit	(73,210,529)	(128,678,779)	(151,105,910)	(151,105,910)
Accumulated other comprehensive income		484,095	361,866	361,866
<b>Total stockholders' equity (deficit)</b>	<b>(70,487,116)</b>	<b>(130,151,371)</b>	<b>(153,405,111)</b>	<b>18,680,549</b>
<b>Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>	<b>\$ 56,119,225</b>	<b>\$ 78,161,095</b>	<b>\$ 66,796,897</b>	<b>\$ 66,796,897</b>

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

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

	Years Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
				(Unaudited)	
Processing and storage revenues	\$ 7,068,742	\$ 20,087,773	\$ 30,884,201	\$ 22,030,882	\$ 27,397,257
Grant and contract revenues	229,167	286,862	995,494	600,898	1,235,502
<b>Total revenues</b>	<b>7,297,909</b>	<b>20,374,635</b>	<b>31,879,695</b>	<b>22,631,780</b>	<b>28,632,759</b>
Operating expenses:					
Cost of revenues:					
Direct costs	3,069,649	5,877,402	7,141,581	5,275,977	5,513,216
Royalty expense			3,257,639		(3,257,639)
<b>Total cost of revenues</b>	<b>3,069,649</b>	<b>5,877,402</b>	<b>10,399,220</b>	<b>5,275,977</b>	<b>2,255,577</b>
Research and development	6,978,088	11,429,043	13,225,957	9,514,863	11,698,441
Sales and marketing	9,348,791	16,578,500	20,959,187	16,202,818	15,081,288
General and administrative	7,086,296	10,919,794	15,221,356	10,722,718	10,400,305
In-process technology	594,295	5,888,713	23,925,023	22,200,046	
Stock-based compensation(1)	4,490,162	6,463,519	3,232,179	2,545,076	2,662,055
Restructuring					1,739,540
<b>Total operating expenses</b>	<b>31,567,281</b>	<b>57,156,971</b>	<b>86,962,922</b>	<b>66,461,498</b>	<b>43,837,206</b>
<b>Loss from operations</b>	<b>(24,269,372)</b>	<b>(36,782,336)</b>	<b>(55,083,227)</b>	<b>(43,829,718)</b>	<b>(15,204,447)</b>
Interest income	2,242,460	891,772	348,476	237,587	402,069
Interest expense	(106,581)	(147,464)	(733,499)	(154,534)	(1,118,227)
<b>Total interest income (expense), net</b>	<b>2,135,879</b>	<b>744,308</b>	<b>(385,023)</b>	<b>83,053</b>	<b>(716,158)</b>
<b>Net loss</b>	<b>(22,133,493)</b>	<b>(36,038,028)</b>	<b>(55,468,250)</b>	<b>(43,746,665)</b>	<b>(15,920,605)</b>
Accretion on redeemable convertible preferred stock	6,619,692	8,143,606	9,416,114	6,700,990	9,944,223
<b>Net loss attributable to common stockholders</b>	<b>\$(28,753,185)</b>	<b>\$(44,181,634)</b>	<b>\$(64,884,364)</b>	<b>\$(50,447,655)</b>	<b>\$(25,864,828)</b>
Net loss per share					
Net loss per common share, basic and diluted	\$ (12.22)	\$ (17.60)	\$ (24.63)	\$ (19.21)	\$ (9.62)
Weighted average shares used in basic and diluted net loss per share computation	2,352,468	2,510,632	2,634,096	2,625,618	2,689,866
Pro forma net loss per common share (basic and diluted) (unaudited)			\$ (2.32)		\$ (0.56)
Weighted average shares used in pro forma net loss per common share			23,865,902		28,500,798

(basic and diluted) computation  
(unaudited)

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

	Years Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
Cost of revenues	\$	\$ 19,792	\$ 7,282	\$ 5,454	\$ 25,047
Research and development	2,249,357	2,488,801	1,073,325	803,196	531,755
Sales and marketing	221,977	670,412	413,571	314,115	183,877
General and administrative	2,018,828	3,284,514	1,738,001	1,422,311	1,677,759
Restructuring					243,617
Total stock-based compensation	\$4,490,162	\$6,463,519	\$3,232,179	\$2,545,076	\$2,662,055

#### Consolidated Statements of Comprehensive Loss

	Years Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
					(Unaudited)
Net loss	\$ (22,133,493)	\$ (36,038,028)	\$ (55,468,250)	\$ (43,746,665)	\$ (15,920,605)
Foreign currency translation adjustment			484,095		(122,229)
Comprehensive loss	\$ (22,133,493)	\$ (36,038,028)	\$ (54,984,155)	\$ (43,746,665)	\$ (16,042,834)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulative Other Comprehensive Income	Total Stockholders Equity (Deficit)
	Number of Shares	\$0.01 Par Value	Number of Shares	\$0.01 Par Value					
<b>Balance, December 31, 2000</b>	182,857	\$ 1,829	2,073,847	\$ 20,739	\$	\$ (359,633)	\$ (15,039,008)	\$	\$ (15,376,073)
Stock option exercises			289,395	2,894	88,922				91,816
Issuance of common stock			64,637	646	99,455				100,101
Stock options issued in connection with the Cerebrotec acquisition					493,932	(390,154)			103,778
Stock options issued to collaborator					594,295				594,295
Accretion of redeemable preferred stock to redemption value					(6,619,692)				(6,619,692)
Non-employee stock compensation					2,195,017				2,195,017
Deferred compensation					10,469,249	(10,469,249)			
Amortization of deferred compensation						2,295,145			2,295,145
Net loss							(22,133,493)		(22,133,493)
<b>Balance, December 31, 2001</b>	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)

Edgar Filing: VIACELL INC - Form 424B4

Net loss							(36,038,028)		(36,038,028)
<b>Balance, December 31, 2002</b>	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
Stock warrant exercises									
Issuance of stock warrants					1,449,826				1,449,826
Accretion of redeemable preferred stock to redemption value					(9,416,114)				(9,416,114)
Non-employee stock compensation					251,480				251,480
Deferred compensation					804,323	(804,323)			
Amortization of deferred compensation						2,980,699			2,980,699
Forfeiture of stock options					(526,929)	526,929			
Net loss							(55,468,250)		(55,468,250)
Foreign exchange translation								\$ 484,095	484,095
<b>Balance, December 31, 2003</b>	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 (unaudited)			48,790	488	70,774				71,262
Accretion of redeemable preferred stock (unaudited)					(3,437,697)		(6,506,526)		(9,944,223)
Non-employee stock compensation (unaudited)					264,600				264,600
Deferred compensation (unaudited)					2,192,051	(2,192,051)			
Amortization of deferred compensation (unaudited)					(989,050)	2,612,211			1,623,161
Stock option modification (unaudited)					774,294				774,294
Forfeiture of stock options (unaudited)					(312,232)	312,232			
Net loss (unaudited)							(15,920,605)		(15,920,605)
Foreign exchange translation (unaudited)								(122,229)	(122,229)
<b>Balance, September 30, 2004</b>	182,857	\$ 1,829	2,708,644	\$ 27,087	\$	\$ (2,689,983)	\$ (151,105,910)	\$ 361,866	\$ (153,405,111)

Edgar Filing: VIACELL INC - Form 424B4

Conversion of redeemable convertible preferred stock and convertible preferred stock into common stock (unaudited)	(182,857)	(1,829)	25,810,932	258,110	171,829,379				172,085,660
<b>Pro forma Balance September 30, 2004 (unaudited)</b>		\$	28,519,576	\$285,197	\$171,829,379	\$ (2,689,983)	\$ (151,105,910)	\$ 361,866	\$ 18,680,549

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

F-5

**Table of Contents**

## ViaCell, Inc.

**Consolidated Statements of Cash Flows**

	Years Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
					(Unaudited)
<b>Cash flows from operating activities</b>					
Net loss	\$(22,133,493)	\$(36,038,028)	\$(55,468,250)	\$(43,746,665)	\$(15,920,605)
Adjustments to reconcile net loss to net cash used in operating activities					
Depreciation and amortization	2,193,754	1,987,743	2,517,646	1,805,222	1,980,153
Stock-based compensation	4,490,162	6,463,519	3,232,179	2,545,076	2,662,080
Noncash charge for acquired in-process research and development	594,295	5,888,713	23,925,023	22,200,046	
Non-cash interest expense on related party note payable					840,000
Loss on disposal of fixed assets					269,119
Other			4,359		22,833
Changes in assets and liabilities, excluding the effect of acquisitions					
Accounts receivable	(2,976,220)	(3,054,339)	(1,256,769)	209,566	(2,226,677)
Prepaid expenses and other current assets	(434,414)	10,465	(2,266,483)	(259,374)	1,948,326
Accounts payable	1,049,254	757,354	414,683	(915,406)	(1,791,932)
Accrued expenses	1,060,893	1,308,179	4,909,771	443,255	(3,029,496)
Deferred revenue	1,910,629	1,580,282	1,497,998	715,122	3,960,336
Deferred rent					84,499
Net cash used in operating activities	<u>(14,245,140)</u>	<u>(21,096,112)</u>	<u>(22,489,843)</u>	<u>(17,003,158)</u>	<u>(11,201,364)</u>
<b>Cash flows from investing activities</b>					
Purchase of property and equipment	(2,391,090)	(4,816,312)	(1,825,870)	(1,549,378)	(1,184,387)
Acquisition of Cerebrotec	(86,132)				
Proceeds from maturities of investments	3,005,845	38,973,455	15,812,672	13,168,440	15,078,732
Purchase of investments	(39,601,820)	(15,579,979)	(9,687,260)	(1,020,365)	(29,290,000)
Changes in other assets	(80,065)	(71,631)	(1,751,350)	(1,352)	196,862
Cash acquired in acquisition of Kourion, net of acquisition costs			<u>3,737,929</u>	<u>3,737,929</u>	
Net cash provided by (used in) investing	<u>(39,153,262)</u>	<u>18,505,533</u>	<u>6,286,121</u>	<u>14,335,274</u>	<u>(15,198,793)</u>

activities					
<b>Cash flows from financing activities</b>					
Proceeds from issuance of redeemable convertible preferred stock, net	14,921,206	1,500,000	36,887,171	10,701,971	
Proceeds from exercise of stock options and warrants	91,816	71,342	42,599	42,575	71,262
Proceeds from issuance of common stock	100,101	20,050			
Restricted cash	(740,000)	(3,792,909)	3,210,105	1,022,377	721,978
Proceeds from credit facilities	1,350,000	4,900,000	5,000,000		
Repayments on credit facilities	(397,164)	(1,087,050)	(5,451,556)	(1,618,483)	(1,161,815)
Repayment of note payable to related party		(215,247)			
Payments on capital lease principal	(22,919)	(11,074)	(49,375)	(29,347)	(60,496)

