VIACELL INC
Form 10-Q
November 14, 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 September 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
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of Exchange Act). Yes o No þ
As of November 11, 2005, 38,352,967 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, amounts in thousands, except per share data)

	September 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,523	$ 6,746
Short-term investments	21,965	21,339
Accounts receivable, net	15,132	10,808
Prepaid expenses and other current assets	2,680	4,928
Total current assets	79,300	43,821
Property and equipment, net	8,958	6,738
Goodwill	3,621	3,621
Intangible assets, net	2,874	3,025
Long-term investments		500
Restricted cash	1,934	1,953
Other assets	762	1,433
Total assets	$ 97,449	$ 61,091
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt obligations	$ 1,834	$ 1,743
Accounts payable	616	1,271
Accrued expenses	8,244	7,490
Notes payable to related party		15,422
Deferred revenue	5,577	3,458
Total current liabilities	16,271	29,384
Deferred revenue	9,423	6,728
Deferred rent	3,767	1,036
Contingent purchase price	8,155	8,155
Long-term debt obligations, net of current portion	245	1,572
Total liabilities	37,861	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):		
Preferred stock, $0.01 par value; authorized 5,000,000 shares, 0 issued and outstanding at September 30, 2005 and December 31, 2004		

Convertible preferred stock, $0.01 par value; authorized 428,191 shares at December 31, 2004, issued and outstanding 182,857 convertible preferred shares at December 31, 2004		
Common stock, $0.01 par value; authorized 100,000,000 and 80,000,000 shares at September 30, 2005 and December 31, 2004, respectively; issued and outstanding 37,996,100 and 2,763,961 shares at September 30, 2005 and December 31, 2004, respectively	380	28
Additional paid-in capital	229,885	
Deferred compensation	(1,431)	(2,530)
Accumulated other comprehensive income	208	309
Accumulated deficit	(169,454)	(158,766)
Total stockholders equity (deficit)	59,588	(160,957)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 97,449	$ 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 September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues:				
Processing and storage revenues	$ 11,555	$ 9,552	$ 32,718	$ 27,397
Grant and contract revenues	135	386	495	1,236
Total revenues	11,690	9,938	33,213	28,633
Operating expenses:				
Cost of processing and storage revenues:				
Direct costs	2,164	1,839	6,136	5,514
Royalty expense				(3,258)
Total cost of processing and storage revenues	2,164	1,839	6,136	2,256
Research and development	3,278	3,824	9,879	11,698
Sales and marketing	6,259	4,651	17,784	15,081
General and administrative	2,847	3,010	8,978	10,401
Stock-based compensation(1)	1,024	793	1,818	2,662
Restructuring	94	1,740	305	1,740
Total operating expenses	15,666	15,857	44,900	43,838
Loss from operations	(3,976)	(5,919)	(11,687)	(15,205)
Interest income (expense):				
Interest income	531	139	1,305	402
Interest expense	(113)	(360)	(306)	(1,118)
Total interest income (expense), net	418	(221)	999	(716)
Net loss	(3,558)	(6,140)	(10,688)	(15,921)
Accretion on redeemable convertible preferred stock		(3,314)	(987)	(9,944)
Net loss attributable to common stockholders	$ (3,558)	$ (9,454)	$ (11,675)	$ (25,865)
Net loss attributable to common stockholders per share:				
Net loss per common share, basic and diluted	$ (0.09)	$ (3.49)	$ (0.33)	$ (9.62)
Weighted average shares used in basic and diluted net loss per share computation	37,771,959	2,707,538	34,877,333	2,689,866

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Cost of processing and storage revenues	$ 5	$ 8	$ 15	$ 25
Research and development	34	37	194	532
Sales and marketing	45	34	165	184
General and administrative	940	714	1,444	1,921
Total stock-based compensation expense	$ 1,024	$ 793	$ 1,818	$ 2,662

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 September 30,		Nine Months Ended September 30,	
	2005	**2004**	**2005**	**2004**
Net loss	$ (3,558)	$ (6,140)	$ (10,688)	$ (15,921)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(46)	74	(101)	(122)
Comprehensive loss	$ (3,604)	$ (6,066)	$ (10,789)	$ (16,043)

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)

	Nine Months Ended September 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (10,688)	$ (15,921)
Adjustments for non-cash expenses to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,493	1,980
Stock-based compensation	1,818	2,662
Reserve for bad debt	372	
Non-cash interest expense on related party note payable	87	840
Loss on disposal of property and equipment	17	269
Other	15	23
Changes in assets and liabilities:		
Accounts receivable	(4,525)	(2,227)
Prepaid expenses and other current assets	2,504	1,948
Accounts payable	(642)	(1,792)
Accrued expenses	352	(3,029)
Deferred revenue	4,812	3,960
Deferred rent	3,394	84
Net cash used in operating activities	(991)	(11,203)
Cash flows from investing activities:		
Purchases of property and equipment	(3,608)	(1,184)
Proceeds from maturities of investments	29,036	15,079
Purchase of investments	(29,162)	(29,290)
Changes in other assets	2	
Net cash used in investing activities	(3,732)	(15,395)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,093	71
Proceeds from issuance of common stock, net	53,249	
Decrease in restricted cash		722
Repayments on long-term debt obligations	(1,244)	(1,162)
Repayment of notes payable to related party	(15,510)	
Proceeds from return of security deposit on debt obligations	203	197
Payments of capital lease obligations	(64)	(60)
Net cash provided by (used in) financing activities	37,727	(232)
Effect of change in exchange rates on cash	(227)	(98)
Net increase (decrease) in cash and cash equivalents	32,777	(26,928)

Cash and cash equivalents, beginning of period		6,746		39,008
Cash and cash equivalents, end of period	$	39,523	$	12,080
Supplemental disclosures of cash flow information and non cash transactions				
Interest paid	$	243	$	255

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. (ViaCell or the Company) was incorporated in the State of Delaware on September 2, 1994 as t.Breeders Inc. In April 2000 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.

