VIACELL INC Form S-1/A December 27, 2004 As filed with the Securities and Exchange Commission on December 27, 2004

Registration No. 333-114209

#### SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

### Amendment No. 5

to

Form S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

### VIACELL, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

8731 (Primary SIC Code Number) 04-3244816 (I.R.S. Employer Identification No.)

245 First Street Cambridge, Massachusetts 02142 617-914-3400

617-914-3400 (Address, including zip code, and telephone number, including area code, of registrant s principal executive offices) Marc D. Beer President and Chief Executive Officer 245 First Street Cambridge, Massachusetts 02142 617-914-3400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 27, 2004

#### Shares

### VIACELL

### Common Stock

Prior to the offering, there has been no public market for our common stock. The initial public offering price of our common stock is expected to be between \$ and \$ per share. We are applying to have our common stock approved for quotation on the Nasdaq National Market under the symbol VIAC.

The underwriters have an option to purchase a maximum of

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.

|   | Price<br>to Public | Underwriting<br>Discounts and<br>Commissions | Proceeds to<br>ViaCell |
|---|--------------------|--|------------------------|
| Per Share   | \$                 | \$   | \$                     |
| Total   | \$                 | \$   | \$                     |
| Delivery of the shares of common stock will be made on or about | , 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

The date of this prospectus is

Leerink Swann & Company

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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** 

Until , 2005, 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.

#### 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,

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 this indication 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 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 October 2004, we had over 61,000 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 obtaining FDA 510(k) clearance for the media, we intend to commercialize this product candidate, Viacyte, 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.

#### **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 storage and cell processing 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, 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;

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

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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. 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<sup>TM</sup> are trademarks of ViaCell, Inc. This prospectus also refers to trademarks and tradenames of other organizations.



#### THE OFFERING

| Common stock offered by ViaCell                   | shares (   | shares if the underwriters  | over-allotment option is fully exercised)  |
|---|--|---|--|
| Common stock to be outstanding after the offering | shares (   | shares if the underwriters  | over-allotment option is fully exercised)  |
| Proposed Nasdaq National Market<br>symbol         | VIAC   |   |  |
| Use of proceeds                                   | activities, to fund clinical tri<br>commercial infrastructure in | al activities, to expand our m<br>the area of reproductive hea<br>ate purposes, including capit | and preclinical research and development<br>banufacturing capacity, to expand our<br>lth, to repay an outstanding promissory note<br>al expenditures and working capital. Please |
| The number of shares to be outstand               | ling immediately after this off                                  | ering is based on:  |  |

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

2,747,394 shares of common stock outstanding as of November 30, 2004;

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; and

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 upon our closing a firm underwritten initial public offering, if the price per share to the public is at least \$9.70 resulting in net proceeds to us of at least \$50 million.

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 if and only if the price per share to the public in, or our net proceeds from, this offering are less than \$9.70 or \$50 million, respectively;

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 that will be reserved for future issuance under our employee stock purchase plan.

#### 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<br>September 30, |             |    |          |    |          |
|---|-------------------------|---------|----|-------------|----|--------------|--------|--------------|------------------------------------|-------------|----|----------|----|----------|
|   |                         | 1999    |    | 2000        |    | 2001         |        | 2002         |                                    | 2003(1)     |    | 2003     |    | 2004     |
| Consolidated                                |                         |         |    |             |    | (in thousand | s, exc | ept share an | d per                              | share data) |    |          |    |          |
| Statement of<br>Operations Data:            |                         |         |    |             |    |              |        |              |                                    |             |    |          |    |          |
| Revenues                                    | \$                      |         | \$ | 2,394       | \$ | 7,298        | \$     | 20,375       | \$                                 | 31,880      | \$ | 22,632   | \$ | 28,633   |
| Operating expenses:<br>Cost of revenues:(2) |                         |         |    |             |    |              |        |              |                                    |             |    |          |    |          |
| Direct costs                                |                         |         |    | 991         |    | 3,070        |        | 5,877        |                                    | 7,141       |    | 5,276    |    | 5,514    |
| Royalty expense                             |                         |         |    | <i>))</i> 1 |    | 5,070        |        | 5,077        |                                    | 3,258       |    | 5,270    |    | (3,258)  |
| Total cost of                               |                         |         | _  |             | -  |              | -      |              | _                                  |             | -  |          |    |          |
| revenues                                    |                         |         |    | 991         |    | 3,070        |        | 5,877        |                                    | 10,399      |    | 5,276    |    | 2,256    |
| Research and                                |                         | 1 102   |    | 2           |    | 6.070        |        | 11.400       |                                    | 10.000      |    | 0 515    |    | 11 (00   |
| development                                 |                         | 1,193   |    | 3,854       |    | 6,978        |        | 11,429       |                                    | 13,226      |    | 9,515    |    | 11,698   |
| Sales and marketing<br>General and          |                         |         |    | 2,177       |    | 9,349        |        | 16,578       |                                    | 20,959      |    | 16,203   |    | 15,081   |
| administrative                              |                         | 1,034   |    | 3,879       |    | 7,086        |        | 10,920       |                                    | 15,222      |    | 10,723   |    | 10,400   |
| In-process                                  |                         | 1,051   |    | 5,077       |    | 7,000        |        | 10,720       |                                    | 13,222      |    | 10,725   |    | 10,100   |
| 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)   |

| diluted<br>Weighted average<br>shares used in<br>computing net loss per<br>common share, basic<br>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<br>common share, basic<br>and diluted  |           |           |           |           | \$ (2.32)  |           | \$ (0.56)  |
| Pro forma weighted<br>average shares used in<br>computing net loss per<br>common share, basic<br>and diluted  |           |           |           |           | 23,865,902 |           | 28,500,798 |
|   |           |           |           |           | - , ,      |           | - , ,      |
|   |           |           | 6         |           |            |           |            |

|   | As of Septer        | Pro Forma<br>As Adjusted(6)   |  |  |  |
|---|---------------------|-------------------------------|--|--|--|
|   | Actual Pro Forma(5) |                               |  |  |  |
|   |                     | (unaudited)<br>(in thousands) |  |  |  |
| Consolidated Balance Sheet Data:                      |                     |                               |  |  |  |
| Cash, cash equivalents and investments                | \$ 34,116           | \$34,116                      |  |  |  |
| Working capital                                       | 12,408              | 12,408                        |  |  |  |
| Total assets  | 66,797              | 66,797                        |  |  |  |
| Long-term debt obligations, including current portion | 19,017              | 19,017                        |  |  |  |
| Redeemable convertible preferred stock                | 172,086             |                               |  |  |  |
| Total stockholders equity (deficit)                   | (153,405)           | 18,681                        |  |  |  |

- (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:

|                                |      | Y     | Nine Months Ended<br>September 30, |         |          |         |         |
|--------------------------------|------|-------|------------------------------------|---------|----------|---------|---------|
|                                | 1999 | 2000  | 2001                               | 2002    | 2003     | 2003    | 2004    |
|                                |      |       |                                    | (in th  | ousands) |         |         |
| 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 |

(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, assuming a public offering price of \$ per share, and our receipt of the net proceeds therefrom.