F-6

**Table of Contents**

	Years Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
				(Unaudited)	
Net cash provided by (used in) financing activities	15,303,040	1,385,112	39,638,944	10,119,093	(429,071)
Effect of change in exchange rates			333,569		(98,232)
Net increase (decrease) in cash and cash equivalents	(38,095,362)	(1,205,467)	23,768,791	7,451,209	(26,927,460)
Cash and cash equivalents, beginning of period	54,539,918	16,444,556	15,239,089	15,239,089	39,007,880
Cash and cash equivalents, end of period	\$ 16,444,556	\$ 15,239,089	\$ 39,007,880	\$ 22,690,298	\$ 12,080,420
<b>Supplemental disclosures of cash flow information and noncash transactions</b>					
Interest paid	\$ 93,669	\$ 183,452	\$ 260,117	\$ 146,333	\$ 254,615
Acquisitions (Note 3)	752,000		28,705,000	28,705,000	
Accretion of redeemable convertible preferred stock	6,619,692	8,143,606	9,416,114	6,700,990	9,944,223
Equipment purchased under capital lease (Note 2)			154,855	154,855	139,593

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

**Table of Contents**

**ViaCell, Inc.**

**Notes to Consolidated Financial Statements**

**(Information as of September 30, 2004 and  
the nine months ended September 30, 2003 and 2004 is unaudited)**

**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 accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company anticipates that its working capital at December 31, 2003 will be sufficient to finance its operations through at least the next twelve months. However, the Company may need to raise additional financing to meet its long-term needs. In the event the Company's operations are not profitable or do not generate sufficient cash to fund the business, or if the Company fails to raise additional financing, the Company may have to substantially cut back its level of operations. These reductions could, in turn, affect the Company's relationships with its strategic partners and customers. The Company's future is dependent upon its ability to generate cash from operations or raise additional financing.

**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.

**Unaudited Pro Forma Presentation**

Unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding, including the pro forma effects of automatic conversion of all outstanding redeemable convertible preferred stock into shares of the Company's common stock effective upon the assumed closing of the Company's proposed initial offering as if such conversions had occurred at the date of original issuance. In addition, all accretion of preferred stock has been eliminated in the determination of net loss attributable to common stockholders.

**Table of Contents**

**ViaCell, Inc.**

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

**2. Summary of Significant Accounting Policies (Continued)**

The unaudited pro forma consolidated balance sheet and the unaudited pro forma information included in the consolidated statements of stockholders' equity (deficit) as of September 30, 2004, reflect the automatic conversion of all outstanding shares of convertible preferred stock into 25,810,932 shares of common stock upon the closing of the Company's proposed initial public offering (IPO).

**Interim Financial Information**

The financial information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004, and related notes, are unaudited but in management's opinion, include all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary for a fair presentation, in all material respects, of its financial position, operating results, and cash flows for the interim date and periods presented. Results for the nine months ended September 30, 2004 are not necessarily indicative of results for the entire fiscal year or future periods.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)  
Cash, Cash Equivalents and Investments**

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Investments with remaining maturities of 12 months or less are classified as short-term investments. Investments with maturities greater than 12 months are classified as long-term investments. Investments in debt securities are classified as either held-to-maturity or available-for-sale based on facts and circumstances at the time of purchase. Investments for which the Company has the positive intent and ability to hold to maturity are classified as held-to-maturity investments and are reported at amortized cost plus accrued interest, which approximates fair market value. 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.

	2002		2003	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Cash and cash equivalents				
Money market accounts	\$ 13,272,731	\$ 13,272,731	\$ 30,393,707	\$ 30,393,707
Government securities			1,725,006	1,725,006
Cash	1,966,358	1,966,358	6,889,167	6,889,167
Total cash and cash equivalents	15,239,089	15,239,089	39,007,880	39,007,880
Short-term investments				
Commercial paper	13,949,264	13,956,073	7,823,852	7,815,775
Total investments	13,949,264	13,956,073	7,823,852	7,815,775
Total cash, cash equivalents and investments	29,188,353	29,195,162	46,831,732	46,823,655
Certificates of deposit (restricted)	5,895,367	5,895,367	2,834,109	2,834,109
Total cash, cash equivalents, certificates of deposit (restricted) and investments	\$ 35,083,720	\$ 35,090,529	\$ 49,665,841	\$ 49,657,764

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 collateralized by certificates of deposit 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.

## Edgar Filing: VIACELL INC - Form 424B4

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

- a) The delivered items have value to a customer on a standalone basis;
- b) There is objective and reliable evidence of the fair value of the undelivered items; and

F-10

---

**Table of Contents**

**ViaCell, Inc.**

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

**2. Summary of Significant Accounting Policies (Continued)**

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.

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 \$6,627,000, \$18,473,000 and \$27,768,000 for the years ended December 31, 2001, 2002, and 2003, respectively.

Revenue from storage fees is recognized over the contractual period on a straight-line basis and amounted to approximately \$442,000, \$1,614,000 and \$3,116,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

Deferred revenue of \$3,905,000 and \$5,403,000 at December 31, 2002 and 2003, respectively, include the unearned portions of annual storage fees and deposits paid by customers prior to completion of our processing service.

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 \$75,600 and \$783,000 for the years ended December 31, 2002 and 2003, respectively. The rebates have been recorded as a reduction in processing revenue. There were no rebates given in the year ended December 31, 2001.

Revenues from short-term research contracts are recognized over the contract period as services are provided. Revenue from research contracts amounted to \$229,000, \$157,000 and \$363,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

The Company recognized approximately \$130,000 and \$633,000 in grant revenue in the years ended December 31, 2002 and 2003, respectively, under the Economic Development Board of Singapore and German economic development grants. Under these grant agreements, the Company is reimbursed for certain defined expenses. The Company did not receive any grant revenue in the year ended December 31, 2001.

**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 \$3,300,000 in the fourth quarter of 2003 following an unfavorable jury verdict in October 2003 which found infringement. This expense included a royalty of approximately \$2,900,000 on

**Table of Contents**

**ViaCell, Inc.**

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

**2. Summary of Significant Accounting Policies (Continued)**

revenues from cord blood preservation through October 29, 2003, plus an accrual 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 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 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, 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 revenue are included in research and development expense. 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.

**Advertising Costs**

Costs of media advertising are expensed at the time the advertising takes place. Advertising expense totaled approximately \$1,462,000, \$1,782,000 and \$1,815,000 for the years ended December 31, 2001, 2002 and 2003, 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 (Notes 3, 9, 10, 11 and 12).

**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.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (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:

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

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

**Fair Value of Financial Instruments**

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

F-13

---

**Table of Contents**

**ViaCell, Inc.**

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

**2. Summary of Significant Accounting Policies (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, 2002 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, 2002 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. The Company performs ongoing evaluations of its receivable balances and maintains

**Table of Contents**

## ViaCell, Inc.

**Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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, 2001	72,160	79,635	(1,595)	150,200
Year ended December 31, 2002	150,200	158,277	(39,496)	268,981
Year ended December 31, 2003	268,981	776,667	(2,080)	1,043,568

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, 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, 2001, 2002 and 2003, the Company issued 1,920,888, 1,383,468 and 713,436 options, respectively, with an exercise price below deemed fair market value as subsequently determined. In 2001, 2002 and 2003, in connection with the grant of employee stock options, the Company recorded deferred stock compensation of approximately \$10,500,000, \$3,200,000 and \$800,000, 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

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

the individual award, generally four years, consistent with the method described in FASB Interpretation No. 28. During the years ended December 31, 2001, 2002 and 2003, the Company recorded amortization of deferred stock compensation of approximately \$2,300,000, \$6,000,000 and \$3,000,000, 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, 2003, approximately \$3,400,000 of deferred stock compensation related to stock options remained unamortized.

During the years ended December 31, 2001, 2002 and 2003, the Company recorded stock-based compensation expense of approximately \$2,200,000, \$449,000 and \$251,000, 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 and \$594,000 of expense in 2001 in connection with options issued to a scientific collaborator.

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, the pro forma net loss per share would have been as follows:

	2001	2002	2003	Nine Months Ended September 30,	
				2003	2004
				(unaudited)	(unaudited)
Net loss attributable to common stockholders as reported	\$ (28,753,185)	\$ (44,181,634)	\$ (64,884,364)	\$ (50,447,655)	\$ (25,864,828)
Add: stock-based compensation expense included in reported net loss	2,295,145	6,014,507	2,980,699	2,545,076	2,662,055
Deduct: total stock-based compensation expense determined under fair value based method for all awards	(1,115,122)	(4,017,251)	(4,256,829)	(3,096,933)	(3,827,183)
Pro forma net loss attributable to common stockholders	\$ (27,573,162)	\$ (42,184,378)	\$ (66,160,494)	\$ (50,999,511)	\$ (27,029,956)
Basic and diluted net loss per share					
As reported	\$ (12.22)	\$ (17.60)	\$ (24.63)	\$ (19.21)	\$ (9.62)
Pro forma	\$ (11.72)	\$ (16.80)	\$ (25.12)	\$ (19.42)	\$ (10.07)

## Edgar Filing: VIACELL INC - Form 424B4

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, 2001, 2002 and 2003 using the Black-Scholes option pricing model prescribed by SFAS No. 123.

F-16

---

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

The assumptions used for the years ended December 31 and the nine-month periods ended September 30, are as follows:

	December 31,			September 30,	
	2001	2002	2003	2003	2004
				(unaudited)	(unaudited)
Risk-free interest rate	5.00%	3.82%	2.00%	2.00%	2.86%
Expected life	5 years	5 years	5 years	5 years	5 years
Expected volatility	0%	110%	100%	100%	100%
Dividend yield	0%	0%	0%	0%	0%

**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, 2003 and September 30, 2004, respectively.

	December 31, 2003	September 30, 2004
		(unaudited)
Long-lived assets		
United States	\$6,483,125	\$6,931,652
Germany	1,408,991	1,852,124
Total long-lived tangible assets	\$7,892,116	\$8,783,776

There were no long-lived tangible assets outside the United States prior to the Company's acquisition of Kourion on September 30, 2003.