ViaCell is a biotechnology company focused on enabling the widespread use of human cells as medicine. The Company is developing a pipeline of proprietary stem cell product candidates intended to address cancer, cardiac disease, and diabetes. CB001, its lead cord blood derived stem cell therapy product candidate, is being developed for hematopoietic stem cell transplantation in patients affected by a variety of cancers. In addition to its therapeutic development programs, ViaCell s reproductive health business unit commercializes ViaCord®, a product that offers expecting families the option of preserving their baby s umbilical cord blood. The Company is also working to leverage its commercial infrastructure and product development capabilities by developing ViaCyte, its investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized 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 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 September 30, 2005 and for the three and nine months ended September 30, 2005 and September 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 Company has prepared its unaudited, consolidated financial statements following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under these rules, the Company has condensed or omitted certain footnotes and other financial information that are normally required by accounting principles generally accepted in the United States. 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 nine months ended September 30, 2005 are not necessarily indicative of results for the entire fiscal year or future periods. The

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 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 September 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 nine-month period ended September 30, 2005, the Company did not issue any stock options to employees with an exercise price below fair market value. During the nine month periods ended September 30, 2005 and September 30, 2004, the Company recorded amortization of deferred compensation related to stock options granted to employees and non-employee directors of approximately $1,818,000 and $2,397,000 respectively. At September 30, 2005 and December 31, 2004 approximately $1,431,000 and $2,530,000, respectively, of deferred stock compensation related to stock options remained unamortized.

During the nine month periods ended September 30, 2005 and September 30, 2004, the Company recorded stock-based compensation expense of approximately $0 and $265,000, respectively, related to stock options granted to non-employees.

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In July 2005 the Company s Board of Directors approved an increase, from 90 days to three years, in the amount of time allowed for non-employee directors to exercise vested options following the termination of their service to the Company. As a result, the Company recognized additional stock-based compensation expense of approximately $700,000 in the quarter ended September 30, 2005 and will recognize approximately $63,000 in the quarter ended December 31, 2005. An additional $241,000 will be recognized in years 2006 through 2008 based on respective vesting schedules associated with each modified option grant.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss attributable to common stockholders as reported	$ (3,558)	$ (9,454)	$ (11,675)	$ (25,865)
Add: employee stock-based compensation expense included in reported net loss	1,024	793	1,818	2,397
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards	(1,298)	(1,130)	(3,520)	(3,827)
Pro forma net loss attributable to common stockholders	$ (3,832)	$ (9,791)	$ (13,377)	$ (27,295)
Basic and diluted net loss per share				
As reported	$ (0.09)	$ (3.49)	$ (0.33)	$ (9.62)
Pro forma	$ (0.10)	$ (3.62)	$ (0.38)	$ (10.15)

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 September 30, 2005 and September 30, 2004 using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The weighted average assumptions used to estimate fair value of the stock options using the Black-Scholes model for the three and nine months ended September 30 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Risk-free interest rate	4.18%	2.86%	3.90%	2.86%
Expected life	5 years	5 years	5 years	5 years
Expected volatility	100%	100%	100%	100%
Dividend yield	0%	0%	0%	0%

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Segment Information

The Company s management currently uses consolidated financial information in determining how to allocate resources and assess performance. The Company has determined that it conducts operations in one business segment. Therefore, our results of operations are discussed on a consolidated basis.

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

	September 30, 2005	December 31, 2004
Long-lived tangible assets		
United States	$ 8,669	$ 6,310
Germany		88
Singapore	289	340
Total long-lived tangible assets	$ 8,958	$ 6,738

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenues	**2005**	**2004**	**2005**	**2004**
United States	$ 11,555	$ 9,566	$ 32,755	$ 27,590
Germany	(61)	291	(101)	834
Singapore	196	81	559	209
Total revenues	$ 11,690	$ 9,938	$ 33,213	$ 28,633

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 dilutive potential common shares outstanding during the period. Potential 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). Potential common shares are excluded from the calculation if their effect is anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Basic and diluted net loss per share:				
Net loss attributable to common stockholders	$ (3,558)	$ (9,454)	$ (11,675)	$ (25,865)
Weighted average number of common shares outstanding	37,772	2,708	34,877	2,690
Basic and diluted net loss per share	$ (0.09)	$ (3.49)	$ (0.33)	$ (9.62)

The following potential common shares were excluded because their effect was antidilutive (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Options	3,895	4,326	3,778	4,241
Warrants	3,409	1,429	3,549	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 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.

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3. Property and Equipment

Property and equipment consisted of (table in thousands):

	September 30, 2005	December 31, 2004
Software	$ 3,098	$ 2,700
Laboratory equipment	5,072	4,675
Office and computer equipment	2,509	1,867
Leasehold improvements	5,562	3,129
Furniture and fixtures	752	717
Construction in progress	14	380
Property and equipment, gross	17,007	13,468
Less: accumulated depreciation	(8,049)	(6,730)
Property and equipment, net	$ 8,958	$ 6,738

At September 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 $280,000 and $251,000, respectively.

Depreciation expense on property and equipment totaled approximately $452,000 and $597,000 for the three months ended September 30, 2005 and September 30, 2004, respectively. Depreciation expense on property and equipment totaled approximately $1,342,000 and $1,781,000 for the nine months ended September 30, 2005 and September 30, 2004, respectively.

4. Intangible Assets

Intangible assets consist of a trademark. Amortization of intangible assets was approximately $50,000 for the three months ended September 30, 2005 and September 30, 2004. Amortization of intangible assets was approximately $151,000 and $199,000 for the nine months ended September 30, 2005 and September 30, 2004, respectively.

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

	September 30, 2005	December 31, 2004
Intangible assets:		
Trademark	$ 4,400	$ 4,400
Less: accumulated amortization	(1,526)	(1,375)
Intangible assets, net	$ 2,874	$ 3,025

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

	September 30, 2005	December 31, 2004
Payroll and payroll related	$ 1,028	$ 1,016
Management incentive	634	723
Professional fees	1,704	2,027
Accrued marketing	1,192	912
Accrued restructuring	689	907
Deferred rent, current	826	238
Accrued taxes	858	648
Other	1,313	1,019
	$ 8,244	$ 7,490

6. Long-Term Debt Obligations

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

	September 30, 2005	December 31, 2004
Debt facility loans	$ 1,905	$ 3,136
Related party note payable		15,422
Capital lease obligations	174	179
Total long-term debt obligations	2,079	18,737
Less: current portion	(1,834)	(17,165)
Total long-term debt obligations, net of current portion	$ 245	$ 1,572

Notes Payable to Related Party

In connection with the acquisition of Kourion Therapeutics, the Company borrowed a total of $14.0 million evidenced by promissory notes. 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, following the completion of its IPO, the Company repaid these related party notes totaling approximately $15,510,000, which included all outstanding principal and interest accrued at that date.