#### **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 studies or clinical trials for certain product candidates in order to focus our resources on more promising product candidates. We may also change the indication being pursued for a particular product candidate or otherwise revise the development plan for that candidate. Moreover, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical or initial clinical testing.

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

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

Revenues from our umbilical cord blood preservation and storage products have grown significantly over the past several years, from \$7.1 million in fiscal 2001, to \$20.1 million in fiscal 2002, to \$30.9 million in fiscal 2003. 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 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 overturned the jury s verdict of infringement of either PharmaStem patent. PharmaStem 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. PharmaStem filed a motion on October 5, 2004 with the court for a



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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 have also filed a motion to stay the Massachusetts litigation pending a ruling on our motion to consolidate the cases. 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;

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 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

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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 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.

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*Oocyte cryopreservation.* There are no established precedents for US and international regulation of oocyte cryopreservation. We anticipate that in the Unites States cryopreservation of oocytes will be regulated similarly to Viacord s family umbilical cord blood cryopreservation product. We also anticipate that some of the components used in this product will be regulated as medical devices under a 510(k) clearance mechanism. For instance, prior to marketing this product, our media supplier will be required to obtain 510(k) clearance for the technology we have licensed for use in the cryopreservation of oocytes. 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. Although we currently anticipate that clinical trials establishing safety and efficacy are not required for commercialization, we cannot assure that this is or would remain the case. 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. The planned development and marketing of this service could also be impeded by delays in the 510(k) process or if the FDA requires us to perform clinical trials in support of a 510(k) submission. 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 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.

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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 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

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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.

### 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.

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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 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 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 in 2005 and transfer all manufacturing activities 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 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. Within the next six months, we plan to begin commercializing our oocyte cryopreservation technology. To do so, we would be required to institute additional and distinct sales and marketing, manufacturing and storage capacities. 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.

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.

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

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

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

The pharmaceutical and biotechnology businesses are highly competitive. We compete with many organizations that are developing cell therapies for the treatment of a variety of human diseases, including companies such as Aastrom Biosciences, Cellerant, Gamida-Cell, Geron, Genzyme, Neuronyx, Osiris Therapeutics and Stem Cells. We also face competition in the cell therapy field from academic institutions and governmental agencies. Some of these competitors, and future competitors, may have similar or better product candidates or technologies, greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities. Specifically, Gamida-Cell, a private company based in Israel, is developing a hematopoetic stem cell therapy product candidate similar to CB001. This product 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 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 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 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.

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

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

Most health care providers, including research collaborators from whom we obtain patient information, are subject to privacy regulations promulgated under the Heath Insurance Portability and Accountability Act of 1996, or HIPAA ( Privacy Rule ). Although we ourselves are not directly regulated by the HIPAA Privacy Rule, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider who has not satisfied the

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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 is known as dilution. Based upon the net tangible book value of our common stock at December 31, 2003, and assuming a public offering price of \$ per share, after this offering, our shares of common stock outstanding will have a pro forma net tangible book value of \$ per share. As a result, immediately after you purchase shares in this offering, the net tangible book value of your shares will be \$ 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 4, 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, if this offering results in net proceeds to us of at least \$50 million at a public offering price per share of \$9.70 or higher, we will release and issue upon closing this offering 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 this offering does not meet that net proceeds or offering price threshold, then we will instead issue warrants to existing investors in our Series J preferred stock to purchase up to 2,190,000 shares of common stock with registration rights. 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 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 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;

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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 % of our outstanding common stock or % 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 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.

### Potential 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 could also negatively impact our results of operations.

The Financial Accounting Standards Board is considering whether to require all companies to treat the fair value of stock options granted to employees as an expense. The US Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies could be required to record a compensation expense equal to the fair value of each stock option granted. Currently, we are generally not required to record compensation expense in connection with stock option grants. If we were required to expense the fair value of stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would 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, in the event we are required to expense stock option grants, our future results of operations would be negatively impacted, as would our ability to use stock options as an employee recruitment and retention tool.

#### 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 si 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.

#### **USE OF PROCEEDS**

We estimate that we will receive net proceeds of approximately \$ million from the sale of the shares offered by us in this offering or \$ million if the underwriters exercise their over-allotment option in full, assuming a public offering price of \$ per share. 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 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 million for preclinical research and development activities relating to our product candidates;

approximately \$15 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 \$ 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.

#### 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:

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

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

our release of 241,481 escrowed shares and issuance of 289,256 contingent shares of common stock to satisfy a contingent purchase price obligation to former shareholders of Kourion Therapeutics, which are due and issuable upon our closing an underwritten initial public offering if the sale price to the public is at least \$9.70 and the offering results in at least \$50 million in net proceeds.

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<br>as Adjusted |  |  |
|   | (in thou                 | sands, except share da | ta)                      |  |  |
| Cash, cash equivalents and investments                              | \$ 34,116                | \$ 34,116              |                          |  |  |
|   |                          |                        |                          |  |  |
| Long-term debt obligations, including current portion               | \$ 19,017                | \$ 19,017              |                          |  |  |
| 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 shares     |                          |                        |                          |  |  |
| issued and outstanding, pro forma as adjusted                       | 27                       | 285                    |                          |  |  |
| Additional paid-in capital  | (2, (2, 2))              | 171,829                |                          |  |  |
| Deferred compensation   | (2,690)                  | (2,690)                |                          |  |  |
| Accumulated deficit   | (151,106)                | (151,106)              |                          |  |  |
| Accumulated other comprehensive income                              | 362                      | 362                    |                          |  |  |
| Total stockholders equity (deficit)                                 | (153,405)                | 18,681                 |                          |  |  |
|   |                          |                        |                          |  |  |
| Total capitalization  | \$ 37,698                | \$ 37,698              |                          |  |  |
|   |                          |                        |                          |  |  |

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The share data in the table above does not include:

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;

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; and

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 and will be issued if and only if the price per share to the public in, or our net proceeds from, this offering are less than \$9.70 or \$50 million, respectively. If this offering equals or exceeds both the \$9.70 per share price and \$50 million net proceeds thresholds, this contingent warrant obligation will terminate, and the warrants will never be issued.