**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.

**Table of Contents**

## ViaCell, Inc.

**Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
Basic and diluted net loss per share					
Net loss attributable to common stockholders	\$ (28,753,185)	\$ (44,181,634)	\$ (64,884,364)	\$ (50,447,655)	\$ (25,864,828)
Weighted average number of common shares outstanding	2,352,468	2,510,632	2,634,096	2,625,618	2,689,866
Basic and diluted net loss per share	\$ (12.22)	\$ (17.60)	\$ (24.63)	\$ (19.21)	\$ (9.62)

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
Options	3,935,258	3,824,199	4,374,160	4,313,217	4,240,549
Warrants	863,333	1,246,666	1,413,906	1,410,000	1,428,750
Convertible preferred stock	20,371,078	20,544,516	25,810,932	20,384,332	25,810,932

The following sets forth the computation of pro forma net loss per share (unaudited):

	Year Ended December 31, 2003	Nine Months Ended September 30, 2004
	Pro forma net loss	
Net loss attributable to common stockholders	\$ (64,884,364)	\$ (25,864,828)
Accretion of preferred stock to redemption value	9,416,114	9,944,223
Pro forma net loss	\$ (55,468,250)	\$ (15,920,605)

Edgar Filing: VIACELL INC - Form 424B4

Shares used in computing pro forma basic and diluted net loss per share		
Weighted average number of common shares outstanding	2,634,096	2,689,866
Weighted average impact of assumed conversion of preferred stock at the beginning of the period	21,231,806	25,810,932
	<u>23,865,902</u>	<u>28,500,798</u>
Shares used in computing pro forma net loss per share		
	<u>23,865,902</u>	<u>28,500,798</u>
Basic and diluted pro forma net loss per share	\$ (2.32)	\$ (0.56)
	<u>\$ (2.32)</u>	<u>\$ (0.56)</u>

Potentially dilutive common shares of 5,788,066, and 5,669,299 for the year ended December 31, 2003, and nine month period ended September 30, 2004 related to the assumed exercise of the outstanding options and warrants, were excluded from the pro forma diluted calculation because their effect would be antidilutive.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)****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.

**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 either a change in control of the Company or an underwritten initial public offering of the Company's 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 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 (USSC's)-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 shareholders' option.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****3. Acquisitions (Continued)**

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. Because the milestone payments are less likely to be paid, the contingent consideration included in purchase price consists of a current liability of \$4.3 million related to the escrow shares and contingent shares, and a noncurrent liability of \$3.9 million relating to the contingent milestone payments.

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
	<hr/>
Total purchase price	\$28,705,000
	<hr/>

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
	<hr/>
	\$28,705,000
	<hr/>

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

F-20

---

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****3. Acquisitions (Continued)**

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.

	<u>2002</u>	<u>2003</u>
Total revenue	\$ 21,441,000	\$ 32,505,000
Net loss	\$ (39,654,000)	\$ (36,277,000)

These pro forma amounts represent the historical operating results of Kourion prior to the date of acquisition, combined with those of the Company with appropriate adjustments which eliminate the write off of the in-process technology and include two years interest expense related to the note payable to a related party for pro forma periods ended December 31, 2002 and 2003, 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.

**Acquisition of Cerebrotec**

In June 2001, the Company acquired all the outstanding shares of common stock of Cerebrotec, Inc. ( Cerebrotec ). The Company issued approximately 92,081 options to purchase common stock of the Company valued at approximately \$494,000 and \$6,000 in cash, in exchange for all the outstanding common stock and options of Cerebrotec. The Company also incurred acquisition costs of approximately \$80,000 in connection with this purchase. The options issued were valued using the Black-Scholes option pricing model with the following assumptions:

Risk-free interest rate	4.71%
Contract term	5 years
Expected volatility	110%
Dividend yield	0%
Exercise price	\$0.95
Fair market value at date of grant	\$5.80

The acquisition has been accounted for as a purchase and, accordingly, the results of operations of Cerebrotec subsequent to June 2001 are included in the Company's consolidated statement of operations.

The aggregate purchase price of \$752,000 consists of the following:

Cash	\$ 6,000
Options to purchase common stock	494,000
Liabilities assumed and acquisition costs	252,000
	<hr/>
Total purchase price	\$752,000
	<hr/>

## Edgar Filing: VIACELL INC - Form 424B4

The purchase price was allocated based upon the fair value of the tangible and intangible assets acquired. In accordance with FIN No. 44, the intrinsic value of the portion of the unvested options related to future service period of \$390,000 has been allocated to deferred compensation in stockholders' deficit.

F-21

---

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****3. Acquisitions (Continued)**

The invested portion is being amortized to operating expense over the remaining vesting period of approximately five years.

The purchase price was allocated as follows:

Current assets, net	\$ 37,000
Property and equipment	8,000
Employment contracts	317,000
Deferred compensation	390,000
	<hr/>
Total assets acquired	\$752,000
	<hr/>

**4. Property and Equipment**

Property and equipment consisted of:

	<b>December 31, 2002</b>	<b>December 31, 2003</b>
	<hr/>	<hr/>
Software	\$ 2,054,813	\$ 2,714,477
Laboratory equipment	3,519,218	5,647,104
Office and computer equipment	1,456,344	2,147,608
Leasehold improvements	2,267,827	2,310,729
Furniture and fixtures	313,083	358,172
Construction in progress		274,030
	<hr/>	<hr/>
Property and equipment, gross	9,611,285	13,452,120
Less: accumulated depreciation and amortization	(2,989,970)	(5,560,004)
	<hr/>	<hr/>
Property and equipment, net	\$ 6,621,315	\$ 7,892,116
	<hr/>	<hr/>

At December 31, 2003 the net book value of property and equipment serving as collateral under loan agreements amounted to \$4,721,000. Prior to October 2003, collateral was supported by letters of credit.

At December 31, 2002 and 2003, equipment held under capital leases totaled \$180,327 and \$584,374, and accumulated depreciation related to this leased equipment totaled approximately \$119,000 and \$224,430, respectively.

Depreciation and amortization expense on property and equipment totaled approximately \$1,266,000, \$1,616,000 and \$2,256,000 in the years ended December 31, 2001, 2002, and 2003.

**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, 2002 and 2003. Based on the results of these analyses, no impairment of goodwill was identified. The Company did not record any amortization of goodwill for the periods ended

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****5. Long-Lived Assets and Goodwill (Continued)**

December 31, 2002 and 2003. Amortization of goodwill and intangible assets subject to SFAS No. 142 was \$385,880 for the year ended December 31, 2001.

2001 net loss attributable to common stockholders as reported	\$(28,753,185)
Add: goodwill amortization	385,880
	<hr/>
Adjusted 2001 net loss attributable to common stockholders	\$(28,367,305)
	<hr/>

In connection with the adoption of SFAS 142, the Company reassessed the useful life of its intangible assets and determined the useful life of the Viacord trademark to be 20 years, not 10 years as estimated at the time of acquisition. As a result of the change in the estimated useful life of this asset, amortization expense recorded for the year ended December 31, 2002 was approximately \$240,000 less than the year ended December 31, 2001. Amortization of intangible assets was approximately \$543,000, \$372,000 and \$261,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

At December 31, 2002, 2003 and September 30, 2004, ViaCell's goodwill and intangible assets consisted of the following:

	<u>December 31, 2002</u>	<u>December 31, 2003</u>	<u>September 30, 2004</u>
			(unaudited)
Goodwill	\$ 4,410,300	\$ 4,410,300	\$ 4,410,300
Less: accumulated amortization	(789,550)	(789,550)	(789,550)
	<hr/>	<hr/>	<hr/>
Goodwill, net	\$ 3,620,750	\$ 3,620,750	\$ 3,620,750
	<hr/>	<hr/>	<hr/>
Intangible assets			
Trademark	\$ 4,400,000	\$ 4,400,000	\$ 4,400,000
Employment agreements	288,338	288,338	288,338
	<hr/>	<hr/>	<hr/>
Less: accumulated amortization	(1,152,283)	(1,413,617)	(1,612,924)
	<hr/>	<hr/>	<hr/>
Intangible assets, net	\$ 3,536,055	\$ 3,274,721	\$ 3,075,414
	<hr/>	<hr/>	<hr/>

**6. Accrued Expenses**

At December 31, 2002 and 2003 and June 30, 2004, accrued expenses consisted of the following:

	<u>December 31, 2002</u>	<u>December 31, 2003</u>	<u>September 30, 2004</u>
			(unaudited)

Edgar Filing: VIACELL INC - Form 424B4

Accrued patent royalties	\$	\$ 3,257,639	\$
Payroll and payroll related	1,154,987	1,487,932	717,186
Management incentive	416,032	481,209	750,119
Professional fees	1,025,660	2,766,042	3,437,050
Accrued marketing	858,637	865,455	742,123
Accrued restructuring			1,424,414
Collection and testing materials	41,985	452,133	169,995
Other	359,189	700,612	1,185,635
	<u>          </u>	<u>          </u>	<u>          </u>
	\$3,856,490	\$10,011,022	\$8,426,522
	<u>          </u>	<u>          </u>	<u>          </u>

F-23

**Table of Contents**

## ViaCell, Inc.

**Notes to Consolidated Financial Statements (Continued)****7. Income Taxes**

The income (loss) before income taxes is as follows at December 31:

	2001	2002	2003
Domestic	\$(22,133,493)	\$(35,667,790)	\$(52,299,065)
Foreign		(370,238)	(3,169,185)
<b>Total Income Before Taxes</b>	<b>\$(22,133,493)</b>	<b>\$(36,038,028)</b>	<b>\$(55,468,250)</b>

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

	For the Years Ended December 31,		
	2001	2002	2003
US Statutory rate	34.0%	34.0%	34.0%
State taxes, net	7.8%	6.9%	2.0%
Foreign rate differential	0.0%	(0.1)%	0.4%
Benefit of tax credits	1.3%	1.6%	1.3%
Change in valuation allowance	(42.0)%	(41.5)%	(14.8)%
Stock based compensation	0.0%	0.0%	(8.1)%
In process R&D	0.0%	0.0%	(14.7)%
Other	(1.1)%	(0.9)%	(0.1)%
<b>Effective tax rate</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>

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:

	For the Years Ended December 31,	
	2002	2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 17,756,996	\$ 31,159,658
Tax credits	2,213,461	2,542,262
Stock-based compensation	6,878,104	3,782,964
Reserves, accruals, and other	3,624,949	6,151,824
<b>Gross deferred tax assets</b>	<b>30,473,510</b>	<b>43,636,708</b>

Edgar Filing: VIACELL INC - Form 424B4

Valuation allowance	(28,965,573)	(42,233,874)
	<u>                    </u>	<u>                    </u>
Net deferred tax assets	1,507,937	1,402,834
Deferred tax liabilities:		
Intangible assets	(1,507,937)	(1,402,834)
	<u>                    </u>	<u>                    </u>
Net deferred tax liabilities	\$ 0	\$ 0
	<u>                    </u>	<u>                    </u>

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

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****7. Income Taxes (Continued)**

deferred tax assets will not be realized in the near future. At December 31, 2003, the Company has federal and state net operating loss carryforwards of approximately \$67,513,985 and \$68,165,739 respectively, which begin to expire in 2009 and 2004, respectively. The Company has federal and state credit carryforwards of approximately \$1,866,414 and \$1,024,011 which begin to expire in 2009 and 2013, respectively. The Company also has foreign net operating loss carryforwards of \$9,225,188. The carryforwards expire through 2023 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.