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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 for ViaCell consisting of various antibodies conjugated with magnetic particles to be used in ViaCell s proprietary Selective Amplification process for the development and commercialization of certain of ViaCell s proprietary cellular therapy product candidates. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the cell separation kit, including making various filings with the U.S. Food and Drug Administration (FDA). The Company is obligated to pay up to $950,000. As of September 30, 2005, the Company had paid $700,000 relating to the development of the product, and is recognizing expense as the work is performed over the two year development period. For the nine months ended September 30, 2005, the Company recognized approximately $600,000 of expense related to this development agreement. The remaining payment of $250,000 relates to a milestone to be paid upon filing the master files for the cell separation kit with the FDA. The agreement terminates 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 cell separation kits by Miltenyi to ViaCell. The initial term of the supply agreement is for seven years. The Company has agreed to purchase at least $1.3 million of cell separation kits within the first year after the process development program has been completed. The Company also has certain minimum annual purchase requirements starting in fiscal 2007 which will apply if its investigational product for hematopoietic stem cell transplantation, CB001, continues in clinical trials or is commercialized.

The Company has entered into an agreement with the Economic Development Board of the Government of Singapore under which the Government of Singapore has agreed to give the Company a grant of up to $4,000,000 to fund stem cell research and development programs conducted in Singapore. Under this agreement, the Government of Singapore reimburses the Company for a portion of research and development expenses incurred for work done in Singapore. The Company funded approximately $337,000 and $277,000 of research and development in Singapore during the three months ended September 30, 2005 and September 30, 2004, respectively, and recorded grant revenue of approximately $196,000 and $81,000 during the three months ended September 30, 2005, and September 30, 2004, respectively. The Company funded approximately $974,000 and $717,000 of research and development in Singapore during the nine months ended September 30, 2005 and September 30, 2004, respectively, and recorded grant revenue of approximately $559,000 and $209,000 during the nine months ended September 30, 2005, and September 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.

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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 September 30, 2005.

Litigation

In 2002, PharmaStem Therapeutics, Inc. (PharmaStem) filed suit against ViaCell and several other defendants in the United States District Court for the District of Delaware, alleging infringement of U.S. Patents No. 5,004,681 (681) and No. 5,192,553 (553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. The Company believes that it does not infringe the patents, and that the patents are invalid.

In 2003, a jury ruled against the Company and the other defendants, CBR Systems, Inc., CorCell, Inc. and Cryo-Cell International Inc **.** , who represent a majority of the family cord blood preservation industry. 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 District Court judge overturned the jury s verdict of infringement against ViaCell, and denied PharmaStem s motion for a preliminary injunction. On January 6, 2005, PharmaStem filed a Notice of Appeal and a Motion to Expedite the Appeal of the District 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. The Company s response to PharmaStem s Motion to Reinstate Appeals was filed on July 26, 2005. On August 10, 2005, PharmaStem s Motion to Reinstate the Appeal was denied. On that date, the Federal Circuit ordered PharmaStem to file a new brief within 60 days. PharmaStem filed its opening brief in the new appeal on September 16, 2005. The Company filed its appeal brief on October 31, 2005.

In August 2004, the U.S. Patent and Trademark Office (U.S. 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 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 District Court s judgment as to non-infringement of the 553 patent and /or the 681 patent is reversed on appeal, the Company could have a significant damages award entered against it, and could also face an injunction which could prohibit it from further engaging in the umbilical cord stem cell business absent a license from PharmaStem to the disputed patents.

In July 2004, PharmaStem also filed a complaint against the Company in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patents No. 6,461,645 (645) and 6,569,427 (427), which also relate to certain aspects of the collection, cryopreservation and storage of

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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. The Company believes the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, the Company filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, the Company s request was granted. The cases have thus been consolidated in Delaware. On October 6, 2005, the Delaware court granted the Company s motion to stay all discovery in the consolidated cases pending decisions from the Federal Circuit on PharmaStem s appeal of the District Court of Delaware s ruling in the original case and from the U.S. PTO on the patent re-examinations. If the consolidated cases proceed and a motion for preliminary injunction 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. While no assurance can be given, the Company believes that PharmaStem s motion for preliminary injunction will be denied.

In April 2005, the U.S. 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. A second re-examination of the 427 patent was ordered on September 13, 2005. The PTO ordered the second re-examination in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010.

In either of the pending cases, if the Company is ultimately found to infringe, it could have a significant damages award entered against it, and could also face an injunction which could prohibit it from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. If PharmaStem is granted an injunction enjoining the Company 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. PharmaStem would be under no legal obligation to grant the Company a license or to do so on economically reasonable terms, and previously informed the Company that it would not do so after October 15, 2004. While the Company does not believe this outcome is likely, in the event of an injunction, if ViaCell is not able to obtain a license under the disputed patents on economically reasonable terms, or at all, and cannot 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.

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

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

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dismissed and the appeal is proceeding. The plaintiff has settled the litigation with all defendants other than ViaCell. The Company is 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 the Company estimate the possible financial consequences should plaintiff prevail. However, the Company believes this suit to be without merit and intends to continue to vigorously defend itself.

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. On October 27, 2005, the Company entered into an agreement to settle the pending litigation with CBR. Under the terms of the agreement the companies agreed to dismiss all outstanding legal claims. There were no financial payments to be made by either party under the settlement agreement.

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 September 30, 2005 which, if adversely decided, would have a material adverse effect on results of operations, financial position or cash flow.

The Company has undertaken a review of its various job classifications for legal compliance under state and federal employment laws. Based on that review, the Company has identified certain job classifications that may be subject to possible challenge and for which there is a reasonable possibility that the Company could incur a liability, although the Company also believes that the present classifications can be supported and defended. Also, it is not possible based on the current available information to reasonably estimate the scope of any potential liability.

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

All of the Company s outstanding 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 nine months ended September 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 September 30, 2005	$

In connection with the September 2003 acquisition of Kourion, the Company issued 241,481 shares of common stock to an escrow account and reserved an additional 289,256 shares for possible future issuance. These shares will be released and issued if a change in control of the Company occurs prior to September 30, 2006. 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 issuance of shares of Series K convertible preferred stock issued to Amgen, Inc. in December 2003, the Company gave Amgen a one-time option to require the Company to redeem up to 1,250,000 of the Series K shares at a price of $8.00 per share. Amgen s option terminated upon completion of the Company s IPO on January 26, 2005. All of the Series K shares converted into shares of common stock in connection with the IPO.

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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 September 30, 2005, none of such preferred stock has been designated and no shares are outstanding.

