VIACELL INC
Form 10-Q
August 15, 2005

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U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2005
o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____.
Commission File Number 0-51110
VIACELL, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3244816**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
245 First Street, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	*(Zip Code)*

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. þ Yes o No
Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). o Yes þ No
As of August 8, 2005, 38,000,753 shares of the Company s common stock, $0.01 par value, were outstanding.

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PART I FINANCIAL INFORMATION

ITEM 1. ***FINANCIAL STATEMENTS***

ViaCell, Inc.
Condensed Consolidated Balance Sheets (unaudited)
(in thousands)

	June 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,693	$ 6,746
Short-term investments	25,228	21,339
Accounts receivable, net	14,194	10,808
Prepaid expenses and other current assets	3,766	4,928
Total current assets	81,881	43,821
Property and equipment, net	8,523	6,738
Goodwill	3,621	3,621
Intangible assets, net	2,924	3,025
Long-term investments		500
Restricted cash	1,944	1,953
Other assets	747	1,433
Total assets	$ 99,640	$ 61,091
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt obligations	$ 1,805	$ 1,743
Accounts payable	1,774	1,271
Accrued expenses	8,263	7,490
Notes payable to related party		15,422
Deferred revenue	5,153	3,458
Total current liabilities	16,995	29,384
Deferred revenue	8,455	6,728
Deferred rent	3,620	1,036
Contingent purchase price	8,155	8,155
Long-term debt obligations, net of current portion	712	1,572
Total liabilities	37,937	46,875
Redeemable convertible preferred stock, authorized 30,396,809 shares at December 31, 2004, issued and outstanding 25,628,075 at December 31, 2004		175,173
Commitments and contingencies (Note 7)		
Stockholders equity (deficit):		
Convertible preferred stock, $0.01 par value; authorized 5,000,000 and 428,191 shares at June 30, 2005 and December 31, 2004, respectively;		2

issued and outstanding 182,857 shares at December 31, 2004		
Common stock, $0.01 par value; authorized 100,000,000 and 80,000,000 shares at June 30, 2005 and December 31, 2004, respectively; issued and outstanding 37,531,110 and 2,763,961 shares at June 30, 2005 and December 31, 2004, respectively	375	28
Additional paid-in capital	228,604	
Deferred compensation	(1,633)	(2,530)
Accumulated other comprehensive income	254	309
Accumulated deficit	(165,897)	(158,766)
Total stockholders equity (deficit)	61,703	(160,957)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 99,640	$ 61,091

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

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ViaCell, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Revenues:				
Processing and storage revenues	$ 11,188	$ 9,263	$ 21,163	$ 17,846
Grant and contract revenues	195	413	360	849
Total revenues	11,383	9,676	21,523	18,695
Operating expenses:				
Cost of processing and storage revenues:				
Direct costs	2,023	1,856	3,971	3,674
Royalty expense		(3,784)		(3,258)
Total cost of processing and storage revenues	2,023	(1,928)	3,971	416
Research and development	3,026	3,889	6,602	7,875
Sales and marketing	6,034	4,776	11,525	10,430
General and administrative	3,367	4,022	6,131	7,390
Stock-based compensation(1)	358	1,005	794	1,869
Restructuring	90		211	
Total operating expenses	14,898	11,764	29,234	27,980
Loss from operations	(3,515)	(2,088)	(7,711)	(9,285)
Interest income (expense):				
Interest income	458	117	773	263
Interest expense	(38)	(364)	(193)	(758)
Total interest income (expense), net	420	(247)	580	(495)
Net loss	(3,095)	(2,335)	(7,131)	(9,780)
Accretion on redeemable convertible preferred stock		3,316	987	6,630
Net loss attributable to common stockholders	$ (3,095)	$ (5,651)	$ (8,118)	$ (16,410)
Net loss attributable to common stockholders per share:				
Net loss per common share, basic and diluted	$ (0.08)	$ (2.10)	$ (0.24)	$ (6.12)
Weighted average shares used in basic and diluted net loss per share computation	37,525,892	2,696,317	33,260,595	2,681,134

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Cost of processing and storage revenues	$ 5	$ 9	$ 10	$ 17
Research and development	90	169	160	495
Sales and marketing	42	45	120	149
General and administrative	221	782	504	1,208
Total stock-based compensation expense	$ 358	$ 1,005	$ 794	$ 1,869

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

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ViaCell, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	**2004**	**2005**	**2004**
Net loss	$ (3,095)	$ (2,335)	$ (7,131)	$ (9,780)
Foreign currency translation adjustment	(13)	(40)	(55)	(196)
Comprehensive loss	$ (3,108)	$ (2,375)	$ (7,186)	$ (9,976)

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

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ViaCell, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (7,131)	$ (9,780)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	991	1,333
Stock-based compensation	794	1,869
Reserve for bad debt	188	
Non-cash interest expense on related party note payable	87	560
Loss on disposal of property and equipment	17	69
Other	11	16
Changes in assets and liabilities:		
Accounts receivable	(3,390)	(1,602)
Prepaid expenses and other current assets	1,448	(1,499)
Accounts payable	510	(2,244)
Accrued expenses	335	(3,032)
Deferred revenue	3,421	2,741
Deferred rent	3,172	75
Net cash provided by (used in) operating activities	453	(11,494)
Cash flows from investing activities:		
Purchases of property and equipment	(2,721)	(1,132)
Proceeds from maturities of investments	14,346	8,978
Purchase of investments	(17,734)	(26,272)
Changes in other assets	210	197
Net cash used in investing activities	(5,899)	(18,229)
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	630	61
Proceeds from issuance of common stock, net	53,249	
Decrease in restricted cash		420
Repayments on long-term debt obligations	(822)	(768)
Repayment of notes payable to related party	(15,510)	
Payments of capital lease obligations	(45)	(34)
Net cash provided by (used in) financing activities	37,502	(321)
Effect of change in exchange rates on cash	(109)	(150)
Net increase (decrease) in cash and cash equivalents	31,947	(30,194)
Cash and cash equivalents, beginning of period	6,746	39,008

Cash and cash equivalents, end of period	$ 38,693	$ 8,814
Supplemental disclosures of cash flow information and non cash transactions		
Interest paid	$ 204	$ 179

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

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ViaCell, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Nature of Business

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

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

The Company restructured its operations in September 2004 and December 2004 to reduce operating expenses and concentrate its research and development resources on four key products and product candidates, and related business initiatives (see Note 10).

On January 26, 2005, the Company completed its initial public offering (IPO). The Company issued 8,625,000 shares of its common stock at $7.00 per share resulting in net proceeds to the Company of approximately $53,300,000 after underwriters discounts and offering expenses. As a result of the IPO, all outstanding shares of the Company s redeemable convertible preferred stock immediately converted into 25,810,932 shares of common stock. On January 26, 2005, the Company paid in full related party notes of approximately $15,510,000, which included all outstanding principal and interest accrued at that date.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial information as of June 30, 2005 and for the three and six months ended June 30, 2005 and June 30, 2004, and related notes, are unaudited but in management s opinion include all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary for fair statement of the interim periods presented. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. The Company s accounting policies are described in the Notes to the Consolidated Financial Statements in the Company s 2004 Annual Report on Form 10-K and updated, as necessary, in this Form 10-Q. Results for the three and six months ended June 30, 2005 are not necessarily indicative of results for the entire fiscal year or future periods. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been

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eliminated. Certain reclassifications of prior year amounts have been made to conform to current year presentation.

Use of Estimates

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

Redeemable Convertible Preferred Stock

The carrying value of redeemable convertible preferred stock is increased by periodic accretions, including cumulative dividends, so that the carrying amount will equal the redemption amount at the earliest redemption date. These increases are effected through charges to additional paid-in capital to the extent there are any and, thereafter, to accumulated deficit. All of the Company s outstanding redeemable convertible preferred shares outstanding automatically converted to the Company s common stock upon the completion of the IPO on January 26, 2005. There were no redeemable convertible preferred shares outstanding as of June 30, 2005.

Stock-Based Compensation

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

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

During the period ended June 30, 2005, the Company did not issue any options to employees with an exercise price below fair market value. During the six month periods ended June 30, 2005 and June 30, 2004, the Company recorded amortization of deferred compensation of approximately $792,000 and $1,587,000 respectively. At June 30, 2005 and December 31, 2004 approximately $1,633,000 and $2,530,000, respectively, of deferred stock compensation related to stock options remained unamortized.

During the six month periods ended June 30, 2005 and June 30, 2004, the Company recorded stock-based compensation expense of approximately $2,000 and $282,000, respectively, related to stock options granted to non-employees.