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
2001	\$ 3,038,000	10,482,000	-	13,520,000
2002	\$ 13,520,000	15,445,573	-	28,965,573
2003	\$ 28,965,573	13,268,301	-	42,233,874

**8. Long-Term Obligations**

The Company had the following long-term debt outstanding as of December 31, 2002, 2003 and September 30, 2004:

	December 31, 2002	December 31, 2003	September 30, 2004
			(unaudited)
Debt facility loans	\$ 5,171,761	\$ 4,668,690	\$ 3,529,909
Related party note payable		14,280,000	15,120,000
Capital lease obligations	1,112	289,586	366,601
Total long-term debt	5,172,873	19,238,276	19,016,510
Less: current portion	(2,130,872)	(15,891,604)	(16,851,667)
Total long-term debt, net of current portion	\$ 3,042,001	\$ 3,346,672	\$ 2,164,843

**Debt facility**

During 2000, 2001 and 2002, 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 \$649,999 certificate of deposit. These borrowings were prepaid in 2003.

## Edgar Filing: VIACELL INC - Form 424B4

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 \$4,669,000 was outstanding under this loan as of December 31, 2003. The Company was also required to make a \$1,750,000 cash deposit with the lender as additional collateral for this loan. This deposit is included with other noncurrent assets in the accompanying consolidated balance sheet. As of

F-25

---

**Table of Contents**

**ViaCell, Inc.**

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

**8. Long-Term Obligations (Continued)**

December 31, 2003, the net book value of the fixed assets which are collateral under this agreement was \$4,721,000.

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. 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 \$4,000 for the period ended December 31, 2003.

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 \$280,000 in accrued interest related to this note for the period ended December 31, 2003. 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 Company has classified this note as a current liability because the Company expects to complete its initial public offering during 2004. The total outstanding principal and unpaid accrued interest on the notes as of December 31, 2003 was \$14,280,000.

**Capital Lease Obligations**

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

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****8. Long-Term Obligations (Continued)**

At December 31, 2003, payments of principal and interest on existing debt were due as follows:

	Year Ending December 31,
2004	\$ 16,208,527
2005	1,917,445
2006	1,578,066
2007	39,640
2008	34,743
Thereafter	132,611
Total payment	19,911,032
Less: interest	(672,756)
Total debt	19,238,276
Less: current portion	(15,891,604)
Total long-term debt	\$ 3,346,672

**9. Commitments and Contingencies****Leases**

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

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

	Year Ending December 31,
2004	\$ 1,675,083
2005	2,027,864
2006	1,926,922
2007	1,963,716
2008	1,767,785
Thereafter	9,942,983
Total lease payments	\$ 19,304,353

Rent expense was approximately \$861,000, \$1,566,000 and \$1,797,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

## Edgar Filing: VIACELL INC - Form 424B4

In connection with the above commitments, the Company has issued letters of credit totaling approximately \$1,922,710 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.

### **Agreements**

In June 2001, the Company obtained an exclusive license to two US patents and four US patent applications owned by Massachusetts General Hospital (MGH) covering methods and compositions invented by Dr. Seth Finklestein for promoting neurological recovery. To maintain this MGH license, ViaCell is obligated to pay minimum royalties of \$10,000 for each of the years ended December 31, 2001

F-27

---

**Table of Contents**

**ViaCell, Inc.**

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

**9. Commitments and Contingencies (Continued)**

through 2003, \$20,000 for each of the years ended December 31, 2004 through 2007 and \$40,000 for each of the years subsequent to December 31, 2007. In addition, the Company will make payments contingent upon the successful achievement of certain product development milestones totaling a minimum of \$1,000,000. This license will expire on a product-by-product and country-by-country basis one year after the Company last sells a product in a given country, unless all underlying patents earlier expire.

In June 2001, Kourion entered into a consulting agreement with Prof. Dr. Peter Wernet, professor at the Institute of Transplantation Immunology and Cell Therapeutics at Heinrich Heine University in Düsseldorf, Germany. Under this agreement, Dr. Wernet will provide consulting services to Kourion related to its scientific and clinical activities. Dr. Wernet will be paid on a per hour basis for services, up to a limit of \$63,000 per year. The agreement runs for a period of ten years, and is cancelable only for cause.

In October 2001, the Company entered into a research collaboration agreement and stock option agreement with Genzyme Corporation. Under the terms of the research agreement, the Company is required to use diligent efforts to test the effect of Genzyme's proprietary stem cell stimulant on the growth of hematopoietic stem cells in the Company's Selective Amplification process. The Company and Genzyme have committed personnel to conduct this research project. The agreement expired in October 2002. As disclosed in Note 12, under the stock option agreement, the Company granted an option to Genzyme to purchase 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 is exercisable at any time after issuance. This portion had a fair value of \$594,000 and was recorded as in-process technology at the time of issuance. The remaining portion vests based on the achievement of certain milestones. As disclosed in Note 12, Genzyme exercised the vested portion in January 2002 to purchase Series I convertible preferred stock, and the Company and Genzyme mutually agreed to terminate the remaining portion of the option.

In January 2002, the Company entered into a marketing agreement with Mothers Work under which the Company is committed to spend a minimum of \$1,150,000 over a 24-month period. As of December 31, 2003, the Company had spent approximately \$1,400,000 related to this agreement and had no further obligation under this agreement.

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 is in the process of establishing new contracts with Dr. Brown and MGH.

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 is remaining. Under this

**Table of Contents**

**ViaCell, Inc.**

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

**9. Commitments and Contingencies (Continued)**

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 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 (less \$10,000 previously paid as an option fee) and has reimbursed MIT for approximately \$9,000 in past patent costs. 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 \$527,000 and \$968,000 of research and development in Singapore during the years ended December 31, 2002 and 2003, 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 in January 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 \$165,000 in annual license fees for as of December 31, 2003.

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, 2003, the Company had paid Gamete \$432,000 for consulting services and expensed \$655,000 in the development of human oocyte cryopreservation. No amounts were paid under the royalty provision.

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 for which Amgen can exercise its option. Each time Amgen exercises its option, it must partially

**Table of Contents**

**ViaCell, Inc.**

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

**9. Commitments and Contingencies (Continued)**

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's bylaws provide for the indemnification of officers and directors for certain events or occurrences while the officer is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments that the Company could be required to make under the bylaws is unlimited; however, the Company has Director and Officer insurance policies that, in most cases, would limit its exposure and enable it to recover a portion of any future amounts paid. The officer and director indemnification provisions were grandfathered under the provisions of FIN 45 as they were in effect prior to December 31, 2002. Accordingly, the Company has no liabilities recorded for these provisions as of December 31, 2003.

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, 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 has placed the amount of the award in an escrow account pending final disposition of this case. This amount is included in other current assets. The Company has 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.

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****9. Commitments and Contingencies (Continued)**

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 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. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court's decision. In response, we may appeal the jury's verdict regarding the validity and enforceability of the patents. On September 24, 2004, the Company's \$2.9 million escrow payment was released to the Company. 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.

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. The

**Table of Contents**

**ViaCell, Inc.**

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

**9. Commitments and Contingencies (Continued)**

Company has filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. The Company has also filed a motion to stay the Massachusetts litigation pending a ruling on our motion to consolidate the cases, and the motion was granted on January 18, 2005.

In light of a relationship between the patents asserted in Delaware and Massachusetts, the Massachusetts litigation may be delayed if an appeal is taken in the Delaware case. Regardless of whether an appeal is taken, the Massachusetts litigation may be transferred or consolidated with one or more of PharmaStem's cases pending against other defendants in other jurisdictions. Thus, 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 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, 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.

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. We believe that the petition will be summarily dismissed and 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.

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, 2003 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

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****9. Commitments and Contingencies (Continued)**

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 September 30, 2004. The reserve is equal to the estimated fair value of the indemnifications in place at 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). 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 September 30, 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, 2002 and 2003:

	<b>For the Years Ended December 31,</b>	
	<b>2002</b>	<b>2003</b>
Balance at the beginning of the period	\$	\$ 5,000
Accrual for additional units sold during the period	5,000	38,000
Payments		
Balance at the end of the period	\$5,000	\$43,000

**Table of Contents**

## ViaCell, Inc.

**Notes to Consolidated Financial Statements (Continued)****10. Redeemable Convertible Preferred Stock, Convertible 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, 2001, 2002 and 2003, respectively:

	Carrying Value at December 31,		
	2001	2002	2003
Series C, \$0.01 par value			
Authorized, issued and outstanding; 919,220 shares	\$ 1,242,271	\$ 1,360,997	\$ 1,469,871
Series D, \$0.01 par value			
Authorized, issued and outstanding; 1,500,000 shares	3,040,740	3,331,349	3,597,857
Series E, \$0.01 par value			
Authorized, issued and outstanding; 1,983,334 shares	7,268,522	7,863,277	8,492,339
Series F, \$0.01 par value			
Authorized, issued and outstanding; 2,666,666 shares	9,146,877	9,844,462	10,660,819
Series G, \$0.01 par value			
Authorized, issued and outstanding; 3,666,667 shares	12,576,961	13,572,807	14,658,631
Series H, \$0.01 par value			
Authorized, issued and outstanding; 7,577,334 shares	52,829,978	56,949,345	61,515,916
Series I, \$0.01 par value			
Authorized, 5,575,000 shares; issued and outstanding; 1,875,000, 2,062,500 and 2,624,854 shares at December 31, 2001, 2002 and 2003, respectively	15,162,722	17,989,440	24,074,390
Series J, \$0.01 par value			
Authorized, 3,750,000 shares; issued and outstanding; 2,190,000 shares at December 31, 2003			16,073,828
Series K, \$0.01 par value			
Authorized, issued and outstanding; 2,500,000 shares at December 31, 2003			21,597,786
<b>Total redeemable convertible preferred stock</b>	<b>\$ 101,268,071</b>	<b>\$ 110,911,677</b>	<b>\$ 162,141,437</b>

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****10. Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders Deficit (Continued)**

The Company's redeemable convertible preferred stock activity for year to date period ended December 1, 2001, 2002, 2003 respectively, consisted of the following:

	Series C		Series D		Series E		Series F		Series G	
	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts
Balance December 31, 2000	919,220	\$ 1,150,251	1,500,000	\$ 2,815,500	1,983,334	\$ 6,730,113	2,666,666	\$ 8,469,331	3,666,667	\$ 11,645,334
Issuance of Shares										
Accretion to Redemption Value		92,020		225,240		538,409		677,546		931,627
Balance December 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	12,576,961
Issuance of Shares										
Accretion to Redemption Value		118,726		290,609		594,755		697,585		995,846
Balance December 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	13,572,807
Issuance of Shares										
Accretion to Redemption Value		108,874		266,508		629,062		816,357		1,085,824
Balance December 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	\$ 14,658,631
Issuance of Shares										
Accretion to Redemption Value		88,194		215,871		509,541		639,648		879,519
Balance September 30, 2004	919,220	\$ 1,558,065	1,500,000	\$ 3,813,728	1,983,334	\$ 9,001,880	2,666,666	\$ 11,300,467	3,666,667	\$ 15,538,150

[Additional columns below]

[Continued from above table, first column(s) repeated]

Series H

Series I

Series J

Series K

Edgar Filing: VIACELL INC - Form 424B4

	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts	Total
Balance December 31, 2000	7,577,334	\$48,916,646		\$		\$		\$	\$ 79,727,175
Issuance of Shares			1,875,000	15,000,000					
Accretion to Redemption Value		3,933,332		162,722					
Balance December 31, 2001	7,577,334	52,849,978	1,875,000	15,162,722					\$ 101,288,071
Issuance of Shares			187,500	1,500,000					
Accretion to Redemption Value		4,099,367		1,326,718					
Balance December 31, 2002	7,577,334	56,949,345	2,062,500	17,989,440					\$ 110,911,677
Issuance of Shares			562,354	4,498,832	2,190,000	15,622,160	2,500,000	21,597,786	
Accretion to Redemption Value		4,566,571		1,586,118		451,668			
Balance December 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	\$ 162,141,437
Issuance of Shares									
Accretion to Redemption Value		3,849,270		1,454,913		1,413,225		894,042	
Balance September 30, 2004	7,577,334	\$65,365,186	2,624,854	\$25,529,303	2,190,000	\$17,487,053	2,500,000	\$22,491,828	\$ 172,085,660

F-35

**Table of Contents****10. Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders Deficit (Continued)**

The Company's convertible preferred stock consists of the following as of December 31, 2002 and 2003, respectively:

	<u>2002</u>	<u>2003</u>
Series A, \$0.01 par value		
Authorized, issued and outstanding 100,000 shares (liquidation preference of \$100,000 at December 31, 2002 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, 2002 and 2003)	829	829
Total convertible preferred stock	<u>\$ 1,829</u>	<u>\$ 1,829</u>

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 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

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****10. Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders Deficit (Continued)**

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 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.

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.

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

**Table of Contents**

**ViaCell, Inc.**

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

**10. Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders Deficit (Continued)**

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.

**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, 2003, 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

**Table of Contents**

**ViaCell, Inc.**

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

**11. Warrants (Continued)**

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 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 January 2002, the Board of Directors increased the number of shares of common stock available for issuance under the Plan to 5,000,000, and in 2003 the Board of Directors increased the pool to 6,000,000. Incentive stock options may only be granted to employees of the Company. The exercise price of each option is determined by the Board of Directors. The exercise price of each incentive stock option, however, may not be less than the fair market value of the stock on the date of grant, as determined by the Board of Directors.

Options granted under the Plan vest over a period of four years and expire ten years from the grant date. At December 31, 2003, there were 801,127 shares available for future grant under the Plan.

**Table of Contents**

## ViaCell, Inc.

**Notes to Consolidated Financial Statements (Continued)****12. Stock Option Plan (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, 2000	4,000,000	2,073,950	\$0.10-0.30	\$ 621,773	\$ 0.30
Granted		1,920,888	0.30-2.00	2,637,568	1.37
Exercised		(289,395)	0.15-0.78	(91,815)	0.32
Canceled		(144,435)	0.15-0.95	(100,632)	0.69
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 (unaudited)	1,200,000				
Granted (unaudited)		660,450	5.00	3,302,250	5.00
Exercised (unaudited)		(48,790)	0.30-5.00	(71,637)	1.47
Cancelled (unaudited)		(977,769)	0.30-5.00	(3,866,584)	(3.95)
Outstanding, September 30, 2004 (unaudited)	7,200,000	4,339,227	\$0.30-5.00	\$ 9,408,141	\$ 2.17
Exercisable, December 31, 2001		667,426	\$0.10-0.95	\$ 204,880	\$ 0.34
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, September 30, 2004 (unaudited)		2,232,652	\$0.30-5.00	\$ 3,070,104	\$ 1.38

Options Exercisable at

Edgar Filing: VIACELL INC - Form 424B4

Options Outstanding at December 31, 2003

December 31, 2003

Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$0.30	1,517,125	6.53	\$0.30	1,039,562	\$0.30
0.75	63,205	7.09	0.75	33,467	0.75
0.95	782,153	7.54	0.95	465,582	0.95
2.00	936,126	8.02	2.00	98,923	2.00
4.00	120,850	8.22	4.00	38,335	4.00
5.00	1,285,877	9.23	5.00	130,759	5.00
	<u>4,705,336</u>	<u>7.78</u>	<u>\$2.13</u>	<u>1,806,628</u>	<u>\$0.99</u>

F-40

**Table of Contents****ViaCell, Inc.****Notes to Consolidated Financial Statements (Continued)****12. Stock Option Plan (Continued)**

The weighted average fair value of options granted in 2001, 2002 and 2003 was \$6.15, \$6.31 and \$6.18, 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. This portion of the option had a fair value of \$594,000 and was recorded as an in-process technology expense in the accompanying consolidated statement of operations. The fair value of this option was estimated at the time of issuance using the Black-Scholes option pricing model and assuming a dividend yield of 8 percent, expected volatility of 110 percent and a risk-free interest rate of 4.71 percent. One half of the option becomes exercisable upon achievement of certain milestones. During 2002, this shareholder exercised the vested portion of this option and purchased 187,500 shares of Series I preferred stock. Concurrently, both the Company and the option holder mutually agreed to terminate the remaining unvested portion of the option.

In September 2004 the Company recorded a stock-based compensation charge of \$774,000 related to the restructuring (see note 14). The Company modified the grants for severed employees to allow them an additional 90 days to exercise their vested options following termination. The impact of the option modification was partially offset by the impact of 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 severances, contract termination costs and the write-down of excess equipment. In December 2004, our board of directors approved a plan to close the facility in Germany in 2005 and transfer these operations to the U.S. The Company expects to record a restructuring charge of approximately \$0.6 million in the fourth quarter of 2004. At September 30, 2004, restructuring charges of \$0.1 million were paid out, the net book value of fixed assets was written down by \$0.2 million, and the accrued liability relating to the restructuring was \$1.4 million. 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.

	2004 Provision	Payments/ Writedowns	Balance as of September 30, 2004
Severance related	\$ 1,315,604	\$(114,523)	\$ 1,201,081
Contractual terminations	208,333		208,333
Other	215,603	(200,603)	15,000
	<u>\$ 1,739,540</u>	<u>\$(315,126)</u>	<u>\$ 1,424,414</u>



**Table of Contents**

**Report of Independent Auditors**

To the Board of Management and Shareholders of Kourion Therapeutics AG

In our opinion, the accompanying balance sheets and the related statements of income present fairly, in all material respects, the financial position of Kourion Therapeutics AG at September 30, 2003 and December 31, 2002 and the results of its operations for the nine months ended September 30, 2003 and for the year ended December 31, 2002, in conformity with accounting principles generally accepted in Germany. 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in the item "general information" in the notes to the financial statements, the ability of the company to continue as a going concern is subject to certain risk conditions.

Accounting principles generally accepted in Germany vary in certain important respects from accounting principles generally accepted in the United States of America. The application of the latter would have affected the determination of net income for the nine-month ended September 30, 2003 and for the year ended December 31, 2002 and the determination of shareholders' equity at September 30, 2003 and December 31, 2002 to the extent summarized in item "other information" in the notes to the financial statements.

/s/ PricewaterhouseCoopers GmbH

/s/ (Schwalm)  
Wirtschaftsprüfer

/s/ (Bröcher)  
Wirtschaftsprüfer

Düsseldorf, March 10, 2004

F-42

---

**Table of Contents****Kourion Therapeutics AG, Langenfeld****Balance Sheet as of**

	<u>September 30, 2003</u>	<u>December 31, 2002</u>
<b>Assets</b>		
<b>A. Fixed assets</b>		
I. Intangible assets		
Concessions, industrial property rights	10,335	14,508
II. Tangible assets		
1. Buildings on leasehold land	0	14,084
2. Other equipment, factory and office equipment	1,462,550	356,618
3. Prepayments and construction in process	48,469	
	<u>1,511,019</u>	<u>370,702</u>
	<u>1,521,354</u>	<u>385,210</u>
<b>B. Current assets</b>		
I. Inventories		
1. Raw materials and supplies	80,226	37,359
2. Prepayments	660	
	<u>80,886</u>	<u>37,359</u>
II. Receivables and other assets		
1. Trade receivables	1,202	
2. Receivables from affiliated companies	876,526	
3. Other assets	800,609	686,179
	<u>1,678,337</u>	<u>686,179</u>
III. Current asset securities		
Other securities	2,047,645	2,351,943
IV. Cash on hand and bank balances		
	<u>2,003,719</u>	<u>5,066,037</u>
	<u>5,810,587</u>	<u>8,141,518</u>
<b>C. Prepaid expenses and deferred charges</b>		
	<u>155,687</u>	<u>5,969</u>
	<u>7,487,628</u>	<u>8,532,697</u>
<b>Shareholders' equity and liabilities</b>		
<b>A. Shareholders' equity</b>		
I. Subscribed capital	52,750	52,750
II. Capital reserve	12,077,182	12,077,182
III. Cumulative losses	(6,349,829)	(4,536,516)
	<u>5,780,103</u>	<u>7,593,416</u>
<b>B. Special account for subsidies and grants</b>		
	<u>428,592</u>	<u>133,087</u>

<b>C. Accruals</b>		
Other accruals	469,819	280,965
<b>D. Accounts payable</b>		
1. Bank loans and overdrafts	212	121
2. Trade payables	645,568	460,438
3. Payables to shareholders	0	443
4. Other liabilities	163,334	63,520
(of which taxes 138,392.55; previous year 39,471.21)		
(of which social security payables 24,497.79; previous year 24,049.12)	809,114	524,522
<b>E. Deferred income</b>		
		707
	7,487,628	8,532,697



**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002**

**I. General information**

The annual financial statements of Kourion Therapeutics AG ( Kourion ) were prepared in accordance with the regulations of the German commercial law (HGB). Furthermore, the regulations of the German stock corporation act (AktG) were also complied with.