9. Warrants

In August 2005, the Company amended its existing license and collaboration agreement with Amgen to include a nonexclusive license to patent rights covering an additional Amgen growth factor. In connection with this amendment, the Company issued Amgen a warrant to purchase 200,000 shares of the Company s common stock at an exercise price of $7.85 per share. The warrant will vest upon the successful treatment of a human in a Phase II clinical trial utilizing the specific growth factor that is the subject of the amendment. The term of the warrant is seven years from the effective date of the amendment. The warrant will be recognized as in-process research and development expense when and if it vests, based on the fair value at that time.

In September and October 2003, the Company issued 2,190,000 shares of its Series J convertible preferred stock for total gross proceeds to the Company of $17,520,000. A right to contingent warrants was granted to all purchasers of Series J preferred stock (the Series J investors). Under that right, upon the earlier to occur of an initial public offering that is not a Qualified Public Offering (an initial public offering at a minimum price of $9.70 per share in which net proceeds equal or exceed $50 million) or September 30, 2006, the Company would be required to issue warrants to the Series J investors for the purchase of Common Stock equal to the number of shares of Series J owned (for a total of 2,190,000 shares). The initial warrant purchase price would be $5.00. The right to the contingent warrants had a fair value of approximately $1,620,000 at the time of grant. The fair value was estimated using a binomial valuation model. The Company recorded the Series J convertible preferred stock and the contingent warrants, at their relative fair values of $15,622,000 and $1,390,000, respectively. In January 2005, the Company completed its initial public offering. Since the offering was not a Qualified Public Offering, the Company issued warrants to purchase a total of 2,190,000 shares of Common Stock to the Series J investors in February 2005. During the quarter ended September 30, 2005, certain Series J investors fully exercised their warrants using a net exercise feature that resulted in the issuance of 37,935 shares of our Common Stock in consideration of canceling the remaining portion of the warrants covering 58,315 shares.

In November 1997, in connection with the issuance of Series D preferred stock, the Company issued warrants to certain stockholders (Series D investors) to purchase 750,000 shares of the Company s common stock at a price per share of $1.50. These warrants vested 100 percent on the date of grant and are exercisable through November 12, 2007. The value ascribed to these warrants was not material. During the quarter ended September 30, 2005, certain Series D investors fully exercised their warrants using a net exercise feature that resulted in the issuance of 142,800 shares of our common stock in consideration of canceling the remaining portion of the warrants covering 23,867 shares.

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

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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 the Company s ViaCord product, and its ViaCyte, CB001 and cardiac research and development programs. 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 a $175,000 payment to terminate its agreement with 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 a contract termination fee of $0.1 million. 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 sublease payments received 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 in discussions with the German grant authorities regarding repayment of part of certain grants made to the Company s German subsidiary in 2003 and 2004. The Company was recently notified that approximately $500,000 in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. As a result, the Company reserved an additional $155,000 for the three months ended September 30, 2005 and $410,000 for the nine months ended September 30, 2005 to reserve its estimated total liability under this grant. The additional reserves recorded resulted in reversals of grant revenue of approximately $61,000 and $105,000 for the three and nine months ended September 30, 2005, respectively. In addition, the Company reclassed approximately $200,000 of accrued restructuring reserves to reduce outstanding grant receivables. 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.

The Company s activity in the restructuring accrual for the nine months ended September 30, 2005 consisted of the following:

(In Thousands)	December 31, 2004	Additions	Writedowns	Adjustments	Payments	September 30, 2005
Severance related	$ 421	$	$	$	$ (421)	$
Contractual terminations	5				(5)	
Facility related	481			275	(67)	689
	$ 907	$	$	$ 275	$ (493)	$ 689

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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 1, Financial Statements , Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, (including the risk factors set forth therein) 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, expenses, income or loss, capital expenditures, plans for product development, collaborative arrangements, and manufacturing efforts, future operations, expectations regarding the outcome and possible impact of pending litigation and patent-related matters, financing needs or plans, as well as assumptions relating to the foregoing. The words believe, expect, will, anticipate, estimate, project, plan, , intend and similar expressions identify forward-looking statements, and speal 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 that May Affect Results

Overview

We are a biotechnology company focused on enabling the widespread use of human cells as medicine. We are developing a pipeline of proprietary stem cell product candidates intended to address cancer, cardiac disease, and diabetes. CB001, our lead cord blood derived stem cell therapy product candidate, is being developed for hematopoietic stem cell transplantation in patients affected by a variety of cancers. In addition to our therapeutic development programs, our reproductive health business unit commercializes ViaCord®, a product that offers expecting families the option of preserving their baby s umbilical cord blood. We are working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte, our investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs.

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.

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As of September 30, 2005, our accumulated deficit was approximately $169.5 million. From inception through September 30, 2005, we have raised approximately $191.6 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;
- the increasing costs associated with the development of ViaCyte, our oocyte cryopreservation product candidate; and
- 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 have determined that we conduct operations in one business segment. The majority of our revenues since inception have been generated in the United States, and the majority of our long-lived assets is located in the United States.

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 storage fee. The annual storage fee provides a growing annuity of future revenue as the number of stored umbilical 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; however, we are unable to predict our future revenues from our umbilical cord blood business.

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 September 30, 2005.

We are in ongoing litigation with PharmaStem Therapeutics over PharmaStem s claims that our cord blood preservation business infringes certain of PharmaStem s patents. In the second half of 2004, the Delaware District Court overturned a jury verdict of infringement against us in such suit. As a result of these rulings, we do not expect the PharmaStem litigation to have a materially adverse impact on our net sales, revenues or income from continuing operations. However, PharmaStem has appealed the court s decision and has also filed a new suit claiming that we infringe additional

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patents. Should we ultimately lose the appeal, or the additional ongoing litigation with PharmaStem in the Delaware court, it could have a material adverse effect on our net sales, revenues or income from continuing operations, including, possibly, an injunction preventing us from operating our cord blood preservation business.

In addition to the revenues generated by our ViaCord product, we recorded revenues from grant agreements with both 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. As a result, 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 the PharmaStem litigation 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 the second half of 2004, the District Court overturned the jury verdict. 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. PharmaStem has appealed the judge s ruling. PharmaStem has also filed a new lawsuit claiming that we infringe additional patents. Pending a decision on the appeal and further action by the court on the new litigation, we do not intend to record a royalty expense in future periods, since we believe PharmaStem s claims are without merit. It is possible that the final outcome of these litigations could result in damages payable for infringement of PharmaStem s patents, at a higher or lower amount than previously awarded by the jury in Delaware. Should this occur, our financial position and results of operations could be materially affected. We may enter into settlement negotiations with PharmaStem regarding the litigation. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts 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, which is currently on clinical hold, 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 preclinical 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

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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 increase in the foreseeable future as we add personnel, expand our clinical trial activities and increase our discovery research and clinical and regulatory capabilities. The amount of these increases is difficult to predict due to the uncertainty inherent in our research, development and manufacturing programs and activities, the timing and scope of our clinical trials, the rate of patient enrollment in our clinical trials, and the detailed design of future clinical trials. In addition, the results from our clinical trials, as well as the results of trials of similar therapeutics under development by others, will influence the number, size and duration of planned and unplanned trials. On an ongoing basis, we evaluate the results of our product candidate programs, all of which 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.