#### 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 million, or \$ book value as of September 30, 2004 was approximately \$ 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 and the release of 241,481 escrowed shares and issuance of 289,256 contingent shares of common stock to former Kourion Therapeutics shareholders as contingent purchase price consideration upon closing this offering if the price to the public is at least \$9.70 and net proceeds to us equal at least \$50 million, was approximately \$ million, or \$ 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 per share after this offering would have been \$ or \$ per share. This represents an immediate increase in pro forma net tangible book value of \$ per share to existing stockholders and an immediate dilution in pro forma net tangible book value of \$ 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 shares in this offering at an assumed public offering price of \$ per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses. The following table illustrates this per share dilution:

| Net tangible book value per share before this offering           | \$ |
|--|----|
| Change attributable to pro forma conversion of preferred stock   | \$ |
| Pro forma net tangible book value per share before this offering | \$ |
| Assumed initial public offering price per share                  | \$ |
| Increase attributable to this offering                           | \$ |
| Pro forma net tangible book value per share after this offering  | \$ |
| Dilution per share to new investors                              | \$ |

The following table summarizes, on a pro forma basis as of September 30, 2004, after giving effect to this offering and assuming a public offering price of \$ per share, 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 Pure | chased  | Total Cons |         |                            |
|---|-------------|---------|------------|---------|----------------------------|
|   | Number      | Percent | Amount     | Percent | Average Price<br>Per Share |
| Existing stockholders   |             | %       | \$         | %       | \$                         |
| New investors<br>Contingent shares to former Kourion Therapeutics |             |         |            |         |                            |
| shareholders  | 289,256     |         |            |         |                            |
| Total   |             |         |            |         |                            |

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;

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; and

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 and will be issued if and only if the price per share to the public in, or our net proceeds from, this offering are less than \$9.70 or \$50 million, respectively.

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 \$ and total dilution per share to new investors would be \$ . The above table assumes no exercise of the underwriters over-allotment option.

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#### 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, |                |                   |                     |                   |                | nths Ended<br>nber 30, |
|--|-------------------------|----------------|-------------------|---------------------|-------------------|----------------|------------------------|
|  | 1999                    | 2000           | 2001              | 2002                | 2003(1)           | 2003           | 2004                   |
|  |                         |                | (in thousand      | s, except share and | per share data)   |                |                        |
| Consolidated<br>Statement of<br>Operations Data: |                         |                |                   |                     |                   |                |                        |
| 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<br>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<br>technology(3)                      |                         |                | 594               | 5,889               | 23,925            | 22,200         |                        |
| Stock-based<br>compensation(4)<br>Restructuring  |                         | 196            | 4,490             | 6,464               | 3,232             | 2,545          | 2,662<br>1,740         |
|  |                         |                |                   |                     |                   |                |                        |
| Total operating expenses                         | 2,227                   | 11,097         | 31,567            | 57,157              | 86,963            | 66,462         | 43,837                 |
| Operating loss                                   | (2,227)<br>90           | (8,703)<br>991 | (24,269)<br>2,136 | (36,782)<br>744     | (55,083)<br>(385) | (43,830)<br>83 | (15,204)<br>(717)      |
|  | 20                      | <i>))</i> 1    | 2,150             | / 7 7               | (505)             | 00             | (/1/)                  |

| Interest income<br>(expense), net<br>Income taxes   |     |         |    |          |    |          |    |           |    |           |    |           |    |           |
|---|-----|---------|----|----------|----|----------|----|-----------|----|-----------|----|-----------|----|-----------|
| Net loss  | \$  | (2,137) | \$ | (7,712)  | \$ | (22,133) | \$ | (36,038)  | \$ | (55,468)  | \$ | (43,747)  | \$ | (15,921)  |
| Net loss<br>attributable to<br>common<br>stockholders   | \$  | (2,692) | \$ | (10,262) | \$ | (28,753) | \$ | (44,182)  | \$ | (64,884)  | \$ | (50,448)  | \$ | (25,865)  |
| Net loss per<br>common share,<br>basic and diluted  | \$  | (2.05)  | \$ | (5.55)   | \$ | (12.22)  | \$ | (17.60)   | \$ | (24.63)   | \$ | (19.21)   | \$ | (9.62)    |
| Weighted average<br>shares used in<br>computing net loss<br>per common share,<br>basic and diluted              | 13  | 16,352  | 1  | ,849,073 | 2  | ,352,468 |    | 2,510,632 | ,  | 2,634,096 |    | 2,625,618 |    | 2,689,866 |
| Pro forma net loss<br>per common share,<br>basic and diluted  | 1,5 | 10,352  | 1  | ,017,075 | 2  | ,552,100 |    | 2,510,052 | \$ | (2.32)    | -  | .,023,010 | \$ | (0.56)    |
| Pro forma<br>weighted average<br>shares used in<br>computing net loss<br>per common share,<br>basic and diluted |     |         |    |          |    |          |    |           | 2: | 3,865,902 |    |           | 2  | 8,500,798 |
|   |     |         |    |          |    |          | 32 |           |    |           |    |           |    |           |

|                                     |          | ~         |           |                |           |                       |
|-------------------------------------|----------|-----------|-----------|----------------|-----------|-----------------------|
|                                     | 1999     | 2000      | 2001      | 2002           | 2003      | September 30,<br>2004 |
|                                     |          |           | (         | (in thousands) |           |                       |
| Consolidated Balance Sheet<br>Data: |          |           |           |                |           |                       |
| 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.

(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, |         |          |         |         | nths Ended<br>nber 30, |
|--------------------------------|------|--------------------------|---------|----------|---------|---------|------------------------|
|                                | 1999 | 2000                     | 2001    | 2002     | 2003    | 2003    | 2004                   |
|                                |      |                          |         | (in thou | sands)  |         |                        |
| 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                |
|                                |      |                          |         |          |         |         |                        |
|                                |      |                          |         |          |         |         |                        |

#### 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.

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. Because we expect to close our German facility in 2005 and transition its research activities to the U.S., 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



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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.

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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. The escrowed shares will be released, and the contingent shares will 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 will revert back to us and the contingent shares will never be issued. If the contingent shares are issued upon a change in control, the recipients of these shares will be issued an additional number of shares equal to 8% of the initial number of shares issued compounded annually from the acquisition closing date to the date of issuance. 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 proforma 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.