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

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss attributable to common stockholders as reported	$ (3,095)	$ (5,651)	$ (8,118)	$ (16,410)
Add: employee stock-based compensation expense included in reported net loss	358	800	792	1,587
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards	(1,144)	(1,377)	(2,222)	(2,697)
Pro forma net loss attributable to common stockholders	$ (3,881)	$ (6,228)	$ (9,548)	$ (17,520)
Basic and diluted net loss per share				
As reported	$ (0.08)	$ (2.10)	$ (0.24)	$ (6.12)
Pro forma	$ (0.10)	$ (2.31)	$ (0.29)	$ (6.53)

The Company has computed the pro forma disclosures required under SFAS No. 123 for all stock options granted to employees and directors of the Company as of June 30, 2005 and June 30, 2004 using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The weighted average assumptions used for the three and six months ended June 30 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Risk-free interest rate	3.61%	2.86%	3.61%	2.86%
Expected life	5 years	5 years	5 years	5 years
Expected volatility	100%	100%	100%	100%
Dividend yield	0%	0%	0%	0%

Segment Information

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

The following table presents total long-lived tangible assets by geographic areas as of June 30, 2005 and December 31, 2004, respectively (table in thousands):

	June 30, 2005	December 31, 2004
Long-lived tangible assets		
United States	$ 8,213	$ 6,310
Germany		88
Singapore	310	340
Total long-lived tangible assets	$ 8,523	$ 6,738

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The following table presents revenues by geographic area for the three and six months ended June 30, 2005 and June 30, 2004, respectively (table in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Revenues				
United States	$ 11,188	$ 9,311	$ 21,201	$ 18,024
Germany		292	(41)	543
Singapore	195	73	363	128
Total Revenues	$ 11,383	$ 9,676	$ 21,523	$ 18,695

Net Loss Per Common Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Basic and diluted net loss per share:				
Net loss attributable to common stockholders	$ (3,095)	$ (5,651)	$ (8,118)	$ (16,410)
Weighted average number of common shares outstanding	37,526	2,696	33,261	2,681
Basic and diluted net loss per share	$ (0.08)	$ (2.10)	$ (0.24)	$ (6.12)

The following potentially dilutive securities were excluded because their effect was antidilutive (table in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Options	4,143	4,848	3,869	4,766
Warrants	3,600	1,410	3,604	1,429
Convertible preferred stock		25,811		25,811

Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) released SFAS No. 123(R) - *Share-Based Payment*. This new accounting standard requires all forms of stock compensation, including stock options, to be reflected as an expense in the Company s financial statements. Public companies must adopt the standard by their first annual fiscal period beginning after June 15, 2005. The Company intends to apply the revised standard in the annual period beginning January, 2006. Although

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

In March 2005, the FASB issued FASB Interpretation No. 47 (FIN 47). FIN 47 clarifies the term *conditional asset retirement obligation* as used in FASB Statement No. 143, *Accounting for Asset Retirement Obligations,* referring to a legal obligation to perform an asset retirement activity. Accordingly, an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation if the fair value of the liability can be reasonably estimated. The provisions of FIN 47 are effective no later than the end of fiscal years ending after December 15, 2005. The Company will adopt this standard for asset retirement activity in the event that these types of transactions are entered into by the Company in future periods.

3. Property and Equipment

Property and equipment consisted of (table in thousands):

	June 30, 2005	December 31, 2004
Software	$ 2,709	$ 2,700
Laboratory equipment	4,674	4,675
Office and computer equipment	2,317	1,867
Leasehold improvements	3,129	3,129
Furniture and fixtures	719	717
Construction in progress	2,572	380
Property and equipment, gross	16,120	13,468
Less: accumulated depreciation	(7,597)	(6,730)
Property and equipment, net	$ 8,523	$ 6,738

At June 30, 2005 and December 31, 2004, equipment held under capital leases totaled approximately $494,000 and $475,000, respectively and accumulated depreciation related to this leased equipment totaled approximately $262,000 and $251,000, respectively.

Depreciation expense on property and equipment totaled approximately $426,000 and $613,000 for the three months ended June 30, 2005 and June 30, 2004, respectively. Depreciation expense on property and equipment totaled approximately $890,000 and $1,184,000 for the six months ended June 30, 2005 and June 30, 2004, respectively.

4. Intangible Assets

Intangible assets consist of a trademark and goodwill. Amortization of intangible assets was approximately $50,000 and $74,000 for the three months ended June 30, 2005 and June 30, 2004, respectively. Amortization of intangible assets was approximately $101,000 and $149,000 for the six months ended June 30, 2005 and June 30, 2004, respectively.

At June 30, 2005 and December 31, 2004, ViaCell s intangible assets consisted of the following (table in thousands):

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	June 30, 2005	December 31, 2004
Intangible assets:		
Trademark	$ 4,400	$ 4,400
Less: accumulated amortization	(1,476)	(1,375)
Intangible assets, net	$ 2,924	$ 3,025

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

5. Accrued Expenses

At June 30, 2005 and December 31, 2004, accrued expenses consisted of the following (table in thousands):

	June 30, 2005	December 31, 2004
Payroll and payroll related	$ 1,213	$ 1,016
Management incentive	553	723
Professional fees	1,647	2,027
Accrued marketing	1,290	912
Accrued restructuring	698	907
Other	2,862	1,905
	$ 8,263	$ 7,490

6. Long-Term Debt Obligations

The Company had the following long-term debt obligations as of June 30, 2005 and December 31, 2004 (table in thousands):

	June 30, 2005	December 31, 2004
Debt facility loans	$ 2,324	$ 3,136
Related party note payable		15,422
Capital lease obligations	193	179
Total long-term debt obligations	2,517	18,737
Less: current portion	(1,805)	(17,165)
Total long-term debt obligations, net of current portion	$ 712	$ 1,572

Notes Payable to Related Party

A portion of the consideration paid by the Company in its acquisition of Kourion Therapeutics consisted of promissory notes in an aggregate principal amount of $14.0 million. The notes were held by several funds that are also stockholders of the Company and that are affiliated with MPM Asset Management LLC, the manager of which served on the Company s board of directors until June 9, 2005. The notes bore interest at a rate of 8% per annum, compounded annually, and were to mature on September 30, 2007. They were subject to mandatory prepayment upon

the earlier of an initial public offering of the Company s common stock or a sale of the Company. The total outstanding principal and unpaid accrued interest on the notes as of December 31, 2004 was $15,422,000. On January 26, 2005,

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following the completion of its IPO, the Company paid off these related party notes totaling approximately $15,510,000, which included all outstanding principal and interest accrued at that date.

7. Commitments and Contingencies

Agreements

In January 2005, the Company entered into development and supply agreements with Miltenyi Biotec GmbH. The development agreement provides for the development by Miltenyi of a cGMP cell separation kit (the Product) for ViaCell consisting of various antibodies conjugated with magnetic particles to be used in ViaCell s Selective Amplification process for the development and commercialization of ViaCell s therapeutic cellular therapy products based on the Selective Amplification technology. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the Product, including making various filings with the US Food and Drug Administration (FDA). The Company is obligated to pay up to $950,000. As of June 30, 2005, the Company had paid $700,000 relating to this development program, and is recognizing expense as the work is performed over the two year development period. The remaining $250,000 is a milestone to be paid upon filing with the FDA. The term of the agreement ends on the earlier of the expiration of both parties obligations under the development agreement or January 24, 2007.

The supply agreement provides for the exclusive supply of the Product by Miltenyi to ViaCell. The initial term of the supply agreement is for seven years. The Company has guaranteed minimum purchase requirements totaling at least $1.6 million within the first year after the process development program has been completed. Also, the Company has certain minimum annual purchase requirements starting in fiscal 2007 which will apply if CB001 continues in clinical trials or is commercialized.

The Company has entered into an agreement with Economic Development Board of the government of Singapore to provide no more than $4,000,000 to fund stem cell research and development programs conducted in Singapore. Under this agreement, the government of Singapore reimburses to the Company a portion of these expenses under a grant. The Company funded approximately $341,000 and $257,000 of research and development in Singapore during the three months ended June 30, 2005 and June 30, 2004, respectively, and recorded grant revenue of approximately $196,000 and $73,000 during the three months ended June 30, 2005, and June 30, 2004, respectively. The Company funded approximately $637,000 and $440,000 of research and development in Singapore during the six months ended June 30, 2005 and June 30, 2004, respectively, and recorded grant revenue of approximately $363,000 and $128,000 during the six months ended June 30, 2005, and June 30, 2004, respectively.

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, typically with business partners, licensors and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the party s activities. Certain indemnification provisions survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of June 30, 2005.

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Litigation

The Company was sued by PharmaStem Therapeutics, Inc. (PharmaStem) for allegedly infringing two patents relating to the Company s Viacord umbilical cord stem cell cryopreservation business after the Company rejected PharmaStem s initial requests seeking a license arrangement because the Company believes that the Company does not infringe these patents and that they are invalid. PharmaStem filed a complaint in early 2002 against ViaCell and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 and No. 5,192,553, relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. In 2003, the jury ruled against the Company 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 ViaCell for approximately $2.9 million, based on 6.125% royalties on the Company s revenue from the processing and storage of umbilical cord blood since April 2000.