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 certain grants made to our German subsidiary in 2003 and 2004. We were recently notified that approximately $500,000 in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. As a result, we reserved an additional $155,000 for the three months ended September 30, 2005 and $410,000 for the nine months ended September 30, 2005 to reserve for our estimated liability under this grant. The additional reserves recorded resulted in reversals of grant revenue of approximately $61,000 and $105,000 for the three and nine months ended September 30, 2005, respectively. In addition, we reclassed approximately $200,000 of accrued restructuring reserves to reduce outstanding grants receivable. As of September 30, 2005 we had received approximately $3.7 million in cumulative grant proceeds from the German grant authorities.

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 we consider this possibility to be remote.

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Results of Operations

Three and Nine Months Ended September 30, 2005 and 2004 (table amounts in thousands)

Revenues:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	2004	Change	2005	2004	Change
Revenues						
Processing and storage revenues	$ 11,555	$ 9,552	21%	$ 32,718	$ 27,397	19%
Grant and contract revenues	135	386	(65%)	495	1,236	(60%)
Total revenues	$ 11,690	$ 9,938	18%	$ 33,213	$ 28,633	16%

The increase in processing and storage revenues of $2.0 million or 21% from the three months ended September 30, 2004 to the three months ended September 30, 2005 was due primarily to increases in the number of umbilical cords processed and the total number of umbilical cords stored during the quarter. The decrease in grant and contract revenues of $0.3 million or 65% from the three months ended September 30, 2004 to the three months ended September 30, 2005 was primarily due to a decrease of $0.3 million in grant revenues from German grant authorities following cessation of our operations in Germany in 2004. Grant and contract revenues also decreased by $0.1 million for the three months ended September 30, 2005 due to the reversal of grant revenue related to certain fixed asset and operating expenditures in Germany which were deemed not reimbursable under the grant and will have to be repaid. These decreases were partially offset by an increase in grant revenues from the Government of Singapore of $0.1 million.

The increase in processing and storage revenues of $5.3 million or 19% from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was due primarily to an increase in the total number of umbilical cords processed and the total number of umbilical cords stored during the respective nine month periods, as well as an increase in pricing. The decrease in grant and contract revenues of $0.7 million or 60% was primarily due to the decrease of $0.8 million in grant revenues from German grant authorities following cessation of our operations in Germany in 2004 and a decrease in contract revenues derived from research activities in the United States of $0.1 million. Grant and contract revenues also decreased by $0.1 million for the nine months ended September 30, 2005 due to the reversal of grant revenue related to certain fixed asset and operating expenditures in Germany which were deemed not reimbursable under the grant and will have to be repaid. These decreases were partially offset by an increase in grant revenues from the Government of Singapore of $0.3 million.

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Cost of Revenues:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	2004	Change	2005	2004	Change
Cost of processing and storage revenues						
Direct costs	$ 2,164	$ 1,839	18%	$ 6,136	$ 5,514	11%
Royalty expense			0%		(3,258)	(100%)
Total cost of processing and storage revenues	$ 2,164	$ 1,839	18%	$ 6,136	$ 2,256	172%

The increase of $0.3 million or 18% in direct costs of processing and storage revenues from the three months ended September 30, 2004 to the three months ended September 30, 2005 and $0.6 million or 11% from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was due primarily to increases in variable expenses related to the increases in the number of umbilical cords processed and the number of umbilical cords stored. These variable expenses relate to transportation of the cord blood and materials for related collection and testing.

The credit in royalty expense of $3.3 million for the nine months ended September 30, 2004 was due to a reversal of an accrued liability after a Delaware District Court judge ruled in our favor in the PharmaStem litigation in the second half of 2004 and overturned a prior jury verdict of infringement. We had recorded the royalty expense in October 2003 based on the jury verdict that was subsequently overturned.

While PharmaStem has appealed the District Court s ruling, we continue to believe that the lawsuit is without merit and, in light of the District Court judge s ruling, have determined that no royalty accrual or expense is required.

Research and Development:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	2004	Change	2005	2004	Change
Research and development						
Clinical development	$ 2,377	$ 2,075	15%	$ 7,140	$ 6,121	17%
Pre-clinical programs	145	896	(84%)	546	2,895	(81%)
Basic research	595	715	(17%)	1,793	2,152	(17%)
Other research and development	161	138	17%	400	530	(25%)
Total research and development	$ 3,278	$ 3,824	(14%)	$ 9,879	$ 11,698	(16%)

Clinical development expense is related primarily to outside services and clinical trial expenses for CB001. The increase in clinical development expense of $0.3 million or 15% from the three months ended September 30, 2004 to the three months ended September 30, 2005 and $1.0 million or 17% from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 reflected the cost of conducting the Phase I clinical trials that commenced in late 2003. In September 2005, we announced that the FDA has placed a clinical hold on the Phase I clinical trial. We do not currently anticipate that the clinical hold will have a material impact on future clinical development expense. The

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decrease in costs associated with preclinical programs of $0.8 million or 84% from the three months ended September 30, 2004 to the three months ended September 30, 2005 and $2.3 million or 81% from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was primarily due to the movement of our cardiac repair program from Germany to the U.S. at the end of 2004 following the closure of our German operations, and the discontinuation of our muscular dystrophy program in September 2004. These changes resulted in lower ongoing employee and facility related costs. Basic research expenses are primarily related to activities at our Singapore and United States research centers. Other research and development expense related primarily to our umbilical cord blood processing and storage business.

Sales and Marketing:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
Sales & marketing	$6,259	$4,651	35%	$17,784	$15,081	18%

The increase in sales and marketing expense of $1.6 million or 35% from the three months ended September 30, 2004 to the three months ended September 30, 2005 was primarily related to increased staffing within the sales organization to strengthen our market presence, as well as an increase in external marketing program spending. The increase in sales and marketing expense of $2.7 million or 18% from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was primarily due to increased spending on external marketing programs, as well as increased staffing within the sales organization to strengthen our market presence.