The income statement is presented in the type of expenses form.

Following the sale of the shares in our company as of September 30, 2003, ViaCell Inc., Boston, Massachusetts/ USA ( ViaCell ) is our company's new sole shareholder. In view of the fact that our financial statements are included in the consolidated financial statements of ViaCell Inc., it is necessary that our financial statements as of September 30, 2003, which were prepared in accordance with German accounting principles, include information about the reconciliation to accounting principles generally accepted in the United States of America (US-GAAP).

The financial year of Kourion Therapeutics AG is the calendar year. The financial statements as of September 30, 2003 and December 31, 2002 to which these Notes are attached have been prepared voluntarily for the periods from January 1 through September 30, 2003 and January 1 through December 31, 2002, respectively.

In so far as we have an option of showing certain information either in the balance sheet or income statement or in the Notes, that information is included in the Notes.

These financial statements have been prepared assuming that Kourion will continue as a going concern. Kourion has incurred losses from operations and negative operating cash flow in the fiscal year ended December 31, 2002 and the nine months ended September 30, 2003. Kourion's existing cash provides the company with sufficient resources to fund operations through April 2005. Thereafter, Kourion will be dependent on additional funding from ViaCell to continue its operations.

**II. Accounting and valuation methods**

Purchased intangible fixed assets are stated at acquisition costs which have been reduced by systematic amortisation.

Tangible fixed assets are stated at acquisition or production costs less systematic depreciation.

Intangible and tangible assets are being amortised or depreciated on the basis of their expected useful lives and the maximum rates accepted for tax purposes. Fixed assets acquired during the financial year are depreciated pro rata temporis. Moveable assets are depreciated taking advantage of the half-year rule which is possible in accordance with Section R 44 (2) EstR (Income Tax Regulations).

The following estimated useful lives are applied to groups of assets:

Intangible assets	3 years
Technical equipment and machinery	5-13 years
Other equipment, factory and office equipment	3-13 years

Inventories are stated at acquisition or production costs. If their values at the balance sheet date are lower, these lower values are used.

Receivables and other assets and current asset securities are valued after taking account of all recognisable risks.

Cash on hand and at banks are stated at their nominal amounts.



**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

Prepaid expenses and deferred charges include payments made which relate to definite periods after the balance sheet date.

Shareholders' equity is stated at its nominal amount.

The Special account for subsidies and grants shows grants received for fixed assets, which have been deferred and are released to income in line with the depreciation provided on the assets concerned. The amounts released are shown under Other operating income in the income statement.

Other accruals have been made for all recognisable uncertain liabilities at amounts based on a prudent businessman's evaluation.

Accounts payable are stated at the amounts payable. Liabilities expressed in foreign currencies have been translated to Euro at rates which were valid at the balance sheet date.

**III. Information on items in the balance sheet and income statement**

***Statement of the development of fixed assets***

Details of and movements on fixed assets, which comprise intangible and tangible assets, can be seen in the statement of the development of fixed assets at the end of these Notes. This statement shows amounts of amortisation and depreciation provided in the individual items of fixed assets in the period under review.

***Inventories***

Inventories as of September 30, 2003 (T 81) are goods classified as raw materials and supplies (T 80) and prepayments made (T 1). Inventories as of December 31, 2002 (T 37) are goods classified as raw materials and supplies.

***Receivables and other assets***

Receivables from affiliated companies (T 877) are all receivable from ViaCell Inc., and reflect amounts taken over by ViaCell in place of the sellers in connection with the share transfer transactions and which Kourion paid as advance payments for ViaCell.

Other assets as of September 30, 2003 (T 801) are mainly claims for tax refunds (T 422) and for grants to be paid (T 322). Other assets as of December 31, 2002 (T 686) are mainly claims for grants to be paid (T 371), interest receivable (T 171) and tax refunds (T 108).

None of the receivables and other assets as of September 30, 2003 are due over periods in excess of one year.

***Current asset securities***

Current asset securities (T 2,048 as of September 30, 2003 and T 2,352 as of December 31, 2002) relate exclusively to money-market funds, which invest in short term bonds.

***Liquid funds***

Liquid funds (T 2,004 as of September 30, 2003 and T 5,066 as of December 31, 2002) consist entirely of bank balances except for cash on hand (T 0.1) for both periods presented.



**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

***Prepaid expenses and deferred charges***

Prepaid expenses and deferred charges as of September 30, 2003 (T 156) relate to prepaid insurance premiums, rents and collaboration costs. Prepaid expenses and deferred charges as of December 31, 2002 (T 6) relate to prepaid insurance premiums, rents and consulting costs.

***Shareholders' equity***

The share capital of the predecessor company Kourion Therapeutics GmbH amounted to 26,400 as of December 31, 2000. The shareholders passed the following resolutions on June 25, 2001:

The company's share capital will be increased

The company will be transformed into an Aktiengesellschaft (Corporation).

The above changes were entered in the Commercial Register on March 19, 2002.

As of September 30, 2003, the company's share capital amounted to 52,750. It was divided into 29,853 ordinary shares and 22,897 preference shares with voting rights.

**Preference shares**

There is only one type of preference share - Series A. These shares have the following characteristics, in contrast to ordinary shares:

Owners of Series A preference shares have no preference rights to dividends compared to owners of ordinary shares. No dividends had been distributed up to September 30, 2003.

Each preference share owner is entitled to one vote.

The following resolutions passed by the shareholders' general meeting require the approval of the preference shareholders to become valid, and those shareholders must pass special resolutions with majorities of 75% of the preference shareholdings represented when the resolutions are passed:

- a. Transformation as defined in Section 1 Umwandlungsgesetz (Transformation Act)
- b. Sale of 75% or more of the company's assets (based on present values)
- c. Changes in the articles of incorporation
- d. Measures concerning obtaining and reducing capital
- e. Liquidation of the company
- f. Approvals of company-transfer agreements as defined in Section 291 et seq AktG
- g. Incorporation as defined in Section 319 AktG
- h. Election of auditors

## Edgar Filing: VIACELL INC - Form 424B4

- i. Distributions to shareholders, including advance dividends
- j. Creation of types of shares which are preferred or equal to those of Series A preference shares
- k. Withdrawal of shares

Owners of preference shares have the following preference rights if the company is liquidated:

Liquidation income will be paid to owners of Series A preference shares initially up to an amount of 425,9851 (the issue price (A) ) per Series A preference share, plus the dividends

F-47

---

**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

which have been resolved but not distributed to owners of Series A preference shares. If the liquidation income is less than the amount mentioned above, that liquidation income will be split between the owners of Series A preference shares in the relationships of their participations to one another.

Each owner of Series A preference shares is entitled to demand after the fifth annual anniversary of the date on which the articles of incorporation were finalised (June 25, 2001), the withdrawal of 25% of the Series A preference shares held by him and, after each year following, of further 25% of the Series A preference shares calculated on the basis of the Series A preference shares held by him on the fifth annual anniversary date. Compensation for the withdrawals will be the issue price (A) per Series A preference share, plus 15% internal interest thereon. The claim for withdrawals referred to above is subject to the limitations stipulated in Section 225 et seq and 237 et seq AktG.

The company's Management Board is authorised to increase the share capital, with the approval of the Supervisory Board, until December 31, 2005, once or several times by up to 5,273 new Series A preference shares showing the owners' names.

***Ordinary shares***

The company was founded on November 2, 2000 in the course of the purchase of a shelf company from six private individuals (Prof. Peter Wernet, Phil Coelho, Dr. Gesine Kögler, Dr. Johannes Fischer, Friedrich Schake and the Kourion Verwaltungs GmbH) for investments of 800 for 3.2%, twice 2,450 for 9.8%, 1,150 for 4.6%, 2,150 for 8.6% and 16,000 for 64%. The share capital totalled 25,000.

The share capital was increased by 1,400 in December 2000, with a share premium of T 108. The share capital was increased by a further 26,350 in July 2001, with a share premium of T 11,958.

Conditional capital of 4,817 shares for the possible implementation of a scheme whereby employees may acquire company shares was resolved at the shareholders' meeting on May 27, 2002. In addition, conditional capital of 6,223 shares was resolved for the purpose of fulfilling bond conversion rights.

Neither of the programmes had been implemented up to September 30, 2003. The programmes have been rendered superfluous as a result of the transaction with ViaCell.

***Special account for subsidies and grants***

The company's applications for the promotion of projects out of funds provided by the State of North-Rhine Westfalia were approved. The subsidy paid in 2002 and up to September 30, 2003 enabled the company to finance fixed assets and other expenses qualifying for such support. A Special account for subsidies and grants was set up on the Shareholders' equity and liabilities side of the balance sheet to defer amounts related to fixed assets acquired by the company up to September 30, 2003; this is being released to income in line with the estimated useful lives of the assets concerned, and amounted to T 429 at the balance sheet date.

The amount approved for promotion funds totalled T 4,807, of which T 1,787 had been requested by Kourion, and paid, up to September 30, 2003. Amounts requested and provided until September 30, 2003 are based on applications prepared by the company. These amounts are subject to an audit of the underlying costs and investments as well as the compliance with certain conditions included in the promotion contract. The audit has not been finalized yet.

**Table of Contents****Kourion Therapeutics AG, Langenfeld****Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)*****Accruals***

Other accruals as of September 30, 2003 (T 470) include mainly amounts for vacation entitlements (T 61), costs related to the merger (T 142) and accruals for advisory services and collaboration agreements. Other accruals as of December 31, 2002 (T 281) include mainly amounts for vacation entitlements (T 31) and accruals for advisory services and collaboration agreements (T 200).

***Accounts payable***

The main items in the accounts payable as of September 30, 2003 (T 809) are trade payables (T 646) and other liabilities ( 163). The main items in the accounts payable as of December 31, 2002 (T 525) are trade payables (T 460) and other liabilities (T 64). For both periods reported, there are no liabilities due over periods of more than one year and no securities have been given.

***Contingent liabilities and other financial commitments***

There are no contingent liabilities, including any related to the provision of guarantees for third party liabilities.

There are the following financial commitments in addition to the liabilities shown in the financial statements:

		<b>September 30, 2003</b>	<b>December 31, 2002</b>
		_____	_____
Commitments from rent contracts	T	1,380	1,189
Commitments from leasing contracts	T	50	55
Commitments from consultancy and co-operation contracts	T	418	412
Commitments for orders placed	T	45	58
Commitments from insurance contracts	T	23	10

Other financial commitments becoming due within one year of September 30, 2003 amount to T 425, those becoming due within five years total T 225.

The rent and leasing contracts end between 2004 and 2012. The consultancy and co-operation contracts cover periods of up to eight years.

***Sales***

Sales (T 17) relate to stem cells sold to a research institute in Switzerland.