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.

### **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<br>2003 to 2004 | % Change<br>2003 to 2004 |  |  |  |
| Processing revenues         | \$20.0 | \$24.0                          | \$4.0                     | 20%                      |  |  |  |
| Storage revenues            | 2.0    | 3.4                             | 1.4                       | 70%                      |  |  |  |
| Total                       | 22.0   | 27.4                            | 5.4                       | 25%                      |  |  |  |
| Grant and contract revenues | 0.6    | 1.2                             | 0.6                       | 100%                     |  |  |  |
| Total revenues              | \$22.6 | \$28.6                          | \$6.0                     | 27%                      |  |  |  |

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 Mo | onths Ended Septembe      | er 30,                   |
|--------------------|-------|---------|---------------------------|--------------------------|
|                    | 2003  | 2004    | \$ Change<br>2003 to 2004 | % Change<br>2003 to 2004 |
| revenues:          |       |         |                           |                          |
|                    | \$5.3 | \$ 5.6  | \$ 0.3                    | 6%                       |
| xpense             |       | (3.3)   | (3.3)                     | 100%                     |
|                    | —     |         |                           |                          |
| l cost of revenues | \$5.3 | \$ 2.3  | \$(3.0)                   | (57%)                    |
|                    |       | _       |                           |                          |

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 announced its intention to 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     |
|------|------|--------------|--------------|
| 2003 | 2004 | 2003 to 2004 | 2003 to 2004 |

| 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 | 0.5   | 0.5    |        |      |
| Total research and development | \$9.5 | \$11.7 | \$ 2.2 | 23%  |
|                                |       |        |        |      |
|                                |       |        |        |      |

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 Mon | ths Ended September       | 30,                      |
|--------|----------|---------------------------|--------------------------|
| 2003   | 2004     | \$ Change<br>2003 to 2004 | % Change<br>2003 to 2004 |
| \$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 Mon | ths Ended September       | 30,                      |
|--------|----------|---------------------------|--------------------------|
| 2003   | 2004     | \$ Change<br>2003 to 2004 | % Change<br>2003 to 2004 |
| \$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 M | onths Ended Septembe      | er 30,                   |
|-----------------------|--------|--------|---------------------------|--------------------------|
|                       | 2003   | 2004   | \$ Change<br>2003 to 2004 | % Change<br>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 Mo | nths Ended Septembe       | r 30,                    |
|-------|---------|---------------------------|--------------------------|
| 2003  | 2004    | \$ Change<br>2003 to 2004 | % Change<br>2003 to 2004 |
| \$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

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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 M | onths Ended Septemb       | ver 30,                  |
|---------------|----|------|--------|---------------------------|--------------------------|
|               |    | 2003 | 2004   | \$ Change<br>2003 to 2004 | % Change<br>2003 to 2004 |
| Restructuring |    |      | \$1.7  | \$1.7                     | 100%                     |
|               | 40 |      |        |                           |                          |

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In September 2004, we restructured our operations to reduce operating expenses and concentrate our resources on four key products and product candidates, and related business initiatives. These products and product candidates consist of Viacord, Viacyte, CB001 and the cardiac development program. As a result, we recorded a \$1.7 million restructuring charge in the third quarter of 2004 related to employee 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<br>2003 to 2004 | % Change<br>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<br>2002 to 2003 | % Change<br>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<br>2002 to 2003 | % Change<br>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.

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.

While PharmaStem has announced its intention to appeal, we continue to believe that the lawsuit is without merit and that the judge s decision will be upheld on appeal.

|                              | 2002     | 2003   | \$ Change<br>2002 to 2003 | % Change<br>2002 to 2003 |
|------------------------------|----------|--------|---------------------------|--------------------------|
| 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%                      |
|                              | <u> </u> |        | —                         |                          |
| Total research & development | \$11.4   | \$13.2 | \$1.8                     | 16%                      |

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 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.

|                   | 2002   | 2003   | \$ Change<br>2002 to 2003 | % Change<br>2002 to 2003 |
|-------------------|--------|--------|---------------------------|--------------------------|
| 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.

|                          | 2002   | 2003   | \$ Change<br>2002 to 2003 | % Change<br>2002 to 2003 |
|--------------------------|--------|--------|---------------------------|--------------------------|
| 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.

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|                       | 2002  | 2003   | \$ Change<br>2002 to 2003 | % Change<br>2002 to 2003 |
|-----------------------|-------|--------|---------------------------|--------------------------|
| 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.

|                          | 2002  | 2003  | \$ Change<br>2002 to 2003 | % Change<br>2002 to 2003 |
|--------------------------|-------|-------|---------------------------|--------------------------|
| 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.

|                                      | 2002    | 2003    | \$ Change<br>2002 to 2003 | % Change<br>2002 to 2003 |
|--------------------------------------|---------|---------|---------------------------|--------------------------|
| 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)

|                             | 2001  | 2002   | \$ Change<br>2001 to 2002 | % Change<br>2001 to 2002 |
|-----------------------------|-------|--------|---------------------------|--------------------------|
| 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.

\$ Change % Change

|  |    | 2001  | 2002  | 2001 to 2002 | 2001 to 2002 |
|--|----|-------|-------|--------------|--------------|
| Cost of revenues:<br>Direct costs<br>Royalty expense |    | \$3.1 | \$5.9 | \$2.8        | 90%          |
| Total cost of revenues                               |    | \$3.1 | \$5.9 | \$2.8        | 90%          |
|  | 43 |       |       |              |              |

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.

|                                | 2001  | 2002   | \$ Change<br>2001 to 2002 | % Change<br>2001 to 2002 |
|--------------------------------|-------|--------|---------------------------|--------------------------|
| 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%                     |
|                                | —     |        | —                         |                          |
| 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.

|                   | 2001  | 2002   | \$ Change<br>2001 to 2002 | % Change<br>2001 to 2002 |
|-------------------|-------|--------|---------------------------|--------------------------|
| 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.

|                          | 2001  | 2002   | \$ Change<br>2001 to 2002 | % Change<br>2001 to 2002 |
|--------------------------|-------|--------|---------------------------|--------------------------|
| 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.

|                       | 2001  | 2002  | \$ Change<br>2001 to 2002 | % Change<br>2001 to 2002 |
|-----------------------|-------|-------|---------------------------|--------------------------|
| 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.

|                          |    | 2001  | 2002  | 2001 to 2002 | 2001 to 2002 |
|--------------------------|----|-------|-------|--------------|--------------|
| Stock-based compensation |    | \$4.5 | \$6.5 | \$2.0        | 44%          |
|                          | 44 |       |       |              |              |

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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<br>2001 to 2002 | % Change<br>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 Decem | ber 31,  |                           | 1 m                       | Nine Months<br>Ended<br>September 30, |
|---|----------|-------------|----------|---------------------------|---------------------------|---------------------------------------|
|   | 2001     | 2002        | 2003     | \$ Change<br>2001 to 2002 | \$ Change<br>2002 to 2003 | 2004                                  |
|   |          |             |          | (in thousands)            |                           |                                       |
| Net cash used in operating activities<br>Net cash provided by (used in) investing | \$(14.2) | \$(21.1)    | \$(22.5) | \$ (6.9)                  | \$ (1.4)                  | \$(11.2)                              |
| 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

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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 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 12 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, expansion of our manufacturing capacity and commercial infrastructure, 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.