General and Administrative:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
General and administrative	$2,847	$3,010	(5%)	$8,978	$10,401	(14%)

The decrease in general and administrative expenses of $0.2 million or 5% from the three months ended September 30, 2004 to the three months ended September 30, 2005 was primarily due to decreases in employee related costs as a result of our restructuring in September 2004, partially offset by insurance costs due to higher premiums associated with being a public company. The decrease in general and administrative expenses of $1.4 million or 14% from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was primarily due to decreases in employee related costs of approximately $1.2 million as a result of our restructuring in September 2004 as well as a decrease in consulting costs related to our ViaCyte program of approximately $0.5 million. These decreases were partially offset by an increase of $0.4 million for the nine months ended September 30, 2005 for insurance costs due to higher premiums associated with being a public company.

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Stock-Based Compensation:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
Stock-based compensation	$1,024	$793	29%	$1,818	$2,662	(32%)

Stock-based compensation expense is primarily due to 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 primarily to options granted prior to our IPO. During the nine months ended September 30, 2005, we did not grant any options with exercise prices less than fair market value on the date of grant.

In July 2005, our 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 ViaCell. As a result of this modification of the option terms, we recorded $0.7 million of stock-based compensation expense in the three months ended September 30, 2005. The additional stock-based compensation expense related to the modified options is the primary reason for the net increase in stock-based compensation expense from the three months ended September 30, 2004 to the three months ended September 30, 2005. The increase related to the modified options is partially offset by decreased amortization of the deferred compensation account since no new options were granted with exercise prices less than fair market value in the three months and nine months ended September 30, 2005.

We will record stock-based compensation expense related to this option modification of approximately $0.1 million in the quarter ended December 31, 2005. An additional $0.2 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.

Restructuring:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
Restructuring	$94	$1,740	(95%)	$305	$1,740	(82%)

In September 2004 we restructured our operations to reduce operating expenses and concentrate resources on four key products and product candidates. As a result, we recorded a $1.7 million restructuring charge related to employee severance, contractual termination fees and the write down of excess equipment.

In 2005 we were recently notified that approximately $500,000 in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. As a result, we reserved an additional $155,000 for the three months ended September 30, 2005 and $410,000 for the nine months ended September 30, 2005 to reserve for our estimated liability under this grant. The additional reserves recorded resulted in charges to restructuring expense of approximately $94,000 and $305,000 for the three and nine months ended September 30, 2005, respectively. It is also possible that the grant authorities could request additional repayment of grant funds

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related to certain operating expenses that were previously funded by the grant authorities for research performed in Germany, however we consider this possibility to be remote. As of September 30, 2005, we had received approximately $3.7 million in grant proceeds from the German grant authorities.

Interest Income (Expense):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2005	**2004**	**Change**	**2005**	**2004**	**Change**
Interest income (expense)						
Interest income	$ 531	$ 139	282%	$ 1,305	$ 402	225%
Interest expense	(113)	(360)	(69%)	(306)	(1,118)	(73%)
Total interest income (expense), net	$ 418	$ (221)		$ 999	$ (716)	

Interest income is earned from the investment of our cash in short-term securities and money market funds. The increase in interest income of $0.4 million or 282% from the three months ended September 30, 2004 to the three months ended September 30, 2005 and $0.9 million or 224% from the nine months ended September 30, 2004 to the nine months ended September 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 $0.2 million or 69% from the three months ended September 30, 2004 to the three months ended September 30, 2005 and $0.8 million or 73% from the nine months ended September 30, 2004 to the nine months ended September 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 September 30, 2005, we have raised $191.5 million in common and preferred stock issuances, which includes $53.3 million in net proceeds from our IPO in January 2005. We used approximately $15.5 million of these net proceeds to repay in full related party notes, including accrued interest. As of September 30, 2005, we had approximately $61.5 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.

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

(In thousands)	**Nine Months Ended September 30, 2005**	**Nine Months Ended September 30, 2004**	**Change 2004 to 2005**
Net cash used in operating activities	$ (991)	$ (11,203)	$10,212
Net cash used in investing activities	(3,732)	(15,395)	11,663
Net cash provided by (used in) financing activities	37,727	(232)	37,959
Cash & cash equivalents, end of period	39,523	12,080	27,443

Net cash used in operating activities was $1.0 million for the nine months ended September 30, 2005, a reduction of $10.2 million over the nine months ended September 30, 2004. For the nine months ended

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September 30, 2005, the $1.0 million in net cash used in operating activities was due to our net loss, net of adjustments for non-cash expenses, of $6.9 million and a net increase in working capital (accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses) of $2.3 million. These net uses of cash in operating activities were partially offset by net increases in deferred rent of $3.4 million and deferred revenue of $4.8 million. The increase in deferred rent was due to 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. The increase in deferred revenue of $4.8 million related to sales of long-term pre-paid storage contracts, as well as advances received in connection with our grant program with the Government of Singapore**.**

Net cash used in investing activities for the nine months ended September 30, 2005 was $3.7 million as compared to $15.4 million for the nine months ended September 30, 2004. For the nine months ended September 30, 2005, $29.0 million of U.S. Government and high-rated corporate securities matured and $29.1 million was invested in similar securities. We also invested approximately $3.6 million in property and equipment for the nine months ended September 30, 2005. Approximately $2.5 million of the total spent on property and equipment during the nine months ended September 30, 2005 related to the build-out of our manufacturing facility and laboratory in Cambridge, which was completed in August 2005. We expect that this facility 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 expect to need to build or acquire another manufacturing facility in order to fully commercialize CB001 and our other product candidates, if successfully developed. The timing and cost of such a facility is not known at this time, however the cost is likely to be substantial.

Net cash provided by financing activities for the nine months ended September 30, 2005 was $37.7 million. Net cash used in financing activities amounted to $0.2 million for the nine months ended September 30, 2004. For the nine months ended September 30, 2005, the net cash provided by financing activities included net proceeds from our IPO of $53.3 million and proceeds of $1.1 million relating to exercised stock options. These proceeds were partially reduced by the amount of cash used to repay related party notes of approximately $15.5 million related to the acquisition of Kourion Therapeutics and repayments of $1.2 million on our long-term debt obligations, net of proceeds received from the return of a security deposit which secured 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.