In 2004, the Delaware Court overturned the judgment against ViaCell on the 553 method patent, ruling that the Company did not infringe the patent. Regarding the 681 composition patent, the Court initially vacated the verdict and ordered a new trial on infringement and damages (if any), in connection with which, PharmaStem sought a preliminary injunction. However, the Court subsequently reversed its ruling, overturning the jury s verdict of infringement of the 681 patent and denying PharmaStem s motion for preliminary injunction. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005, that Motion to Expedite the Appeal was denied. PharmaStem s appeal brief was filed on March 22, 2005, and ViaCell s appeal brief was filed on May 16, 2005. On June 3, 2005, PharmaStem s appeal was dismissed for lack of appellate jurisdiction. The Federal Circuit held that the District Court case was not final because there was an unresolved Motion for Contempt Sanctions pending against PharmaStem. Following that dismissal, the parties to the Delaware litigation negotiated a resolution of the Motion for Contempt Sanctions, under which PharmaStem made changes to its website. On July 1, 2005, with the agreement of the parties, the court entered an Order denying as moot the Motion for Contempt Sanctions and directing the clerk to enter final judgment. On July 14, 2005, PharmaStem filed a Motion to Reinstate the Appeal. Our response to PharmaStem s Motion to Reinstate Appeals was filed on July 26, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both the 553 method patent and the 681 composition patent based on the prior art. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 patent as invalid over prior art. On May 18, 2005, the PTO vacated and terminated the re-examination of the 681 composition patent. On July 18, 2005, the re-examination requestor filed a Petition for Review of the PTO s Order vacating and terminating the re-examination of the 681 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 patent is reversed on appeal and if the Company is subsequently enjoined from further engaging in its umbilical cord stem cell cryopreservation business, the Company will not be able to conduct this business unless PharmaStem grants a license to the Company, which PharmaStem previously informed the Company that it would not do after October 15, 2004. While the Company does not believe this outcome is likely, if, in the event of an injunction, ViaCell is not able to obtain a license under the disputed patents or operate under an equitable doctrine known as intervening rights, the Company will be required to stop preserving and storing cord blood and to cease using cryopreserved umbilical cord blood as a source for stem cell products.

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PharmaStem also filed a complaint against the Company in July 2004 in the United States District Court for the District of Massachusetts, alleging infringement of US Patents No. 6,461,645 and 6,569,427, which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. By agreement of the parties, ViaCell responded to the complaint on December 16, 2004. The Company continues to believe that the patents in this new action are invalid and that the Company does not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That Motion is currently stayed. If this Motion is granted, the Company could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if the Company loses the case. ViaCell believes that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, the Company believes that PharmaStem s Motion will be denied. If the Company is ultimately found to infringe, it could have a significant damages award entered against it, and ViaCell could also face an injunction which could prohibit it from further engaging in the umbilical cord stem cell business absent a license from PharmaStem on the disputed patents. The Company believes the issues presented in this case are substantially the same as the issues presented in the Delaware litigation. Accordingly, the Company filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On January 21, 2005, the Massachusetts case was stayed pending a ruling on this request. On February 16, 2005, the Company s request was granted. The cases have thus been consolidated in Delaware. An initial pretrial conference regarding the schedule for litigating the consolidated cases has been set for October 6, 2005.

In April 2005, the US PTO ordered re-examination of claims of the patents at issue in the second litigation, the 645 and 427 patents, based on the prior art.

The timing and order of the litigations involving ViaCell and PharmaStem are not presently known. Decisions in the re-examination proceedings of the 553, 645, and 427 patents, now pending before the US PTO, may also affect these factors.

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

On May 13, 2004, the Company received a First Amended Complaint filed in the Superior Court of the State of California by Kenneth D. Worth, by and for the People of the State of California, and naming as defendants a number of private cord blood banks, including ViaCell. 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. On October 7, 2004, the Court orally granted a motion to strike the complaint under the California anti-SLAPP statute and dismissed the complaint as to all defendants without leave to amend. Judgment has been entered, dismissing the complaint, and plaintiff has filed a notice of appeal and a brief for the appeal and a petition for a writ of mandate. The petition has been dismissed and the appeal is proceeding. The plaintiff has settled the litigation with all defendants other than us. We are not yet able to conclude as to the likelihood that plaintiff s claims would be upheld if the judgment of dismissal were reversed on appeal, nor can we estimate the possible financial consequences should plaintiff prevail. However, we believe this suit to be without merit and intend to continue to vigorously defend ourselves.

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On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against the Company in the United States District Court for the Northern District of California alleging false and misleading advertising by the Company in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. On April 13, 2005, the Company answered the complaint, denying Cbr s allegations, and filed counterclaims alleging false and misleading advertising by Cbr. The Company s counterclaims seek an injunction and damages, and the Company intends to vigorously defend itself in this action.

From time to time, the Company becomes subject to legal proceedings and claims arising in connection with its business. With the exception of the PharmaStem complaint noted above, the Company does not believe that there were any asserted claims against it as of June 30, 2005 which, if adversely decided, would have a material adverse effect on results of operations, financial position or cash flow.

8. Redeemable Convertible Preferred Stock, Convertible Preferred Stock, and Stockholders Deficit

All of the Company s redeemable convertible preferred stock and convertible preferred stock converted to common stock upon closing the Company s IPO on January 26, 2005.

The Company s redeemable convertible preferred stock activity for period ended June 30, 2005 consisted of the following (table in thousands):

Balance December 31, 2004	$ 175,173
Issuance of Shares	
Accretion to Redemption Value	987
Conversion to Common Stock	(176,160)
Balance June 30, 2005	$

In connection with the September 2003 acquisition of Kourion, the Company issued 241,481 shares to an escrow account and reserved 289,256 shares for possible future issuance. These shares will be released and issued if a change in control of the Company occurs. If that event does not occur prior to September 30, 2006, the escrow shares will revert back to the Company and the reserved shares will not be issued.

In connection with the shares of Series K convertible preferred stock issued to Amgen and the current PharmaStem litigation, the Company has a side agreement under which Amgen had a one-time option to require the Company to redeem up to 1,250,000 of its Series K shares at a price of $8.00 per share. This option is triggered upon the occurrence of the earliest of June 23, 2007, a settlement or final judgment against the Company for a total amount exceeding $30 million (including the initial judgment amount as well as certain royalties, if any, that the Company becomes obligated to pay PharmaStem), or an injunction enjoining the Company s cord blood preservation operations that has not been stayed or vacated. This option expired upon the earliest of the second anniversary of the triggering event, a settlement or final judgment against the Company for a total amount less than or equal to $30 million (provided that an injunction is not currently in effect at the time), or a public offering of the Company s common stock in which all outstanding shares of convertible preferred stock of the Company automatically convert into common stock. All preferred stock immediately converted to common stock upon the completion of the Company s IPO in January 2005 and therefore this Amgen option terminated.

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Preferred Stock

Upon the closing of the Company s IPO on January 26, 2005, the Company amended its charter to provide for the authorization of 5,000,000 shares of undesignated preferred stock, par value $0.01 per share. As of June 30, 2005, none of such preferred stock has been designated and no shares are outstanding.

9. Warrants

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

10. Restructuring

In September 2004, the Company restructured its operations to reduce operating expenses and concentrate its resources on four key products and product candidates, and related business initiatives. These products and product candidates consist of Viacord, Viacyte, CB001 and the cardiac development program. As a result, the Company recorded a $1.7 million restructuring charge in the third quarter of 2004 related to employee severance, contract termination costs and the write-down of excess equipment. The majority of the contract termination costs related to the Company exercising the termination provision in its agreement with Gamete Technologies, under which the Company was required to pay $175,000 to Gamete Technologies.

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

The Company is still in discussions with the German grant authorities regarding repayment of part of the grant following the cessation of operations in Germany. In March 2005, the Company was notified that approximately $165,000 in grant proceeds related to fixed asset expenditures in Germany were not reimbursable under the grant and would have to be repaid. The Company recorded this liability in the three months ended March 31, 2005 by reversing $44,000 of grant revenue and recording $121,000 in additional restructuring expense. Following more recent discussions with the grant authorities, the

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Company believes it is probable that the grant authorities will request repayment by the Company of additional grant funds that were used to build out the German facility. The Company estimates the total repayment necessary will be approximately $340,000 and has increased its liability by an additional $90,000 during the three months ended June 30, 2005 to reserve for this potential repayment. It is also possible that the grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany, however the Company considers this possibility to be remote.

(In Thousands)	December 31, 2004	Additions	Writedowns	Adjustments	Payments	June 30, 2005
Severance related	$ 421	$	$	$	$ (421)	$
Contractual terminations	5				(5)	
Facility related	481			255	(38)	698
	$ 907	$	$	$ 255	$ (464)	$ 698

11. Subsequent Event

In July 2005 the Company s Board of Directors approved an increase, from 90 days to three years, in the amount of time allowed for non-employee directors to exercise vested options following the termination of service to the Company. As a result, the Company will recognize up to $1,004,000 in additional stock-based compensation expense. The recognition of the additional stock-based compensation expense will be approximately $637,000 and approximately $126,000 for the quarters ended September 30, 2005 and December 31, 2005, respectively. The remaining $241,000 will be recognized in years 2006 through 2008 based on respective vesting schedules associated with each modified option grant.