# **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):

|                               |        |                       | Payments b            | y Due Period          |                     |
|-------------------------------|--------|-----------------------|-----------------------|-----------------------|---------------------|
| Contractual Obligations       | Total  | Less than<br>One Year | One to Three<br>Years | Four to Five<br>Years | After Five<br>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                 |
|                               |        |                       |                       | —                     |                     |
| Total contractual obligations | \$50.8 | \$19.6                | \$11.4                | \$5.0                 | \$14.8              |
|                               |        |                       |                       |                       |                     |

- (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 expect the number of physicians enrolled in this program will increase in the fourth quarter of 2004 and may record additional charges as more physicians participate in this program.

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### Loan Obligation

In October 2003, we entered into a \$5.0 million loan agreement with General Electric Capital Corporation. Borrowings under this agreement bear interest at 6.9% percent per annum and are collateralized by our fixed assets. Payments of principal and interest are due monthly through October 2006, and approximately \$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 will commence 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 U.S. 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 at the time of issuance at the election of each seller. Also, in our acquisition of Kourion Therapeutics, we



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issued and deposited 241,481 shares of our Series I preferred stock into an escrow account, which will 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 will 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, the Company 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, the Company 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 the Company 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 judgment 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 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 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 \$3.3 million in 2003 following a jury verdict in October 2003 which found infringement. This expense included a royalty of approximately \$2.9 million on revenues from cord blood preservation through October 29, 2003, plus an accrual of 6.125% of subsequent revenues through December 31, 2003. We also

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

Accounting for research and development expenses. Our research and development expenses primarily consist of costs associated with product development for CB001, the development of Selective Amplification and our other stem cell therapy technologies and our oocyte cryopreservation program. These expenses represent both clinical development costs and the costs associated with non-clinical support activities such as toxicological testing, manufacturing process development and regulatory consulting services. Clinical development costs represent internal costs for personnel, external costs incurred at clinical sites and contracted payments to third party clinical research organizations to perform certain clinical trials. We also report the costs of patent licenses in 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.

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).

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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 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 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.

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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.

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#### 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

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 \$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 candidate 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 obtaining FDA clearance for our media, we intend to commercialize Viacyte in 2005 through our existing commercial and operational infrastructure.

#### **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

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

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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.

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 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 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

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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 in 2005 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.

# 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

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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, which we expect to occur in 2005.

#### 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 preservation. This technology is expected to allow women to better preserve their fertility. In the future, we may pursue additional strategic acquisitions of technologies, product candidates and businesses to further strengthen or expand our current programs.

# **Our Technology**

## Selective Amplification Our Method to Expand Stem Cell Populations

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

The Selective Amplification process is described below:

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

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

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

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

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

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

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

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

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

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

#### 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.



# **Our Product and Product Candidates**

The following table summarizes our product and pipeline of programs:

| Product/Program       | Intended Use  | Status               |  |  |
|-----------------------|---|----------------------|--|--|
| Viacord               | Pediatric hematopoietic stem cell transplantation for the donor and siblings                | Marketed             |  |  |
| Viacyte               | Preservation of fertility   | Pre-Commercial Stage |  |  |
| Hematopoietic (CB001) | Hematopoietic stem cell transplantation for a variety of cancers and other serious diseases | Phase I              |  |  |
| Cardiac Disease       | Congestive heart failure<br>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

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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. Adding patients would potentially lengthen the study by approximately 6 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 trial outcome measures to establish that CB001 is superior 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

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hospitals in the United States. We currently store over 61,000 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 sumbilical 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 cyopreservation 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.

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*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. 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.

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.

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 superceded by this license and collaboration agreement.

## GlaxoSmithKline and Glaxo Group

In January 2003, we obtained a worldwide, non-exclusive license from GlaxoSmithKline and Glaxo Group to four forms of TPO-mimetic for use as a reagent in producing stem cell therapy products, including CB001. We paid an initial fee of \$115,000 and issued to the licensors 12,500 shares of our Series I preferred stock valued at \$8.00 per share (equaling \$0.1 million worth of preferred stock), and agreed to pay annual license maintenance fees over the next ten years totaling \$1.6 million and milestone payments potentially totaling \$2.1 million. Additionally, we will pay royalties on sales of any products using the licensed technology, creditable against any remaining maintenance fees. We are responsible for all manufacturing and related costs associated with our use of TPO-mimetic. Unless earlier terminated, the license extends on a country-by-country basis until the expiration of the underlying technology patents. The expiration of the issued patents will occur, no earlier than 2022, subject to extension upon the issuance of a patent based on a pending application provided that such issuance occurs within seven years of the filing date of the application. The agreement may be terminated by either party following an uncured material breach by the other party or in certain events involving the other s bankruptcy or insolvency. In addition, we can terminate the license at any time upon 30 days advanced notice. We did

not incur any royalties and recognized \$165,000 of expenses in connection with the annual license 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. 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 MGH, contingent upon the achievement of certain milestones as defined in the agreement, totaling a

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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. The escrowed shares will be released, and the contingent shares will 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. 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 either a qualified public offering, or 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 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 U.S. The Company expects 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           | Expiration Date  |           |
|-------------------------|--|-----------|
| US Patent No. 5,674,750 | Continuous Selective Clonogenic Expansion of Relatively Undifferentiated<br>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   | 10/6/2017 |
|                         | Producing Same   |           |
| 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 those that may issue to us in the future may be challenged, invalidated or circumvented, and the rights

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granted thereunder may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Expiration of patents we own or license could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

#### Competition

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

Gamida-Cell, a private company based in Israel, has a hematopoetic stem cell product candidate made from umbilical cord blood that is intended for use in hematopoietic stem cell transplants, similar to CB001. Gamida-Cell s product candidate 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 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 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.