The Company recognizes revenue from a research cooperation, for which stem cells were delivered to a unrelated company. These revenues are recognized as Sales revenues and amounted to 16,722 for the nine months ended September 30, 2003.

***Other operating income***

Other operating income for the period ended September 30, 2003 (T 769) includes mainly investment grants (T 545), credits for releases of accruals (T 101) and other operating income (T 94). Other operating income for the year ended December 31, 2002 (T 1,177) includes mainly investment grants (T 1,094), credits for releases of accruals (T 48) and other operating income (T 34).

**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

***Revenue recognition***

The majority of the Company's revenue is derived from investment grants from German governmental agencies. The investment grants are a German economic development grant given by the State of Northrhine-Westphalia. Under the grant agreement, the Company is reimbursed for certain defined expenses, e.g. Personnel expenses, consumables, collaborations. Investment grant revenue is recognized as the defined expenses are incurred with the exception of reimbursements for defined fixed asset expenditures, which are recognized over the useful life of the fixed asset.

Investment grant revenue is classified as Other operating income and amounted to (T 545) for the nine months ended September 30, 2003.

Other Operating income also includes (T 101) and (T 94) for credits for the release of accruals and other operating income for the nine months ended September 30, 2003.

Credits for releases of accruals include the release of the compensation of a member of the board of directors in the amount of (T 75) and the release of a collaboration accrual with a collaboration partner in the amount of (T 26) for the nine months ended September 30, 2003.

Other operating income (T 94) includes merger related expenses from the year 2002 which were reimbursed in the context of the merger with Viacell in 2003.

***Cost of materials***

Cost of materials for the period ended September 30, 2003 (T 309) includes costs of raw materials and supplies (T 171) and costs of purchased services (T 138). Costs of materials for the year ended December 31, 2002 (T 695) includes costs of raw materials and supplies (T 234) and costs of purchased services (T 461).

***Personnel expenses***

Personnel expenses for the period ended September 30, 2003 (T 1,007) include T 852 for wages and salaries and T 129 for social charges. They also include T 26 for additions to accruals. Personnel expenses for the year ended December 31, 2002 (T 1,620) include T 1,400 for wages and salaries and T 220 for social charges.

The average number of employees in the period from January 1 to September 30, 2003 was 21 (20 in the year 2002).

***Other operating expenses***

Other operating expenses for the period ended September 30, 2003 (T 1,231) include mainly consultancy expenses (T 409), travel expenses (T 152) and rent payments (T 156). Other operating expenses for the year ended December 31, 2002 include mainly consultancy expenses (T 881), travel expenses (T 283) and rent payments (T 65).

***Financial results***

The net income from financial activities as of September 30, 2003 (T 58) comprises T 59 income from current asset securities less interest expenses of T 1. The net income from financial activities for the year ended December 31, 2002 (T 98) comprises income from current asset securities of T 251 less expenses for the write down of those securities at year end.

**Table of Contents****Kourion Therapeutics AG, Langenfeld****Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)****Taxes**

Other taxes show a refund of car tax of ( 62) for the period ended September 30, 2003. Other taxes for the year ended December 31, 2002 include car tax charges 122.

**Cumulative losses**

The cumulative losses are made up of the losses brought forward (T 4,537) and the net loss for the period from January to September 2003 (T 1,813). Plans are that the cumulative losses will be carried forward.

**IV. Other information****Reconciliation to accounting principles generally accepted in the United States of America ( US GAAP )**

The financial statements of the Company have been prepared in accordance with German GAAP. These principles and practices differ in various respects from US GAAP. The Company currently has devoted substantially all of its efforts to research and development activities and has not derived significant revenues from operating activities.

## 1) Reconciliation of net loss and shareholders' equity

The effects of the application of US GAAP to net income and shareholders' equity are set out in the reconciliations below:

	<b>Nine Months Ended September 30, 2003</b>	<b>Year Ended December 31, 2002</b>
	<b>(Euro)</b>	<b>(Euro)</b>
Net loss under German GAAP	(1,813,313)	(2,646,274)
(a) R&D supplies	(42,867)	(6,453)
(b) Capital leases	(3,365)	(2,769)
(c) Pension obligations		16,563
	<hr/>	<hr/>
Net loss as adjusted for US GAAP	(1,859,545)	(2,638,933)
Shareholders' equity under German GAAP	5,780,103	7,593,416
(a) R&D supplies	(80,226)	(37,359)
(b) Capital leases	(4,649)	(1,284)
	<hr/>	<hr/>
Shareholders' equity as adjusted for US GAAP	<u>5,695,228</u>	<u>7,554,773</u>

## a) Research and development supplies:

Under German GAAP, research and development costs are expensed when incurred and related supplies are expensed when used. Under US GAAP, SFAS No. 2, Accounting for Research and Development Costs, the costs of materials, equipment, or facilities that are acquired or constructed for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time the costs are incurred. The Company has elected to expense diminutive items as incurred for US GAAP reporting that are capitalized as inventories under German GAAP.



**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

b) Capital leases

Under German GAAP, the commercial code does not make any explicit provisions for leasing arrangements. Leases are accounted for in accordance with German tax legislation, which in practice generally results in leased assets being capitalized by the lessor. Under US GAAP, SFAS No. 13, Accounting for Leases, specifies that if certain criteria are met, leases are classified as either operating or capital leases. Certain leases of the Company that are recorded as operating leases qualify for capital lease accounting under US GAAP. The adjustment represents the difference between expenses recorded under capital leases compared to those recorded under operating leases.

c) Provisions for pensions and similar obligations

Under German GAAP, pension liabilities are often calculated by the differential method in accordance with German tax legislation (Section 6A of the German Income Tax Act) and generally represent the minimum amount that must be recorded in the financial statements. Under US GAAP, pension costs for defined benefit plans are accounted for in accordance with SFAS No. 87, Employers Accounting for Pensions. Differences exist between the valuation methods and treatment of certain costs. The adjustment represents the difference in valuation under US GAAP. The pension plan was discontinued in 2002 and no adjustment in 2003 was required.

2) Cash flow statement

Under German GAAP, a statement of cash flows is not required as part of the basic set of financial statements. Under US GAAP, cash flow statements are presented in accordance with SFAS No. 95, Statement of Cash Flows. SFAS No. 95 requires a classification of cash flows resulting from operating, investing and financing activities.

Under SFAS No. 95, cash and cash equivalents include cash and short-term investments with original maturities of three months or less. Under German GAAP, cash comprises of cash and short-term investments which may include original maturities of more than three months.

**Table of Contents****Kourion Therapeutics AG, Langenfeld****Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

The following presents the cash flow statement in accordance with US GAAP and includes adjustments to reconcile cash and cash equivalents under US GAAP to cash and short-term investments reported under German GAAP. Net loss as presented below is the Company's net loss in accordance with U.S. GAAP.

	Nine Months Ended September 30, 2003	Year Ended December 31, 2002
	( )	( )
Cash flows from operating activities:		
Net loss	(1,859,545)	(2,638,933)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	122,621	98,619
Loss on disposal of property and equipment	12,285	
Changes in operating assets and liabilities:		
Accounts receivable	(1,202)	
Prepaid expenses and other current assets	(256,348)	(482,497)
Due from related parties	(876,525)	
Restricted cash	(115,600)	
Other non-current assets	1,159	(5,343)
Short-term debt	212	
Accounts payable and accrued liabilities	462,907	397,236
Pension liability		(40,094)
Net cash used in operating activities	(2,510,035)	(2,671,012)
Cash flows from investing activities:		
Purchases of property and equipment	(946,880)	(16,631)
Net cash used in investing activities	(946,880)	(16,631)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock		8,600,350
Principal payments on capital lease obligation	(25,301)	(22,887)
Net cash (used in) provided by financing activities	(25,301)	8,577,463
Net (decrease) increase in cash and cash equivalents	(3,482,216)	5,889,820
Cash and cash equivalents at beginning of period	7,417,980	1,528,160
Cash and cash equivalents at end of period	3,935,764	7,417,980
Includes restricted cash not part of cash and cash equivalents under US GAAP	115,600	0
Cash and short-term investments under German GAAP end of year	4,051,364	7,417,980
Supplemental disclosures of cash flow information:		
Cash paid for interest	7,067	6,045

Edgar Filing: VIACELL INC - Form 424B4

Supplemental disclosure of non cash investing and financing activities:

Conversion of GmbH share capital into AG common stock		29,853
	<u>          </u>	<u>          </u>
Conversion of GmbH share capital into AG preferred stock		22,897
	<u>          </u>	<u>          </u>

F-53

---

**Table of Contents**

**Kourion Therapeutics AG, Langenfeld**

**Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)**

**V. Subsequent Event (Unaudited)**

On December 8, 2004, the Board of Directors of Viacell approved a plan to close down Kourion's operations by June 30, 2005. Pursuant to this plan, one Kourion employee will relocate to the United States on a permanent basis and two others will relocate on a temporary basis to assist with transition activities, while all other Kourion employees will be terminated between December 2004 and June 2005.

*Names of the members of the company's corporate bodies*

**The members of the Management Board were:**

Dr. Hans-Dieter Royer, Düsseldorf, Doctor of Medicine (until February 19, 2003)

Dr. Manfred Zoltbrocki, Frankfurt, Qualified Chemist (until March 8, 2003)

Dr. Stephan Wnendt, Aachen, Qualified Biochemist (since March 6, 2003).

If only one person is appointed as a member of the Management Board this person is authorised to represent the company alone. If several persons are appointed as members of the Management Board, the company is jointly represented by two Management Board members or by one Management Board member together with a Prokurist (a person with limited powers of representation). The Supervisory Board can authorise one or more or all members of the Management Board to represent the company alone. It can authorise Management Board members together or individually to conclude legal transactions at the same time for the company and as representative of a company affiliated with it (as defined in Section 15 AktG), and, in individual cases, both for the company and as a representative of a third party. Management Board member Dr. Stephan Wnendt is authorised to represent the company alone.

**The members of the Supervisory Board were as follows:**

Prof. Dr. Peter Wernet, Chairman	Doctor of Medicine, until October 1, 2003
Dr. Ansbert Gädicke	Doctor of Medicine, until October 1, 2003
Dr. Georg Nebgen	Pharmacist, until February 18, 2003
Mr. Phil Coelho	Businessman, until October 1, 2003
Prof. Dr. Detlev Riesner	Dipl. Physicist, until October 1, 2003
Dr. Stefan Röhrborn	Lawyer, until October 1, 2003
Dr. Markus Hosang	Biochemist, from February 20, 2003 until October 1, 2003
Mr. Marc Beer, Chairman	MBA, since October 23, 2003
Mr. Paul Hastings	MBA, since October 23, 2003
Mr. Jan van Heek	MBA, since October 23, 2003

Section 10 (1) of the articles of incorporation was amended at an extraordinary general meeting of shareholders on October 23, 2003 so that the Supervisory Board is comprised of three members.