ITEM 2. ***MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

Forward-Looking Statements

The information set forth in this report in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Item 3, Quantitative and Qualitative Disclosure about Market Risk, includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and is subject to the safe harbor created by that section. Such statements may include, but are not limited to, projections of revenues, income or loss, capital expenditures, plans for product development and cooperative arrangements, future operations, financing needs or plans of ViaCell, as well as assumptions relating to the foregoing. The words believe, expect, will, anticipate, estimate, project, plan, and similar expressions i forward-looking statements, which speak only as of the date the statement was made. Factors that could cause results to differ materially from those projected or implied in the forward-looking statements are set forth below under the caption Risk Factors Relating to ViaCell s 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 products, and we are developing a pipeline of proprietary product candidates intended to address cancer, cardiac disease, diabetes and infertility, and a commercial business dedicated to the preservation of umbilical cord blood. Our research and development efforts focus primarily on developing cord

blood-derived stem cell

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product candidates in therapeutically useful quantities. CB001, our lead stem cell therapy product candidate, is currently in a Phase 1 clinical trial. We are developing applications of a proprietary type of stem cell called Unrestricted Somatic Stem Cells (USSCs) for the treatment of cardiac disease. In addition, we have a research stage program in collaboration with Genzyme targeting applications in diabetes. 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 business in the United States;
- expanding our pipeline of novel stem cell and other product candidates through internal development, and the acquisition or licensing 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 June 30, 2005, our accumulated deficit was approximately $165.9 million. From inception through June 30, 2005, we have raised approximately $191.1 million in common and preferred stock issuances, which includes approximately $53.3 million in net proceeds from our initial public offering in January 2005. 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 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.
- the working capital costs associated with anticipated growth of our ViaCell Reproductive Health business within the United States;

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 revenues from the sale of stem cell therapies. For these reasons, we have determined that we conduct operations in one business segment. The majority of our revenues since inception has been generated in the United States, and the majority of our long-lived assets is located in the United States.

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Revenues

Our current revenues are derived primarily from fees charged to families for the preservation and storage of a child s umbilical cord blood collected at birth. These fees consist of an initial fee for collection, processing and freezing of the umbilical cord blood and an annual 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 with 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 June 30, 2005. Following the September 2004 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, revenues or income from continuing operations.

In addition to the revenues generated by our Viacord product, we recorded revenues from grant agreements with the governments of Singapore and Germany. We maintain a research facility in Singapore. We decided to close our German research facility in December 2004, and have transitioned the research activities that had been performed there to the United States. Therefore, revenues from grants in Germany have ceased as of December 31, 2004.

Operating Expenses

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

We recorded a royalty expense of 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 approximately $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 and have not recorded any royalties since.

Pending further action by the courts, including the separate action recently consolidated with other litigation in Delaware, 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

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operations could be materially affected. In addition, we may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts by us to PharmaStem, or what those amounts might be.

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

We expect that research and development expenses will 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.

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

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

We are in discussions with the German grant authorities regarding repayment of part of the grant following the cessation of operations in Germany during the first quarter of 2005. In March 2005, we were notified that approximately $165,000 in grant proceeds related to certain fixed asset expenditures on our clean room in Germany were not reimbursable under the grant and would have to be repaid. We recorded this liability in the three months ended March 31, 2005 by reversing $44,000 of grant revenue and recording $121,000 in additional restructuring expense. Following more recent discussions with the grant authorities, we believe it is probable that the grant authorities will request repayment us of additional grant funds that were used to build out the German facility. As a result of these discussions, we estimate the total repayment necessary will be approximately $340,000 and have increased our liability by an additional $90,000 during the three months ended June 30, 2005 to reserve for this

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potential repayment. It is also possible that the grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany. Although we consider this possibility to be remote, and therefore have not established a reserve for these amounts, the German government could increase its demands for repayment and we may have to refund additional grant revenues beyond the amounts reserved although we can not estimate the amount at this time. As of June 30, 2005 we had received approximately $3.7 million in grant proceeds from the German grant authorities.

Results of Operations

Three and Six Months Ended June 30, 2005 and 2004 (table amounts in thousands)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
Revenues						
Processing revenues	$ 9,349	$ 8,193	14%	$ 17,668	$ 15,754	12%
Storage revenues	1,839	1,070	72%	3,495	2,092	67%
Processing and storage revenues	11,188	9,263	21%	21,163	17,846	19%
Grant and contract revenues	195	413	(53%)	360	849	(58%)
Total revenues	$ 11,383	$ 9,676	18%	$ 21,523	$ 18,695	15%

The increase in processing and storage revenues of $1.9 million or 21% from the three months ended June 30, 2004 to the three months ended June 30, 2005 was due primarily to increases in the number of cords processed and the total number of cords stored during the quarter, as well as an increase in pricing. The decrease in grant and contract revenues of $0.2 million or 53% was primarily due to the decrease in grant revenues of $0.3 million from Kourion Therapeutics, our German subsidiary, which was closed in 2004 and a decrease in contract revenues derived from research activities in the United States of $0.1 million. These decreases were partially offset by increases in grant revenues from the government of Singapore of $0.1 million.

The increase in processing and storage revenues of $3.3 million or 19% from the six months ended June 30, 2004 to the six months ended June 30, 2005 was due primarily to an increase in pricing, as well as an increase in the total number of cords processed and the total number of cords stored during the respective six month periods. The decrease in grant and contract revenues of $0.5 million or 58% was primarily due to the decrease of grant revenues of $0.6 million from Kourion Therapeutics, our German subsidiary, which was closed in 2004 and a decrease in contract revenues derived from research activities in the United States of $0.2 million. These decreases were partially offset by increases in grant revenues from the government of Singapore of $0.2 million.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
Cost of processing and storage revenues						
Direct costs	$ 2,023	$ 1,856	9%	$ 3,971	$ 3,674	8%
Royalty expense		(3,784)	(100%)		(3,258)	(100%)
Total cost of processing and storage revenues	$ 2,023	$ (1,928)	(205%)	$ 3,971	$ 416	855%

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The increase in direct costs of processing and storage revenues of $0.2 million or 9% from the three months ended June 30, 2004 to the three months ended June 30, 2005 and $0.3 million or 8% from the six months ended June 30, 2004 to the six months ended June 30, 2005 was due primarily to increases in variable expenses related to the increases in the number of cords processed and the number of cords stored. These variable expenses relate to transportation of, materials for collecting, and testing of the cord blood.

The credit in royalty expense of $3.8 million for the three months ended June 30, 2004 and $3.3 million for the six months ended June 30, 2004 was due to the reversal of the accrued liability in connection with the PharmaStem lawsuit following the judge s ruling in September 2004 that overturned a prior jury verdict, announced in October 2003, based on which we recorded a royalty expense. On December 14, 2004, the federal district court reversed its post-trial ruling granting a new trial on the issues of infringement and damages (if any) of the second patent and overturned the jury s verdict of infringement of that patent. In its September and December 2004 decisions, the judge found that there was no legally sufficient basis for finding infringement of either PharmaStem patent.

While PharmaStem has appealed the district court s judgment, we believe that the lawsuit is without merit and that, in light of the judge s ruling, no royalty accrual or expense is required.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	Change	2005	2004	Change
Research and development						
Clinical development	$ 2,219	$ 1,983	12%	$ 4,764	$ 4,047	18%
Pre-clinical programs	70	978	(93%)	401	1,999	(80%)
Basic research	596	729	(18%)	1,197	1,437	(17%)
Other research and development	141	199	(29%)	240	392	(39%)
Total research and development	$ 3,026	$ 3,889	(22%)	$ 6,602	$ 7,875	(16%)

Clinical development expense is related primarily to outside services and clinical trial expenses for CB001, and the increase of $0.2 million or 12% from the three months ended June 30, 2004 to the three months ended June 30, 2005 and $0.7 million or 18% from the six months ended June 30, 2004 to the six months ended June 30, 2005 reflected the cost of conducting the Phase I clinical trials that commenced in late 2003. The decrease in pre-clinical programs of $0.9 million or 93% from the three months ended June 30, 2004 to the three months ended June 30, 2005 and $1.6 million or 80% from the six months ended June 30, 2004 to the six months ended June 30, 2005 was primarily due to the movement of our cardiac repair program from Germany to the US at the end of 2004 following the closure of our German operations, and the discontinuation of our muscular dystrophy program in September 2004. This resulted in lower ongoing employee and facility related costs. Basic research expenses are primarily related to activity at our Singapore research center. Other research and development expense related primarily to our umbilical cord blood processing and storage business.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	Change	2005	2004	Change
Sales and marketing	$ 6,034	$ 4,776	26%	11,525	$ 10,430	10%