#### 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

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labeling. As with BLA and NDA submissions, FDA must first grant filing and review of the PMA for a specific indication. FDA review of the PMA typically takes one to three years, but may last longer, especially if the FDA asks for more information or clarification of information already provided. As part of the PMA review, the FDA will typically inspect the manufacturer s facilities for compliance with the Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures.

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

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

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

labeling regulations;

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

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

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

*Compliance Requirements after BLA Licensure, NDA Approval, 510(k) Clearance, or PMA Approval.* Manufacturers of BLA licensed, NDA approved, 510(k) cleared, or PMA approved products must comply with FDA requirements for labeling, advertising, promotion, record keeping, reporting of adverse experiences and other reporting requirements. Violations of FDA or other governmental regulatory requirements during either the pre- or post-marketing stages may result in various adverse consequences, including:

issuance of warning letters;

fines, injunctions, and civil penalties;

recall or seizure of products;

cessation of clinical studies;

operating restrictions, partial suspension or total shutdown of production;

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

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

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

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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



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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. 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.

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 U.S. 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.

#### Employees

As of November 4, 2004, we employed 182 individuals, of which 17 hold an M.D. or Ph.D. degree. 98 of our employees are engaged in cord blood commercial operations, 52 are engaged in research and development activities, and 32 are engaged in senior management and administrative functions. Of our 182 employees, 166 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

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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. PharmaStem has stated its intention to appeal one or more of the Court s post-trial rulings. 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 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 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. We continue to believe that the patents in this new Massachusetts action are invalid and that we do not infringe them in any event. 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



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Delaware. We have also filed a motion to stay the Massachusetts litigation pending a ruling on our motion to consolidate the cases.

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.

#### 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, she specializes in immunology and stem cell transplantation.

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*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 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.

## MANAGEMENT

#### **Executive Officers, Key Employees and Directors**

Set forth below is information regarding our executive officers, key employees and directors, as of September 30, 2004.

| Name                         | Age | Positions   |  |  |
|------------------------------|-----|---|--|--|
| Executive Officers:          |     |   |  |  |
| Marc D. Beer                 | 39  | President, Chief Executive Officer and Director                                 |  |  |
| Stephen G. Dance             | 53  | Senior Vice President, Finance and Chief Financial Officer                      |  |  |
| Christoph M. Adams, Ph.D.    | 47  | Senior Vice President, Business Development                                     |  |  |
|                              |     | Senior Vice President, Clinical and Regulatory Affairs and Government Relations |  |  |
| Key Employees:               |     |   |  |  |
| Morey Kraus                  | 46  | Vice President and Chief Technical Officer                                      |  |  |
| Mary Larson-Marlowe          | 38  | Vice President, Therapeutic Development Operations                              |  |  |
| Mary T. Thistle              | 44  | General Manager, ViaCell Reproductive Health                                    |  |  |
| Stephan Wnendt, Ph.D.        | 42  | Senior Vice President, Research and Development                                 |  |  |
| Directors:                   |     |   |  |  |
| Vaughn M. Kailian            | 60  | Chairman of the Board   |  |  |
| George Daley, M.D., Ph.D.    | 43  | 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.

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*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.

#### 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 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.

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



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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 Aachen, Germany, received a Diploma in Biochemistry from the Free University of Berlin and a Ph.D. from the University of Technology, Berlin.

#### **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 the Biotechnology Industry Organization (BIO), the California Healthcare Institute, the Pharmaceutical Foundation Advisory Council at the University of Texas at Austin and he is a director of NicOx, S.A. and Millenium Pharmaceuticals, Inc. Mr. Kailian serves as vice chairperson of the Board of Directors of Millennium Pharmaceuticals as well as, since February 2002, head of the Millennium commercial organization. From 1990 to 2002, Mr. Kailian was CEO, President, and director of COR Therapeutics, Inc. 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.

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*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.

#### **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 was paid a total of \$21,500 in cash for his board service in 2003. Mr. van Heek was paid a total of \$6,000 in cash and is due 3,063 shares of common stock and also received options to purchase a total of 5,000 shares of our common stock at \$5.00 per share for his service in 2003 and has been granted options to purchase 15,000 shares of our common stock at \$5.00 per share to date for his services in 2004. Mr. Kailian began his service on our board in January 2004. For his service as chairman of the board, we have agreed to pay him \$100,000 per year, plus \$2,000 for each meeting attended and



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granted him in January 2004 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.

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 2003, Dr. Daley was paid \$10,500.

#### **Compensation Committee Interlocks and Insider Participation**

During 2003, our compensation committee consisted of Mr. Hastings, Dr. Gadicke and Mr. Tullis. 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 2003, 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 four other most highly compensated executive officers during 2003. We refer to these five people as the named executive officers.

#### **Summary Compensation Table**

|  | <b>2003</b> A | Annual Compens | Long-term<br>Compensation       |                                     |                           |
|--|---------------|----------------|---------------------------------|-------------------------------------|---------------------------|
| Name And Principal Position  | Salary        | Bonus          | Other Annual<br>Compensation(2) | Securities<br>Underlying<br>Options | All Other<br>Compensation |
| Marc D. Beer<br>President and Chief Executive Officer  | \$325,000     | \$87,750       |                                 |                                     |                           |
| Christoph M. Adams, Ph.D.<br>Senior Vice President, Business<br>Development                                | 209,535       | 39,255         |                                 |                                     |                           |
| Grant Bogle(3)<br>President, ViaCell Commercial<br>Operations  | 249,953       |                |                                 |                                     |                           |
| Kurt Gunter, M.D.<br>Senior Vice President, Clinical and<br>Regulatory Affairs and<br>Government Relations | 218,599       | 21,000         |                                 |                                     |                           |
| Jeffrey A. Sacher(4)<br>Chief Financial Officer  | 204,346       |                |                                 | 200,000                             | 115,179                   |

On January 1, 2004, Stephen G. Dance, our current Senior Vice President, Finance and Chief Financial Officer, joined us; his base salary for 2004 is \$235,000.

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

<sup>(2)</sup> 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.

(3) Mr. Bogle s employment with us terminated on March 31, 2004. 90

(4) Mr. Sacher s employment with us terminated on February 2, 2004. All other compensation reflects payments made to Mr. Sacher to reimburse his relocation expenses.

# **Stock Options**

The table below provides information regarding stock option grants by us to Mr. Sacher, who was the only named executive officer in 2003 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 713,436 shares of our common stock granted by us in 2003 to our employees, including the named executive officers.