Members of the Supervisory Board received remuneration amounting to T 32 in the period under review, plus remuneration in accordance with consultancy contracts in the amount of T 55.

Management Board members received remuneration of, in total, T 80 in the period under review.

100% shareholder of Kourion Therapeutics AG is ViaCell Inc., 245 First St., Cambridge MA 02142, USA.

Langenfeld, March 9, 2004

The Management Board

/s/

---

(Dr. Stephan Wnendt)

F-54

---

**Table of Contents****Kourion Therapeutics AG, Langenfeld****Notes to the Financial Statements as of September 30, 2003 and December 31, 2002 (Continued)****Development of Fixed Assets in the Period from****January 1, 2002 through September 30, 2003**

	Acquisition costs			Cumulative amortisation and depreciation			Book values		
	January 1, 2002	Additions	Disposals	December 31, 2002	January 1, 2002	Additions	Disposals	December 31, 2002	December 31, 2001
<b>Intangible assets</b>									
Concessions, industrial property rights		16,691		16,691		2,183		2,183	14,508
		16,691		16,691		2,183		2,183	14,508
<b>Tangible assets</b>									
Buildings on leasehold land	18,688			18,688	2,203	2,401		4,604	14,084
Other equipment, factory and office equipment	344,247	133,027		477,274	52,277	68,379		120,656	356,618
Prepayments and construction in process									
	362,935	133,027		495,962	54,480	70,780		125,260	370,702
	362,935	149,718		512,653	54,480	72,963		127,443	385,210

	Acquisition costs			Cumulative amortisation and depreciation			Book values		
	January 1, 2003	Additions	Disposals	September 30, 2003	January 1, 2003	Additions	Disposals	September 30, 2003	December 31, 2002
<b>Intangible assets</b>									
Concessions, industrial property rights	16,691			16,691	2,183	4,173		6,356	10,335
<b>Tangible assets</b>									
Buildings on leasehold land	18,688		18,688		4,604	1,799	6,403		14,084
Other equipment, factory and office equipment	477,273	1,210,399		1,687,673	120,656	104,467		225,123	1,462,550
Prepayments and construction in process		48,469		48,469					48,469
	495,961	1,258,868	18,688	1,736,142	125,260	106,266	6,403	225,123	1,511,019
	512,652	1,258,868	18,688	1,752,833	127,443	110,439	6,403	231,479	1,521,354

**Table of Contents**

**PRO FORMA FINANCIAL DATA**

The following unaudited pro forma combined financial statements give effect to the acquisition of Kourion Therapeutics AG ( Kourion ) by ViaCell, Inc. ( ViaCell ) that occurred on September 30, 2003 in a transaction which was accounted for as a business combination. The unaudited pro forma combined statements of operations combine the historical consolidated statement of operations of ViaCell for the year ended December 31, 2003 included elsewhere in this prospectus, and Kourion for the nine months ended September 30, 2003, giving effect to the merger as if it occurred on January 1, 2003, reflecting only pro forma adjustments expected to have a continuing impact on the combined results. A pro forma balance sheet is not presented because Kourion is included in ViaCell s consolidated balance sheet at December 31, 2003. The results of operations of Kourion for the nine months ended September 30, 2003 are presented in accordance with accounting principles generally accepted in the United States.

These unaudited pro forma combined financial statement are for informational purposes only. They do not purport to indicate the results that would have actually been obtained had the merger been completed on the assumed date or for the periods presented, or which may be realized in the future. To produce the pro forma financial information, ViaCell allocated the purchase price using its best estimates of fair value, based in part on a valuation that was performed. The unaudited pro forma combined financial statements should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the historical consolidated financial statements, including the related notes, of ViaCell and Kourion covering these periods, included elsewhere in this prospectus.

**Table of Contents****ViaCell, Inc.****Unaudited Pro Forma Combined Statement of Operations****For the Year Ended December 31, 2003**

	Year Ended December 31, 2003 ViaCell	Nine Months Ended September 30, 2003 Kourion(1)	Pro Forma Adjustments	Note Reference	Pro Forma Combined
Processing and storage revenue	\$ 30,884,201	\$			\$ 30,884,201
Grant and contract revenue	995,494	625,174			1,620,668
<b>Total revenues</b>	<b>31,879,695</b>	<b>625,174</b>			<b>32,504,869</b>
<b>Operating expenses</b>					
Cost of revenues					
Direct costs	7,141,581				7,141,581
Royalty expense	3,257,639				3,257,639
<b>Total cost of revenues</b>	<b>10,399,220</b>				<b>10,399,220</b>
Research and development	13,225,957	1,511,536			14,737,493
Sales and marketing	20,959,187				20,959,187
General and administrative	15,221,356	1,249,568			16,470,924
In-process technology	23,925,023		(22,100,000)	(A)	1,825,023
Stock-based compensation(1)	3,232,179				3,232,179
<b>Operating expenses</b>	<b>86,962,922</b>	<b>2,761,104</b>	<b>(22,100,000)</b>		<b>67,624,026</b>
<b>Loss from operations</b>	<b>(55,083,227)</b>	<b>(2,135,930)</b>	<b>22,100,000</b>		<b>(35,119,157)</b>
<b>Interest income (expense)</b>					
Interest income	348,476	(10,864)			337,612
Interest expense	(733,499)	65,339	(840,000)	(B)	(1,508,160)
Other income		13,104			13,104
<b>Total interest income (expense), net</b>	<b>(385,023)</b>	<b>67,579</b>	<b>(840,000)</b>		<b>(1,157,444)</b>
<b>Net loss</b>	<b>(55,468,250)</b>	<b>(2,068,351)</b>	<b>21,260,000</b>		<b>(36,276,601)</b>
Accretion on redeemable convertible preferred stock	9,416,114		263,920	(C)	9,680,034
<b>Net loss attributable to common stockholders</b>	<b>\$(64,884,364)</b>	<b>\$(2,068,351)</b>	<b>20,996,080</b>		<b>\$(45,956,635)</b>
<b>Net loss per share</b>					
Net loss per common share, basic and diluted	\$ (24.63)				\$ (17.45)
Weighted average shares used in basic and diluted net loss per share computation	2,634,096				2,634,096
<b>Pro forma net loss per common share (basic and diluted)</b>	<b>\$(2.32)</b>				<b>\$(1.52)</b>
	23,865,902				23,865,902

Weighted average shares used in  
pro forma net loss per common  
share (basic and diluted)  
computation

---

- (1) Kourion's financial statements were translated from local currency (the Euro) into a reporting currency (the US dollar) in accordance with FASB 52. Accordingly, the Statement of Operations was translated based on the average rate of exchange for the nine months ended September 30, 2003. Kourion's results have also been converted from German GAAP to US GAAP for purposes of this presentation.
- (A) To reverse the cost of in-process research and development related to the Kourion acquisition.
- (B) To adjust MPM note interest expense to reflect a full year of interest expense.
- (C) To reflect a full year of accretion related to the issued series I preferred shares related to the acquisition.

F-57

---

**Table of Contents****Notes to Unaudited Pro Forma Combined Statement of Operations**

(\$ in thousands, except share amounts)

**Note 1. Basis of Presentation and Pro Forma Information**

The unaudited pro forma combined statement of operations data contained herein describes the pro forma effect of the acquisition of Kourion by ViaCell that took place on September 30, 2003, as if it occurred on January 1, 2003. The acquisition was completed as of September 30, 2003 and the results of operations of Kourion from October 1, 2003 through December 31, 2003 are included in the ViaCell historical results of operations. Historical results represents the results of operations of Kourion for the nine months ended September 30, 2003, prior to its acquisition by ViaCell.

**Note 2. Description of Transaction**

On September 30, 2003, ViaCell acquired the outstanding shares of Kourion and accounted for the acquisition as a business combination. Under the terms of the agreement, shareholders of Kourion exchanged all their outstanding shares for a \$14 million note and 549,854 shares of Series I convertible preferred stock of ViaCell. As potential additional consideration, ViaCell issued 241,481 shares of Series I convertible preferred stock to an escrow account and reserved 289,256 shares of Series I convertible preferred stock which are issuable upon completion of ViaCell's IPO. Kourion is a pre-clinical stage biotechnology company developing therapeutic applications of a proprietary stem cell type called unrestricted somatic stem cells. Based on a valuation performed of Kourion and the intangible assets acquired, the purchase price was estimated at \$28,705,000 and is comprised of the following:

Note issued	\$ 14,000,000
Series I convertible preferred stock	4,400,000
Acquisition costs	2,150,000
Contingent consideration	8,155,000
	\$ 28,705,000
Total purchase price	\$ 28,705,000

In addition, ViaCell has agreed to pay Kourion's shareholders up to \$12 million upon achievement of certain development milestones. Pursuant to SFAS No. 141, approximately \$8.2 million of contingent consideration has been included in the determination of the purchase price.

The purchase price has been allocated to the acquired tangible and intangible assets and liabilities based on their estimated fair values as of September 30, 2003 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
Accounts payable and accrued expenses assumed	(513,000)
Capital lease obligation assumed	(141,000)
In-process technology expensed	22,100,000
	\$ 28,705,000
	\$ 28,705,000

Kourion is performing studies to test the effect of unrestricted somatic stem cell (USSC) in the transvascular catheter-based application route and in the epicardial syringe-based delivery route in parallel, using swine. Kourion is also performing studies in a critical defect model in the rat to determine suitability of certain combinations of biomaterials with the USSC. Additional studies are being performed using a large model animal (sheep) of bone regeneration. The Company estimates that the development of the Kourion programs through clinical trials to commercial viability would take approximately eight years.



**Table of Contents**

**Notes to Unaudited Pro Forma Combined Statement of Operations (Continued)**  
**(\$ in thousands, except share amounts)**

**Note 2. Description of Transaction (Continued)**

Management assumes responsibility for determining the in-process research and development valuation. The fair value assigned to purchase in-process research and development was estimated by discounting, to present value, the probability-adjusted net cash flows expected to result once the technology has reached technological feasibility. A discount rate of 23% was applied to estimate the present value of the cash flows and is consistent with the overall risks of developing these projects. As of December 31, 2003, the technological feasibility of the projects had not been reached and management believes the assumptions include in the valuation analysis continue to be valid. In the allocation of the purchase price, the concept of alternative future use was considered. The projects under development have no current alternative future uses for the underlying technology in the event the projects are unsuccessful.

F-59

---

**Table of Contents**

---

---

**VIACELL**

---

---