The increase in sales and marketing expense of $1.3 million or 26% from the three months ended June 30, 2004 to the three months ended June 30, 2005 was primarily related to external marketing program spending as well as increased staffing within the sales organization to strengthen our market

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presence. The increase in sales and marketing expense of $1.1 million or 10% from the six months ended June 30, 2004 to the six months ended June 30, 2005 was primarily due to increased spending on external marketing programs.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	Change	2005	2004	Change
General and administrative	$ 3,367	$ 4,022	(16%)	$ 6,131	$ 7,390	(17%)

The decrease in general and administrative expenses of $0.7 million or 16% from the three months ended June 30, 2004 to the three months ended June 30, 2005 and $1.3 million or 17% from the six months ended June 30, 2004 to the six months ended June 30, 2005 was primarily due to decreases in employee related costs as a result of our restructuring in September 2004 as well as a decrease in consulting costs related to our Viacyte program of approximately $0.4 million for the three months ended June 30, 2005 and $0.5 million for the six months ended June 30, 2005. These decreases were partially offset by an increase of $0.1 million for the three months ended June 30, 2005 and $0.3 million for the six months ended June 30, 2005 for insurance costs due to higher premiums associated with being a public company.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	Change	2005	2004	Change
Stock-based compensation	$ 358	$ 1,005	(64%)	$ 794	$ 1,869	(58%)

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 and relates to options granted prior to the Company s IPO. During the six months ended June 30, 2005, we did not grant any options with exercise prices less than fair market value.

In July 2005, the Company s Board of Directors approved an increase, from 90 days to three years, in the amount of time allowed for non-employee directors to exercise vested options following termination of service to the Company. This change was made in order to bring our non-employee director option grants in closer alignment with those of other companies in our industry. The stock-based compensation expense resulting from this change in option terms will be up to $1.0 million, of which approximately $0.6 million and approximately $0.1 million will be recognized in the quarters ended September 30, 2005 and December 31, 2005, respectively. The remaining $0.3 million will be recognized in years 2006 through 2008 based on respective vesting schedules associated with each modified option grant.

The amount of stock-based compensation actually recognized in future periods could decrease if options for which accrued but unvested compensation has been recorded are forfeited.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	Change	2005	2004	Change
Restructuring	$ 90	$	100%	$ 211	$	100%

The $0.1 million charge recorded in the three months ended March 31, 2005 is due to revised restructuring estimates related to the closure of our German facility. We are in discussions with

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the German grant authorities regarding repayment of part of the grant following the cessation of operations in Germany during the first quarter of 2005. In March 2005, we were notified that approximately $165,000 in grant proceeds related to certain fixed asset expenditures on our clean room in Germany were not reimbursable under the grant and would have to be repaid. We recorded this liability in the three months ended March 31, 2005 by reversing $44,000 of grant revenue and recording $121,000 in additional restructuring expense. Following more recent discussions with the grant authorities, we believe it is probable that the grant authorities will request repayment us of additional grant funds that were used to build out the German facility. As a result of these discussions, we estimate the total repayment necessary will be approximately $340,000 and have increased our liability by an additional $90,000 during the three months ended June 30, 2005 to reserve for this potential repayment. It is also possible that the grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany. Although we consider this possibility to be remote, and therefore have not established a reserve for these amounts, the German government could increase its demands for repayment and we may have to refund additional grant revenues beyond the amounts reserved although we can not estimate the amount at this time. As of June 30, 2005 we had received approximately $3.7 million in grant proceeds from the German grant authorities.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2005	2004	Change	2005	2004	Change
Interest income (expense)						
Interest income	$ 458	$ 117	292%	$ 773	$ 263	194%
Interest expense	(38)	(364)	(90%)	(193)	(758)	(75%)
Total interest income (expense), net	$ 420	$ (247)		$ 580	$ (495)	

Interest income is earned from the investment of our cash in short-term securities and money market funds. The increase in interest income of $0.3 million or 292% from the three months ended June 30, 2004 to the three months ended June 30, 2005 and $0.5 million or 194% from the six months ended June 30, 2004 to the six months ended June 30, 2005 primarily relates to increased average investment balances resulting from a higher cash balance available for investment following our initial public offering in January 2005. The decrease in interest expense of $0.3 million or 90% from the three months ended June 30, 2004 to the three months ended June 30, 2005 and $0.6 million or 75% from the six months ended June 30, 2004 to the six months ended June 30, 2005 relates to the reduction of interest on the related party notes payable, which were paid in full following the closing of our IPO in January 2005.

Liquidity and Capital Resources

From inception through June 30, 2005, we have raised $191.1 million in common and preferred stock issuances, which includes $53.3 million in net proceeds from our IPO in January 2005. We used approximately $15.5 million of these net proceeds to repay in full related party notes, including accrued interest. As of June 30, 2005, we had approximately $63.9 million in cash, cash equivalents and investments, which we believe is sufficient to meet our anticipated liquidity needs for at least the next three years.

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Table excerpted from the Company s Condensed Consolidated Statements of Cash Flows.

(000 s)	Six Months Ended June 30, 2005	Six Months Ended June 30, 2004	Change 2004 to 2005
Net cash provided by (used in) operating activities	$ 453	$ (11,494)	$ 11,947
Net cash used in investing activities	(5,899)	(18,229)	12,330
Net cash provided by (used in) financing activities	37,502	(321)	37,823
Cash & cash equivalents, end of period	$ 38,693	$ 8,814	$ 29,879

Net cash provided by operating activities was $0.5 million for the six months ended June 30, 2005, an increase of $11.9 million over the six months ended June 30, 2004. For the six months ended June 30, 2005, the $0.5 million in net cash provided by operating activities was due to a net increase in deferred rent of $3.2 million for payments from our landlord related to the build-out of our laboratory facility in Cambridge and prepaid rent received by us from a sublease tenant in Germany. In addition, we had a net increase in deferred revenue of $3.4 million related to increases in long-term pre-paid storage contracts, as well as advances received in connection with our grant program with the government of Singapore. These net increases in cash from operating activities were offset by our net loss, net of non-cash expenses, of $5.0 million and a net increase in working capital of $1.1 million.

Net cash used in investing activities for the six months ended June 30, 2005 was $5.9 million as compared to $18.2 million for the six months ended June 30, 2004. For the six months ended June 30, 2005, $14.3 million of US Government and high-rated corporate securities matured and $17.7 million was invested in similar securities. For the six months ended June 30, 2004, $9.0 million of US Government and high-rated corporate securities matured and $26.3 million was invested in similar securities. We also invested approximately $2.7 million and $1.1 million in property and equipment for the six months ended June 30, 2005 and 2004, respectively. Approximately $2.2 million of the total spent on property and equipment during the six months ended June 30, 2005 relates to the build-out of our manufacturing facility and laboratory in Cambridge. We expect to incur approximately $2.5 million in capital expenditures in 2005 in order to complete the build out of this facility, of which approximately $2.5 million is reimbursable by our landlord under a lease agreement. This facility, when completed, will give us the capacity to complete Phase II and Phase III clinical trials and proceed to initial commercialization of CB001, if successfully developed. We will need to build or acquire another 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. For the six months ended June 30, 2005, other assets decreased by $0.2 million, which relates to a portion of the GE Deposit becoming current.

Net cash provided by financing activities for the six months ended June 30, 2005 was $37.5 million. Net cash used in financing activities amounted to $0.3 million for the six months ended June 30, 2004, For the six months ended June 30, 2005, the net cash provided by financing activities included net proceeds from our IPO of $53.3 million and proceeds of $0.6 million relating to stock options exercised. These proceeds were partially reduced by cash used to repay related party notes of approximately $15.5 million related to the acquisition of Kourion Therapeutics and repayments of $0.8 million on our long-term debt obligations.

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

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Off-Balance Sheet Transactions

We did not have any off balance sheet transactions as of June 30, 2005.

Other Arrangements

In January 2005, we entered into development and supply agreements with Miltenyi Biotec GmbH. The development agreement provides for the development by Miltenyi of a cGMP cell separation kit (the Product) for us consisting of various antibodies conjugated with magnetic particles to be used in our Selective Amplification process for the development and commercialization of our therapeutic cellular therapy products based on the Selective Amplification technology. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the Product, including making various filings with the FDA. We are obligated to pay up to $950,000. As of June 30, 2005, we had paid $700,000 relating to this development program, and we are recognizing expense as the work is performed over the two year development period. The remaining $250,000 is a milestone to be paid upon filing with the FDA. The term of the agreement ends on the earlier of the expiration of both parties obligations under the development agreement and January 24, 2007.

The supply agreement provides for the exclusive supply of the Product by Miltenyi to us. The initial term of the supply agreement is for seven years. We have guaranteed minimum purchase requirements totaling at least $1.6 million within the first year after the process development program has been completed. Also, we have certain minimum annual purchase requirements starting in fiscal 2007 which will apply if CB001 continues in clinical trials or is commercialized.