## **Option Grants in Fiscal Year 2003**

|                      |                                       | Individu                               | al Grants             |                 | Assumed<br>Rates o | le Value       |
|----------------------|---------------------------------------|--|-----------------------|-----------------|--------------------|----------------|
|                      | Number of<br>Securities<br>Underlying | Percent of Total<br>Options Granted to | Exercise<br>Price Per | Expiration      | for O              | ption<br>ns(1) |
| Name                 | Options Granted                       | Employees in 2003                      | Share                 | Date            | 5%                 | 10%            |
| Jeffrey A. Sacher(2) | 200,000                               | 28.0%                                  | \$5.00                | January 1, 2013 | \$                 | \$             |

- (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 (assumed to be \$ 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.
- (2) In January 2003, we granted Mr. Sacher options to purchase 125,000 shares of our common stock at an exercise price of \$5.00 per share. These options vest quarterly over a period of four years. In January 2003, 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 the achievement of certain share prices following the completion of this offering. Under the terms of a mutual release and early separation agreement, Mr. Sacher s options will continue to vest until February 2, 2005, on which date all of Mr. Sacher s unexercised options (whether vested or unvested) will terminate.

The table below provides information regarding unexercised stock options held on December 31, 2003 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**

|                    | Number<br>Underlying<br>Opt<br>Decemb | Value of Unexercised<br>In-the-Money Options at<br>December 31, 2003(1) |             |               |
|--------------------|---------------------------------------|---|-------------|---------------|
| Name               | Exercisable                           | Unexercisable   | Exercisable | Unexercisable |
| Marc D. Beer       | 537,500                               | 962,500   | \$          | \$            |
| Christoph M. Adams | 56,250                                | 73,750  |             |               |
| Grant Bogle        | 78,125                                | 221,875   |             |               |
| Kurt Gunter        | 70,625                                | 89,375  |             |               |
| Jeffrey A. Sacher  |                                       | 200,000   |             |               |

(1) Based on the difference between the option exercise price and an assumed initial public offering price of \$ 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 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. 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.

## **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 \_\_\_\_\_\_\_, 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



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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 , 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.

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.

## 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 2006, we either experience a change in control or complete an underwritten initial public offering for a price per share of at least \$9.70 resulting in net proceeds of \$50 million or more. 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 issue to the rights holders if and only if the public offering price of our common stock in this offering, or the total net proceeds of the offering, is less than \$9.70 or \$50 million, respectively. If issued, 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.

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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.

## PRINCIPAL STOCKHOLDERS

The table below provides information about the beneficial ownership of our capital stock as of November 30, 2004 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 28,799,807 shares outstanding as of November 30, 2004, including shares of preferred stock on an as-converted basis, and also lists applicable percentage ownership based on 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 November 30, 2004, 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.

| Number of Shores                       | Percentage of Shares Outstanding   |   |  |
|--|--|---|--|
| Rumber of Shares<br>Beneficially Owned | Before Offering  | After Offering  |  |
| 5,597,096                              | 19.1%  | %   |  |
| 3,060,000                              | 10.4   |   |  |
| 2,761,822                              | 9.5  |   |  |
| 2,576,499                              | 8.9  |   |  |
| 2,350,776                              | 8.2  |   |  |
| 1,889,934                              | 6.6  |   |  |
| 1,692,184                              | 5.9  |   |  |
| 1,556,408                              | 5.4  |   |  |
| 5,602,096                              | 19.2   |   |  |
|  | 5,597,096<br>3,060,000<br>2,761,822<br>2,576,499<br>2,350,776<br>1,889,934<br>1,692,184<br>1,556,408 | Number of Shares Before Offering   5,597,096 19.1%   3,060,000 10.4   2,761,822 9.5   2,576,499 8.9   1,889,934 6.6   1,692,184 5.9   1,556,408 5.4 |  |

|  |  | Percentage of Shares Outstanding |                |
|--|--|----------------------------------|----------------|
| Name and Address of Beneficial Owners(1)                         | Number of Shares<br>Beneficially Owned | Before Offering                  | After Offering |
| James Tullis(10)   | 2,766,822                              | 9.5                              |                |
| c/o Tullis-Dickerson & Co., Inc.                                 |  |                                  |                |
| 2 Greenwich Plaza, 4th Floor                                     |  |                                  |                |
| Greenwich, CT 06830  |  |                                  |                |
| Denise Pollard-Knight(11)  | 1,697,184                              | 5.9                              |                |
| c/o Nomura International plc                                     |  |                                  |                |
| 1 St. Martin s le Grand  |  |                                  |                |
| London, EC1A 4NP, United Kingdom                                 |  |                                  |                |
| Marc D. Beer(12)   | 600,000                                | 2.0                              |                |
| George Q. Daley, M.D., Ph.D.(13)                                 | 181,198                                | *                                | *              |
| Childrens Hospital   |  |                                  |                |
| Division of Hematology/Oncology                                  |  |                                  |                |
| 1 Blackfan Circle  |  |                                  |                |
| Boston, MA 02114   |  |                                  |                |
| Kurt C. Gunter, M.D.(14)   | 113,125                                | *                                | *              |
| Christoph M. Adams, Ph.D.(15)                                    | 87,500                                 | *                                | *              |
| Jeff Sacher(16)  | 79,500                                 | *                                | *              |
| 12 Chanticleer Road  |  |                                  |                |
| Sudbury, MA 01776  |  |                                  |                |
| Vaughn Kailian(17)   | 40,000                                 | *                                | *              |
| Paul Hastings(18)  | 28,291                                 | *                                | *              |
| QLT Inc.   | ,                                      |                                  |                |
| 887 Great Northern Way   |  |                                  |                |
| Vancouver, BC  |  |                                  |                |
| Canada V5T 4T5   |  |                                  |                |
| Jan van Heek(19)   | 20,875                                 | *                                | *              |
| Genzyme Corporation  | ,                                      |                                  |                |
| One Kendall Square   |  |                                  |                |
| Cambridge, MA 02139  |  |                                  |                |
| Grant Bogle  |  | *                                | *              |
| All executive officers and directors as a group (11 persons)(20) | 11,168,340                             | 36.6%                            | %              |

\* 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 and fully-exercisable warrant to purchase 433,333 shares of common stock owned by BB BioVentures, L.P.

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

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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.