Off-Balance Sheet Transactions

We did not have any off balance sheet transactions as of September 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 for us consisting of various antibodies conjugated with magnetic particles to be used in our proprietary

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Selective Amplification process for the development and commercialization of certain of our cellular therapy product candidates. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the cell separation kit, including making various filings with the U.S. Food and Drug Administration (FDA). We are obligated to pay up to $950,000. As of September 30, 2005, we had paid $700,000 relating to the development of the product, and are recognizing expense as the work is performed over the two year development period. For the nine months ended September 30, 2005, we recognized approximately $600,000 of expenses related to this development agreement. The remaining payment of $250,000 relates to a milestone to be paid upon filing the master files for the cell separation kit with the FDA. The agreement terminates 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 cell separation kits to us by Miltenyi. The initial term of the supply agreement is for seven years. We have agreed to purchase at least $1.3 million of cell separation kits within the first year after the process development program has been completed. We also have certain minimum annual purchase requirements starting in fiscal 2007 which will apply if our investigational product for hematopoietic stem cell transplantation, 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

In 2002, PharmaStem Therapeutics, Inc. filed suit 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 (681) and No. 5,192,553 (553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that we do not infringe these patents and that the patents are invalid.

In 2003, a jury ruled against us and the other defendants, CBR Systems Inc, CorCell, Inc. and Cryo-Cell International Inc, who represent a majority of the family cord blood preservation industry. A judgment was entered against us for approximately $2.9 million, based on 6.125% royalties on our revenue from the processing and storage of umbilical cord blood since April 2000.

In 2004, the District Court judge overturned the jury s verdict of infringement against us and denied 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 District 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

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to PharmaStem s Motion to Reinstate Appeals was filed on July 26, 2005. On August 10, 2005, PharmaStem s Motion to Reinstate the Appeal was denied. On that date, the Federal Circuit ordered PharmaStem to file a new brief within 60 days. PharmaStem filed its opening brief in the new appeal on September 16, 2005. We filed our appeal brief on October 31, 2005.

In August 2004, the U.S. Patent and Trademark Office (U.S. 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 District Court s judgment as to non-infringement of the 553 patent and / or the 681 patent is reversed on appeal , we could have a significant damages award entered against us, and could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem to the disputed patents.

In July 2004, PharmaStem also filed a complaint against us in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patents No. 6,461,645 (645) and 6,569,427 (427), which also relate to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. By agreement of the defendants, we 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. We believe the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, our request was granted. The cases have thus been consolidated in Delaware. On October 6, 2005, the Delaware court granted our motion to stay all discovery in the consolidated cases pending decisions from the Federal Circuit on PharmaStem s appeal of the District Court of Delaware s ruling in the original case and from the U.S. PTO on the patent re-examinations. If the consolidated cases proceed and a motion for preliminary injunction 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.

In April 2005, the U.S. 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. A second re-examination of the 427 patent was ordered on September 13, 2005. The PTO ordered the second re-examination in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010.

In either of the pending cases, if the Company is ultimately found to infringe, it could have a significant damages award entered against it, and could also face an injunction which could prohibit it from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would

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be under no legal obligation to grant the Company a license or to do so on economically reasonable terms, and previously informed the Company that it would not do after October 15, 2004. While we do not believe this outcome is likely, in the event of an injunction, if we are not able to obtain a license under the disputed patents on economically reasonable terms or at all and we cannot operate under an equitable doctrine known as intervening rights, we 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.

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

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. On October 27, 2005, we entered into an agreement to settle the pending litigation with CBR. Under terms of the agreement the companies agreed to dismiss all outstanding legal claims. There were no financial payments to be made by either party under the settlement agreement.

We have undertaken a review of our various job classifications for legal compliance under state and federal employment laws. Based on that review, we have identified certain job classifications that may be subject to possible challenge and for which there is a reasonable possibility that we could incur a liability, although we also believe that the present classifications can be supported and defended. Also, it is not possible based on the current available information to reasonably estimate the scope of any potential liability.

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

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

We have generated operating losses since our inception. As of September 30, 2005, we had cumulative net losses of approximately $169.5 million. These losses have resulted principally from the costs of our

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research and development activities, which have totaled approximately $98.2 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 Phase I trial for CB001, if the clinical hold is lifted and enrollment re-commences, and our planned clinical trial for our ViaCyte oocyte preservation product candidate, submissions for regulatory approvals, the potential commercialization of future products, and the expansion of clinical and 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. 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 umbilical cord blood banking industry, are defendants in lawsuits brought by PharmaStem Therapeutics, Inc. 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.

In 2002, PharmaStem filed suit against us and the other defendants in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 5,004,681 (681) and No. 5,192,553 (553) relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that we do not infringe these patents and that the patents are invalid.

In October 2003, a jury in this case ruled against us and the other defendants. A judgment was entered against us for approximately $2.9 million, based on a 6.125% royalty rate on our revenue from processing and storage of umbilical cord blood since April 2000. In 2004, the District Court judge overturned the jury verdict of infringement against us and denied PharmaStem s motion for a 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. On August 10, 2005, PharmaStem s Motion to Reinstate the Appeal was denied. On that date, the Federal Circuit ordered PharmaStem to file a new brief within 60 days. PharmaStem filed its opening brief in the new appeal on September 16, 2005. We filed our appeal brief on October 31, 2005.

In August 2004, the U.S. Patent and Trademark Office (U.S. PTO) ordered the re-examination of both of the 553 and 681 patents based on the prior art submitted. On February 2, 2005, the U.S. PTO issued an Office Action rejecting all claims of the 553 method patent as unpatentable over the prior art. On May 18, 2005, the U.S.PTO vacated and terminated the re-examination of the 681 composition patent.

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On July 18, 2005, the re-examination requestor filed a Petition for Review of the U.S. PTO s Order vacating and terminating the re-examination of the 681 patent. Should the U.S. PTO find the claims of the patents to be unpatentable then the litigation proceedings between us and PharmaStem as to the unpatentable claims would cease. If the District Court s judgment as to non-infringement of the 553 patent or the 681 patent is reversed on appeal, we could have a significant damages award entered against us, and could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem to the disputed patents.

In July 2004, PharmaStem filed a new complaint against us in federal district court in Massachusetts alleging infringement of two different but related patents. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the new litigation. That motion is currently stayed. We believe the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, our request was granted. The cases have thus been consolidated in Delaware. On October 6, 2005, the Delaware court granted our motion to stay all discovery in the consolidated cases pending decisions from the Federal Circuit on PharmaStem s appeal of the District Court s ruling in the original case and from the U.S. PTO on the patent re-examinations. If the consolidated cases proceed and the motion for preliminary injunction is granted, we could be enjoined from collecting and storing umbilical cord blood that had not been collected as of the date the injunction is issued while the case is litigated. While no assurance can be given, we believe that PharmaStem s motion for preliminary injunction will be denied.