We are a party to various agreements including license, research collaboration, consulting and employment agreements and may 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.

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 in early 2002 against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 and No. 5,192,553, relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. In 2003, 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.

In 2004, the Delaware Court overturned the judgment against ViaCell on the 553 method patent, ruling that we the Company did not infringe the patent. Regarding the 681 composition patent, the Court initially vacated the verdict and ordered a new trial on infringement and damages (if any), in connection with which, PharmaStem sought a preliminary injunction. However, the Court subsequently reversed its ruling, overturning the jury s verdict of infringement of the 681 patent and denying PharmaStem s motion for preliminary injunction. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005, that Motion to Expedite the Appeal

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was denied. PharmaStem s appeal brief was filed on March 22, 2005, and ViaCell s appeal brief was filed on May 16, 2005. On June 3, 2005, PharmaStem s appeal was dismissed for lack of appellate jurisdiction. The Federal Circuit held that the District Court case was not final because there was an unresolved Motion for Contempt Sanctions pending against PharmaStem. Following that dismissal, the parties to the Delaware litigation negotiated a resolution of the Motion for Contempt Sanctions, under which PharmaStem made changes to its website. On July 1, 2005, with the agreement of the parties, the court entered an Order denying as moot the Motion for Contempt Sanctions and directing the clerk to enter final judgment. The Company expects PharmaStem to file a new notice of appeal shortly. On July 14, 2005, PharmaStem filed a Motion to Reinstate the Appeal. Our response to PharmaStem s Motion to Reinstate Appeals was filed on July 26, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both the 553 method patent and the 681 composition patent based on the prior art. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 patent as invalid over prior art. On May 18, 2005, the PTO vacated and terminated the re-examination of the 681 composition patent. On July 18, 2005, the re-examination requestor filed a Petition for Review of the PTO s Order vacating and terminating the re-examination of the 681 patent.

Should the US PTO find the claims of these patents to be unpatentable, then the litigation proceedings between us and PharmaStem with respect to the unpatentable claims would cease. If the Court s judgment as to non-infringement of the 553 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 in July 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 action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That Motion is currently stayed. If this Motion is granted, we could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if we lose the case. We believe that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, we believe that PharmaStem s Motion will be denied. If we are ultimately found to infringe, we could have a significant damages award entered against us, and we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem on the disputed patents. We believe the issues presented in this case are substantially the same as the issues presented in the Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On January 21, 2005, the Massachusetts case was stayed pending a ruling on this request. On February 16, 2005, our request was granted. The cases have thus been consolidated in Delaware. An initial pretrial conference regarding the schedule for litigating the consolidated cases has been set for October 5, 2005.

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In April 2005, the US PTO ordered re-examination of claims of the patents at issue in the second litigation, the 645 and 427 patents, based on the prior art.

The timing and order of the litigations involving ViaCell and PharmaStem are not presently known. Decisions in the re-examination proceedings of the 553, 645 and 427 patents, now pending before the US PTO, 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 brief for the appeal and a petition for a writ of mandate. The petition has been dismissed and the appeal is proceeding. The plaintiff has settled the litigation with all defendants other than us. We are not yet able to conclude as to the likelihood that plaintiff s claims would be upheld if the judgment of dismissal were reversed on appeal, nor can we estimate the possible financial consequences should plaintiff prevail. However, we believe this suit to be without merit and intend to continue to vigorously defend ourselves.

On February 24, 2005, Cbr Systems, Inc., a private cord blood banking company, filed a complaint against us in the United States District Court for the Northern District of California alleging false and misleading advertising by us in violation of the federal Lanham Act and various California statutes and common law and seeking an injunction from continuing such advertising and unspecified damages. On April 13, 2005, we answered the complaint, denying Cbr s allegations, and filed counterclaims alleging false and misleading advertising by Cbr. Our counterclaims seek an injunction and damages, and we intend to vigorously defend ourselves in this action.

Critical Accounting Policies and Estimates

The Company s critical accounting estimates are disclosed in the section Management s Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Estimates of our Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

Risk Factors that May Affect Results

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

Our cellular therapy product candidates are in the early stages of development. In particular, our lead stem cell product candidate, CB001, has only recently entered Phase I clinical trials. CB001 has not previously been studied in humans, and we have very limited safety and no efficacy data on this product

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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 has progressed past Phase I clinical trials, we cannot determine whether our preclinical testing methodologies are predictive of clinical safety or efficacy. As we obtain results from further preclinical or clinical trials, we may elect to discontinue or delay preclinical studies or clinical trials for certain product candidates in order to focus our resources on more promising product candidates. We may also change the indication being pursued for a particular product candidate or otherwise revise the development plan for that candidate. Moreover, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical or initial clinical testing.

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

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

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

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

We have generated operating losses since our inception. As of June 30, 2005, we had cumulative net losses of approximately $165.9 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately $94.9 million since our inception. We expect our losses to continue for the next several years as we make substantial expenditures to further develop and commercialize our product candidates. In particular, we expect that our rate of spending will accelerate over the next several years as a result of increased costs and expenses associated with clinical trials, including our current Phase I trial for CB001 and our planned clinical trial for Viacyte, submissions for regulatory approvals and potential commercialization of our products, including the build out of commercial scale manufacturing facilities. Furthermore, we expect to make additional investments in the near term in our ViaCell Reproductive Health franchise, as we seek to expand the market for our Viacord product offering and develop our Viacyte product candidate. Our ability to become profitable will depend on many factors, including our ability to establish the safety and efficacy of our product candidates, obtain necessary regulatory approvals and successfully commercialize products. We cannot assure you that we will ever become profitable.

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

We were sued for allegedly 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 2004, the federal district court overturned the jury verdict against ViaCell on one of the two patents, ruling that we did not infringe the patent. Regarding the other patent, the Court initially vacated the verdict and granted a new trial on infringement and damages (if any) in connection with which PharmaStem sought a preliminary injunction. However, the Court subsequently reversed its ruling, overturning the jury s verdict of infringement of the patent and denying PharmaStem s motion for preliminary injunction. On January 6, 2005, PharmaStem filed a Notice of Appeal and on March 22, 2005 filed its appeal brief. Our appeal brief was filed on May 16, 2005. On June 3, 2005, PharmaStem s appeal was dismissed for lack of appellate jurisdiction. The Federal Circuit held that the District Court case was not final because there was an unresolved Motion for Contempt Sanctions pending against PharmaStem. Following that dismissal, the parties to the Delaware litigation negotiated a resolution of the Motion for Contempt Sanctions, under which PharmaStem made changes to its website. On July 1, 2005, with the agreement of the parties, the court entered an Order denying as moot the Motion for Contempt Sanctions and directing the clerk to enter final judgment. On July 14, 2005, PharmaStem filed a Motion to Reinstate the Appeal. Our response to PharmaStem s Motion to Reinstate Appeals was filed on July 26, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both of these patents based on the prior art submitted. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 method patent as unpatentable over the prior art. On May 18, 2005, the PTO vacated and terminated the re-examination of the 681 composition patent. On July 18, 2005, the re-examination requestor filed a Petition for Review of the PTO s Order vacating and terminating the re-examination of the 681 patent.

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PharmaStem will now have an opportunity to respond to this Office Action by arguing that its claims are patentable. If the US PTO does not find the claims of the patents to be unpatentable and if an appeal in the litigation is not resolved favorably to us, we could be enjoined from further engaging in our umbilical cord stem cell cryopreservation business. In such case, we will not be able to conduct this business unless PharmaStem grants a license to us. In such event, PharmaStem would be under no legal obligation to grant us a license or to do so on economically reasonable terms, and previously informed us that it would not do so at all 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, it would have a material adverse effect on our business, results of operations and financial condition, as we would no longer have access to the current source of almost all of our revenues. We had revenues of approximately $36.8 million in 2004 from Viacord sales. The judgment in the case, which was subsequently overturned, was entered against us for approximately $2.9 million relating to past infringement, based on 6.125% royalties on our revenue from the storage of umbilical cord blood since April 2000. If it becomes necessary, and we are able, to obtain a license from PharmaStem, it may be at a royalty rate greater than 6.125% or on terms less favorable than PharmaStem has granted to other cord blood banks. For example, we understand PharmaStem has licensed other cord blood banks under its patents for royalty rates of 15%. We have also been sued again by PharmaStem in federal district court in Massachusetts on two different but related patents, as have several others in the family cord blood preservation industry, albeit in separate actions in other courts, and many of the same risks are present in that litigation as in the original Delaware litigation. We filed and were subsequently granted - a motion to consolidate the Massachusetts case with six other actions in a single proceeding in the District of Delaware. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. If this Motion is granted, we could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if we lose the case. We believe that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, we believe that PharmaStem s Motion will be denied. We may enter into settlement negotiations with PharmaStem regarding our litigation with PharmaStem. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all. For a fuller discussion of the PharmaStem litigation, see the section entitled Part II, Item 1 Legal Proceedings of this report.