If the offering being made by this prospectus results in net proceeds to us of at least \$50 million at a public offering price of \$9.70 per share or higher, we will issue immediately after the offering a total of 289,256 shares to several MPM affiliated funds that are former stockholders of Kourion Therapeutics, a company we acquired in September 2003, as follows: 173,720 shares to MPM BioVentures II-QP, L.P., 61,175 shares to MPM BioVentures GmbH & Co. Parallel Bet. KG, 19,173 shares to MPM BioVentures, II, L.P., 3,603 shares to MPM Asset Management Investors 2001 LLC and 31,585 shares to MPM Founders LLC. Those shares are not reflected in this table. If those shares were to issue immediately after the closing of this offering, the MPM-affiliated funds would beneficially own an aggregate of 5,886,352 shares, or %, of our outstanding common stock.

If, however, this offering does not result in net proceeds to us of at least \$50 million, or if the public offering price is below \$9.70 per share, we will instead issue, immediately after the offering, warrants to purchase up to a total of 125,000 shares of common stock 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. Those shares are not reflected in this table. If those shares were to issue immediately after the closing of this offering, the MPM affiliated funds would beneficially own an aggregate of 5,722,096 shares, or %, of our outstanding common stock.

- (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. 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.



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(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 November 30, 2004.

(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 November 30, 2004.

(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 November 30, 2004.

- (12) Consists solely of options currently exercisable or exercisable within 60 days of November 30, 2004.
- (13) Includes 136,875 options currently exercisable or exercisable within 60 days of November 30, 2004.
- (14) Consists solely of options currently exercisable or exercisable within 60 days of November 30, 2004.
- (15) Consists solely of options currently exercisable or exercisable within 60 days of November 30, 2004.
- (16) Includes 62,500 options currently exercisable or exercisable within 60 days of November 30, 2004.
- (17) Consists solely of options currently exercisable or exercisable within 60 days of November 30, 2004.
- (18) Includes 25,000 options currently exercisable or exercisable within 60 days of November 30, 2004.
- (19) Includes 20,000 options currently exercisable or exercisable within 60 days of November 30, 2004.
- (20) Includes 1,068,749 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days of November 30, 2004 and fully-exercisable warrants to purchase 683,333 shares of stock.
  - 100

## 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 2,747,394 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 shares of common stock will be outstanding after giving effect to the sale of common stock we are offering hereunder, which:

includes 241,481 escrowed shares of common stock that we must release and 289,256 shares of common stock that we must issue to certain former stockholders of Kourion Therapeutics upon our closing a firm underwritten initial public offering if the price per share to the public is at least \$9.70 and the offering results in net proceeds to us of at least \$50 million; and

does not include any exercise of the underwriters over-allotment option or of any options or warrants.

## **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 September 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

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 existing investors in our Series J preferred stock if this offering results in net proceeds to us of less than \$50 million or if the public offering price per share 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.

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, if this offering results in net proceeds to us of at least \$50 million at a public offering price per share of \$9.70 or higher, we will release and issue upon closing this offering 241,481 escrowed shares and 289,256 contingent shares, respectively, of common stock with registration rights to former shareholders of Kourion Therapeutics. If this offering does not meet that net proceeds or that offering price threshold, then we will instead issue warrants to existing investors in our Series J preferred stock 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. 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

## NASDAQ National Market Listing

We are applying for our common stock to be quoted on the Nasdaq National Market under the symbol VIAC.

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#### 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 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

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, restricted shares will be eligible for resale, subject to the volume and other limitations imposed by Rule 144 as described below. Beginning 181 days after the date of this prospectus, restricted shares will be eligible for sale in the US public market, subject to the limitations imposed by Rule 144. The remainder of the shares of common stock outstanding will become eligible for sale under Rule 144 at various times over a period of approximately 18 months following the expiration of the 180 day lock-up period. In addition, as of December 10, 2004, there were outstanding options to purchase 4,446,236 shares of common stock and warrants to purchase 1,428,750 shares of common stock. Substantially all 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 be approximately

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. 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. 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. 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. However, 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.

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

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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.

### 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 , 2004, we have agreed to sell to the underwriters named below, for whom Credit Suisse First Boston LLC, UBS Securities LLC, Lazard Frères & Co. LLC and Leerink Swann & Company are acting as representatives, the following respective number of shares of common stock:

| Underwriters                   | Number<br>of Shares |
|--------------------------------|---------------------|
|                                |                     |
| Credit Suisse First Boston LLC |                     |
| UBS Securities LLC             |                     |
| Lazard Frères & Co. LLC        |                     |
| Leerink Swann & Company        |                     |
| Total                          |                     |

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 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 \$ per share on sales to other broker/ dealers. The underwriters and selling group members may allow a discount of \$ per share on sales to other broker/ dealers. After the initial public offering, the representatives may change the public offering price and concession and discount to broker/ dealers.

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

|  | Per Share      |                | Total          |                |
|--|----------------|----------------|----------------|----------------|
|  | Without        | With           | Without        | With           |
|  | Over-allotment | Over-allotment | Over-allotment | Over-allotment |
| Underwriting Discounts and Commissions paid by us Expenses payable by us | \$             | \$             | \$             | \$             |
|  | \$             | \$             | \$             | \$             |

The representatives of 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 or options, in each case outstanding on the date hereof, grants of employee stock options pursuant to the terms of a plan in effect on the date hereof (provided such options are not exercisable during the aforementioned 180-day period) and issuances of shares in connection with strategic acquisitions of technologies or businesses or establishment of strategic partnerships or collaborations complementary to

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our business (provided such shares are subject to restrictions on transfer for the remainder of the aforementioned 180-day period).

Our executive officers, directors, other senior management and substantially all of our securityholders 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 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.

We are applying to list the shares of common stock 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 will be determined by negotiation between us and the underwriters. The principal factors to be considered in determining the initial public offering price include the following:

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

market conditions for initial public offerings;

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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 representatives 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 representatives may agree to allocate a number of shares to underwriters and 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.

## 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 or ur 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 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.

# 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, 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 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.

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# ViaCell, Inc.

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## **Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying consolidated balance sheets and the related statements of operations, comprehensive loss, stockholders 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 statement, 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

## ViaCell, Inc.

# **Consolidated Balance Sheets**

|                           | As of Dec    | As of December 31, |                       | Pro Forma<br>As of          |  |
|---------------------------|--------------|--------------------|-----------------------|-----------------------------|--|
|                           | 2002         | 2003               | September 30,<br>2004 | September 30,<br>2004       |  |
|                           |              |                    | (Unaudited)           | (See Note 2)<br>(Unaudited) |  |
| ASSETS                    |              |                    |                       |                             |  |
| 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                   |  |