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

As of June 30, 2005, we had approximately $63.9 million in cash, cash equivalents and short-term 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 and development, preclinical testing and clinical trials. While we anticipate that our existing cash, cash equivalents and investments will be sufficient to fund our current operations for the next three years, we may need or want to raise additional funding sooner, particularly if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. We expect to attempt to raise additional funds well in advance of completely depleting our available funds.

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

the level of cash flows from our umbilical cord blood preservation activities;

the scope and results of our research and development programs;

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the scope and results of our clinical trials, particularly those involving CB001, which is currently in a Phase I trial and Viacyte;

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; and

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

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

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

The potential of stem cell therapy to treat serious diseases is currently being explored by us and other companies. It has not been proven in clinical trials that stem cell therapy will be an effective treatment for diseases other than those currently addressed by hematopoietic stem cell transplants. No stem cell products have been successfully developed and commercialized to date, and none has received regulatory approval in the United States or internationally. Stem cell therapy may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval or commercial use. If the potential of stem cell therapy to treat serious diseases is not realized, the value of our Selective Amplification technology and our development programs could be significantly reduced.

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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 at least three to five years 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. To date, enrollment in our Phase I clinical trial for CB001 has been slower than anticipated and we can not predict when enrollment will be completed. Negative or inconclusive results from or adverse medical events during a clinical trial could cause the clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful.

The FDA can place a clinical trial on hold if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury. If safety concerns develop, we or the FDA could stop our trials before completion. 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. Also, one of our trial subjects has experienced grade four acute graft versus host disease (GVHD) and another trial subject has failed to engraft within 42 days of CB001 infusion. Under our current protocol, if another subject experiences grade 4 acute GVHD, or if another subject fails to engraft within 42 days, we must halt the trial and, with the FDA and the institutional review boards, assess the extent to which, if at all, such incidences are related to CB001, and if related, whether the current Phase I trial can be continued or must be redesigned or terminated.

We continue to refine our Selective Amplification process, attempting to increase the expansion of undifferentiated stem cells, in order to increase the potential efficacy of the product candidate. In improving our Selective Amplification process, the resulting product candidate may be viewed by the FDA as sufficiently different from the product candidate being used in our current Phase I clinical trial to require that we conduct new Phase I clinical trials using the product candidate manufactured using the improved process to generate appropriate safety data to support later Phase II and III trials. Also, there is evidence that clinicians are increasingly using a new procedure for stem cell transplant patients involving less toxic doses of chemotherapy and radiation than used in conventional transplants. This so called mini-transplant procedure is not being used in our Phase I trials. If we need to redesign trials for CB001 that incorporates mini-transplants, it could require repeating earlier trials to support such additional trials or our marketing application. Repeating clinical trials for any of the reasons cited above would significantly delay our receipt of marketing approval for CB001, if received at all.

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

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based on cellular medicine generally. As a result, the pathway to regulatory approval for CB001 may be more complex and lengthy than the pathway for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the United States, we will need to submit clinical data concerning our products and receive regulatory approval from 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. The FDA has recently adopted new good tissue practice (GTP) regulations that establish a comprehensive regulatory program for human cellular and tissue-based products. Our Viacord cord blood preservation product is subject to these GTP regulations. 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. We believe that we comply with the new GTP regulations as recently adopted, however we have not yet been inspected by the FDA. However, we may not be able to maintain this compliance or comply with future regulatory requirements that may be imposed on us, including product standards that may be developed. Moreover, the cost of compliance with government regulations may adversely affect our revenue and profitability. Regulation of our cord blood preservation services in foreign jurisdictions is still evolving.

Consistent with industry practice, the Viacord 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 all of these states. If other states adopt requirements for the licensing or registration of cord blood preservation services, we would have to obtain licenses or register to continue providing services in those states.

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

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

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

Clinical data were not included in the original 510(k) application. Our media supplier responded to the FDA letter by submitting existing, published third party clinical data in lieu of the requested study.

In April of 2005 our media supplier received another letter from the FDA indicating:

a statement that our media supplier had not demonstrated substantial equivalence of the media to a predicate device and therefore the FDA did not clear the media for commercial use.

a statement that our media supplier could submit a new 510(k) when additional data supporting substantial equivalence of the media to a predicate device are available. The Company believes data from a new clinical trial could a support substantial equivalence determination and a new 510(k) submission.

a statement that, at present, the media has been classified as a class III device and that in order to commercially market the device in the U.S. an approved PMA would be required.

a statement that any clinical investigation preformed using the media in the U.S. will require an investigation device exemption (IDE).

We believe that a 510(k) pathway is still possible for this device, but that the FDA will require a new clinical study to support the new 510(k) submission. Even if such a study is conducted, we cannot assure you that the FDA will find the data sufficient to grant 510(k) clearance or that the FDA will not continue to require PMA approval in order to market this product.

We believe that the time to conduct a clinical study, prepare a new 510(k), and receive FDA clearance will be approximately 3-4 years. Again, we cannot assure you that the media will be cleared for marketing by the FDA even following submission of a new 510(k) supported by a clinical study. If we receive FDA clearance for the media following this pathway and timeframe, we believe we could commence a U.S. product launch in approximately 2008-09.

If we conduct a new clinical study and submit a new 510(k), and the FDA does not find the information adequate to support 510(k) clearance, we would need to obtain PMA approval. This requirement would substantially lengthen our planned developmental timeline and increase the costs of commercializing this product. We believe the time to prepare the necessary regulatory filings for a PMA and allow for FDA review would add approximately one year to the timeline, which would support a U.S. product launch in approximately 2009-10. We cannot assure you that this product will receive either 510(k) clearance or PMA approval within these estimated time frames, or at all.

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

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to six US patents and three international patents. We also own or have exclusive licenses to 13 pending applications in the United States and over 50 pending applications in foreign countries. Our pending patent applications may not issue, and we may not receive any additional patents. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the 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.

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;

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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 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 June 30, 2005 of approximately $7.0 million. Depending upon the extent of the appeals process concerning either or both patents asserted in Delaware, and the extent we litigate the additional patent infringement lawsuit originally brought by PharmaStem in Massachusetts and any related appeals, we estimate that we could incur at least an additional $1.0 million to $2.0 million in litigation expenses. Further, if other patent infringement suits were brought against us, our collaborators or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or

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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.

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.

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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.

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

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

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

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

Certain antibodies, growth factors and other reagents are critical components used in our stem cell production process. Our Selective Amplification process currently uses components sold to us by certain manufacturers, and we need to establish relationships with other suppliers to manufacture cGMP grade products for commercial sale. We are materially dependent on our suppliers for such components. Some of these components are supplied to us by Amgen, GlaxoSmithKline and Miltenyi Biotec, with whom we have agreements to supply SCF, Flt-3, Tpo mimetic and cGMP grade antibodies conjugated with magnetic particles and who are 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 and R&D Systems, with which we do not have relationships. In order to continue our clinical trials and commercialize our Selective Amplification products, we will need to establish relationships with some of these suppliers. In the event that our suppliers are unable or unwilling to produce such components on commercially reasonable terms, and we are unable to find substitute suppliers for such components, we may not be able to commercialize our stem cell products. We depend on our suppliers to perform their obligations in a timely manner and in accordance with applicable government regulations. In the event that any of these suppliers becomes unwilling or unable to continue to supply necessary components for the manufacture of our stem cell products, we will need to repeat certain development work to identify and demonstrate the equivalence of alternative components purchased from other suppliers. If we are unable to demonstrate the equivalence of alternative components in a timely manner, or purchase these alternative components on commercially reasonable terms, development of our products may be delayed and we may not be able to complete development of or market our stem cell products.

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

In order to produce cells for use in clinical studies and produce stem cell products for commercial sale, certain biological components used in our production process will need to be manufactured in compliance with current Good Manufacturing Practices, or cGMP. To meet this requirement, we will need to enter into supply agreements with firms who manufacture these components to cGMP standards. We are currently in discussions with multiple firms who we may engage as suppliers for these components. Once we engage these third parties, we may be materially dependent on them for supply of cGMP grade components. If we are unable to obtain cGMP grade biological components for our products, we may not be able to market our stem cell products.

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

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

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

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

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

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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. Any of our key employees could terminate his or her relationship with us at any time and, despite any non-competition agreement with us, work for one of our competitors. Furthermore, our future growth will require hiring a significant number of qualified technical, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success.

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

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

We expect to continue expanding our reproductive health services in the United States. This expansion could put significant strain on our management, operational and financial resources. Currently, our only facilities abroad are offices and laboratories in Singapore. To manage future growth, we would need to hire, train and manage additional employees, particularly a specially-trained sales force. We plan to begin commercializing our oocyte cryopreservation technology if and when the cryopreservation media obtains FDA clearance. In April 2005, our media supplier received a letter from the FDA stating that a new clinical trial would be required, that the media had been reclassified as a class 3 device and that in order to commercially market the device in the U.S. an approved PMA would be required, unless the device was later reclassified, in which case the media could be cleared for marketing based on a 510(k) filing. Should the media be cleared for marketing to commercialize this product, we would be required to institute additional and distinct sales and marketing, manufacturing and storage capacities in addition to leveraging our existing capabilities in these areas. Concurrent with expanding our reproductive health activities, we will also be increasing our research and development activities, most significantly the clinical development of our lead product candidate, CB001, with the expectation of ultimately commercializing that product candidate.

Prior to our recently completed initial public offering in January, we maintained a small finance and accounting staff because we were a private company. Our new reporting obligations as a public company, as well as our need to comply with the requirements of the Sarbanes-Oxley Act of 2002, the rules and regulations of the Securities and Exchange Commission and the Nasdaq National Market, place significant additional demands on our finance and accounting staff, on our financial, accounting and information systems and on our internal controls. We intend have added 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

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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.

We may be liable for reimbursement of funds received from the German grant authorities.

We are in discussions with the German grant authorities regarding repayment of part of the grant following the cessation of operations in Germany during the first quarter of 2005. In March 2005, we were notified that approximately $165,000 in grant proceeds related to certain fixed asset expenditures on our clean room in Germany were not reimbursable under the grant and would have to be repaid. Following more recent discussions with the grant authorities, we believe it is probable that the grant authorities will request additional repayment of grant funds related to these fixed asset expenditures. As a result of these discussions, we estimate the total repayment necessary will be approximately $340,000 and we have increased our reserves to account for this potential liability. It is also possible that the grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany. Although we consider this possibility to be remote, and therefore have not established a reserve for these amounts, the German government could increase its demands for repayment and we may have to refund additional grant revenues beyond the amounts reserved although we can not estimate the amount at this time. As of June 30, 2005 we had received approximately $3.7 million in grant proceeds from the German grant authorities.

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

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

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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 ourselves as a premium provider of cord blood preservation among our competitors. While we seek to maintain high standards in all aspects of our provision of products and services, we cannot guarantee that we will not experience 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

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

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

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

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

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

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

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

The use of embryonic stem cells for research and stem cell therapy has been the subject of debate regarding related ethical, legal and social issues. Although we do not currently use embryonic stem cells as a source for our research programs, the use of other types of human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with embryonic stem cells. The

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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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Investment Risk

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

Foreign Exchange Risk

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

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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 bonds and money market instruments. These investments are denominated in US dollars. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

ITEM 4. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2005 and, based on their evaluation, our principal executive officer and principal financial officer have concluded that these controls and procedures are effective. Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

There were no changes in our internal controls over financial reporting during the quarter ended June 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

PharmaStem Litigation

As discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, 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 in early 2002 against us and several other defendants in the United States District Court for the District of Delaware, alleging infringement of US Patents No. 5,004,681 and No. 5,192,553, relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. In 2003, 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.

In 2004, the Delaware Court overturned the judgment against ViaCell on the 553 method patent, ruling that we did not infringe the patent. Regarding the 681 composition patent, the Court initially vacated the verdict and ordered a new trial on infringement and damages (if any), in connection with which, PharmaStem sought a preliminary injunction. However, the Court subsequently reversed its ruling, overturning the jury s verdict of infringement of the 681 patent and denying PharmaStem s motion for preliminary injunction. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the Court s decision. On February 15, 2005, that Motion to Expedite the Appeal

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was denied. PharmaStem s appeal brief was filed on March 22, 2005, and our appeal brief was filed on May 16, 2005. On June 3, 2005, PharmaStem s appeal was dismissed for lack of appellate jurisdiction. The Federal Circuit held that the District Court case was not final because there was an unresolved Motion for Contempt Sanctions pending against PharmaStem. Following that dismissal, the parties to the Delaware litigation negotiated a resolution of the Motion for Contempt Sanctions, under which PharmaStem made changes to its website. On July 1, 2005, with the agreement of the parties, the court entered an Order denying as moot the Motion for Contempt Sanctions and directing the clerk to enter final judgment. On July 14, 2005, PharmaStem filed a Motion to Reinstate the Appeal. Our response to PharmaStem s Motion to Reinstate Appeals was filed on July 26, 2005.

In August 2004, the US Patent and Trademark Office (US PTO) ordered the re-examination of both the 553 method patent and the 681 composition patent based on the prior art. On February 2, 2005, the PTO issued an Office Action rejecting all claims of the 553 patent as invalid over prior art. On May 18, 2005, the PTO vacated and terminated the reexamination of the 681 composition patent. On July 18, 2005, the re-examination requestor filed a Petition for Review of the PTO s Order vacating and terminating the reexamination of the 681 patent.

Should the US PTO find the claims of these patents to be unpatentable, then the litigation proceedings between us and PharmaStem with respect to the unpatentable claims would cease. If the Court s judgment as to non-infringement of the 553 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 in July 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 action are invalid and that we do not infringe them in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That Motion is currently stayed. If this Motion is granted, we could be enjoined from collecting and storing cord blood that had not been collected as of the date the injunction is issued while the case is litigated and thereafter if we lose the case. We believe that the issues presented in PharmaStem s Motion are substantially the same as the issues presented in the Delaware litigation and, while no assurance can be given, we believe that PharmaStem s Motion will be denied. If we are ultimately found to infringe, we could have a significant damages award entered against us, and we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem on the disputed patents. We believe the issues presented in this case are substantially the same as the issues presented in the Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On January 21, 2005, the Massachusetts case was stayed pending a ruling on this request. On February 16, 2005, our request was granted. The cases have thus been consolidated in Delaware. An initial pretrial conference regarding the schedule for litigating the consolidated cases has been set for October 6, 2005.

In April 2005, the US PTO ordered re-examination of claims of the patents at issue in the second litigation, the 645 and 427 patents, based on the prior art.

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The timing and order of the litigations involving ViaCell and PharmaStem are not presently known. Decisions in the re-examination proceedings of the 553, 645 and 427 patents, now pending before the US PTO, 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.

Worth Litigation

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Changes in Securities

None.

Use of Proceeds from Registered Securities

Our common stock has been traded on the NASDAQ National Market System under the symbol VIAC since January 21, 2005. Prior to that time there was no established public trading market for our common stock.

In connection with our initial public offering, we registered shares of our common stock under the Securities Act of 1933, as amended. Our registration statement on Form S-1 (Reg. No. 333-114209) was declared effective by the SEC on January 19, 2005. The net offering proceeds to us were approximately $53,300,000 after deducting expenses.

During the six months ended June 30, 2005, the Company used the net proceeds of the IPO in the following manner:

- approximately $15,510,000 to pay off all outstanding principal and interest on promissory notes held by funds affiliated with MPM Asset Management LLC, the manager of which served on the Company s board of directors until June 9, 2005;

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approximately $7,000,000 toward working capital and property and equipment, including our clinical trials for CB001 and preclinical research and development activities relating to our product candidates; and

approximately $30,790,000 in temporary investments.

Other than repayment of certain promissory notes, no payments of such proceeds were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

At the Annual Meeting of Stockholders held on June 9, 2005, ViaCell s stockholders voted as follows:

To elect the following nominees to the Board of Directors:

Nominee	Total Vote FOR	Total Vote WITHHELD
Barbara Bierer	27,209,710	72,197
Denise Pollard-Knight	27,048,560	233,347
James Tullis	27,229,441	52,466

All nominees received a plurality of the votes cast by stockholders entitled to vote thereon and, therefore, Dr. Bierer, Dr. Pollard-Knight and Mr. Tullis were elected to the Board of Directors for a term of three years. In addition, the terms in office of Mr. Hastings, Mr. van Heek, Mr. Daley, Mr.Beer, and Mr. Kailian continued after the meeting.

ITEM 5. OTHER INFORMATION

Executive Management Equity Awards

On April 27, 2005, the Board approved the Compensation Committee s recommendation to grant Christoph Adams, Senior Vice President, Business Development and Kurt Gunter, Senior Vice President. Clinical and Regulatory Affairs and Government Relations, each an incentive stock option to purchase 25,000 shares of ViaCell common stock at an exercise price of $7.25 per share (the closing price of our common stock on the Nasdaq National Market on the date preceding the date of grant), vesting quarterly in sixteen equal installments with respect to the underlying shares commencing on May 18, 2005 and continuing on each three month anniversary of such date.

ITEM 6. EXHIBITS

See the Exhibit Index following the Signatures page below.

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SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VIACELL, INC.

Date: August 15, 2005

/s/ MARC D. BEER
Marc D. Beer
Chief Executive Officer
(Principal Executive Officer)

Date: August 15, 2005

/s/ STEPHEN G. DANCE
Stephen G. Dance
Chief Financial Officer
(Principal Financial Officer)

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EXHIBIT INDEX

No.	Item
31.1	Chief Executive Officer Certification Pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer Certification Pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chief Executive Officer Certification pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer Certification pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002