In either of the pending cases, if we are ultimately found to infringe, we could have a significant damages award entered against us, and could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant us a license or to do so on economically reasonable terms, and previously informed us that it would not do so after October 15, 2004. If it becomes necessary to obtain a license, but none is available on economically reasonable terms, or at all, we will not be able to further engage in our umbilical cord stem cell cryopreservation business. If we cannot continue our umbilical 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 jury verdict in the original case, which was subsequently overturned, was entered against us for approximately $2.9 million relating to past infringement, based on a royalty rate of 6.125% 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 umbilical cord blood banks. For example, we understand PharmaStem has licensed other umbilical cord blood banks under its patents for royalty rates of 15%.

We may enter into settlement negotiations with PharmaStem regarding the litigation. We cannot predict whether any such negotiations would lead to a settlement of these lawsuits or what the terms or timing of any such settlement might be, if it occurs at all. For a more detailed discussion of the PharmaStem litigation, see the section entitled Part II, Item 1 Legal Proceedings of this report.

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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. Only one of our product candidates, CB001, has entered human clinical trials. CB001 consists of a highly enriched population of hematopoietic stem cells which are selectively amplified from umbilical cord blood. CB001 is being studied for hematopoietic stem cell transplantation in patients affected by a variety of cancers to provide regeneration of blood and immune systems. In September 2005, we announced that the FDA has placed a clinical hold on the CB001 Phase I clinical trial. The FDA s action followed our decision to suspend enrollment in the trial. We suspended enrollment after two patients in the trial experienced acute Grade IV graft-versus-host disease, or aGVHD, a potential and common side effect in transplantation.

Under the study protocol, two cases of Grade IV aGVHD called for suspension of enrollment. Both patients recovered from Grade IV aGVHD and have been released from the hospital. We are reviewing these cases and relevant data with the FDA, the investigators, and the institutional review boards for the clinical trial sites, and we will need their agreement to continue the trial. There is no assurance that the FDA, the investigators, and the institutional review boards for the clinical sites will permit the trial to continue.

While our Selective Amplification technology has shown successful results in preclinical research, those results have not been 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. 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 product candidates to:

- properly engraft into the recipient s body in the desired manner;
- provide the intended therapeutic benefits; or
- achieve benefits or a safety profile that is better or equal to existing therapies.

As a result, there is substantial uncertainty about the effectiveness of CB001 and our other stem cell product candidates. 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. There is no assurance, for example, that the results of the CB001 Phase I clinical trial will warrant further clinical assessment. 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.

There is no assurance that we will be able to show that CB001 or any other stem cell product candidate is safe or effective in any indication. Even if our product candidates do prove to be safe and effective in clinical trials there is no assurance that we will be able to manufacture cells in sufficient quantities for commercial use.

We expect that none of our cellular therapy product candidates will be commercially available for at least several years, if at all. We will need to devote significant additional research and development, financial resources and personnel to develop commercially viable products and obtain regulatory

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approvals.

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

Revenues from ViaCord, our umbilical cord blood preservation and storage product, have grown significantly over the past several years, from $7.1 million in fiscal 2001, to $20.1 million, $30.9 million, and $36.8 million in fiscal 2002, 2003, and 2004, respectively. We believe that this is a result of our increased marketing efforts and from increased awareness by the public generally of the concept of umbilical 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 competition from other private cord blood banks, litigation, 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.

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

As of September 30, 2005, we had approximately $61.5 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;

the clinical pathway for each of our product candidates, including the number, size, scope and cost of clinical trials required to establish safety and efficacy, particularly for CB001 and for our ViaCyte product candidate;

the results of litigation

the timing of and the costs involved in obtaining regulatory approvals for our product candidates, 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 research and development work focused on developing clinical and commercial scale processes for manufacturing cellular products and the costs of building and operating our manufacturing facilities, both in the near-term to support our clinical activities, and also in anticipation of growing our commercialization activities;

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funds spent in connection with acquisitions of related technologies or businesses, including contingent payments that may be made in connection with our acquisition of Kourion Therapeutics;

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

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

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

We cannot sell CB001, or other cellular product candidates, until regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and 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

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requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the U.S. Food & Drug Administration, or FDA, that CB001 is safe and effective for each disease for which we seek approval. In September 2005, we announced that the FDA has placed a clinical hold on the Phase I clinical trial of CB001. The FDA s action followed our decision to suspend enrollment in the trial after two patients in the trial experienced acute Grade IV graft-versus-host disease, or aGVHD, a potential and common side effect in transplantation. Under the study protocol, two cases of Grade IV aGVHD called for suspension of enrollment. Both patients recovered from Grade IV aGVHD and have been released from the hospital. We are reviewing these cases and relevant data with the FDA, the investigators, and the institutional review boards for the clinical trial sites, and we will need their agreement to continue the trial. There is no assurance that the FDA, the investigators, and the institutional review boards for the clinical sites and the investigators will permit the trial to continue. Even if the trial were to continue, the FDA could place an additional hold on the Phase I trial or any other clinical trial 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. While we believe that the serious adverse event profiles we have observed with CB001 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 the FDA will lift the clinical hold on the Phase I trial or that additional safety concerns regarding CB001 will not develop. For example, if the trial were to continue and 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 incidence is related to CB001, and if related, whether the current Phase I trial can be continued or must be redesigned or terminated.

If we are permitted to continue the trial by the FDA and institutional review boards, several factors could prevent completion or cause significant delay of this trial or subsequent trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that CB001 is safe and effective 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 whether enrollment will continue and, if so, when enrollment will be completed. Negative or inconclusive results from or adverse medical events during a clinical trial have caused a delay and 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.

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 reason would significantly delay our receipt of marketing approval for CB001, if received at all.

The industry and the FDA have relatively little experience with therapeutics based on cellular medicine generally. As a result, the pathway to regulatory approval for CB001 and our other stem cell-based product candidates may be more complex and lengthy than the pathway for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the United States, we will need to submit clinical data concerning our products and receive regulatory approval from

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governmental agencies, which in certain countries includes approval of the price we intend to charge for our product. Standards for approval outside the United States may differ from those required by the FDA. We may encounter delays or rejections if changes occur in regulatory agency policies during the period in which we develop a product candidate or during the period required for review of any application for regulatory agency approval. If we are not able to obtain regulatory approvals for use of CB001 or other product candidates 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 product is subject to these GTP regulations. We have registered with the FDA as an umbilical 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, though we have not yet been inspected by the FDA. However, we may not be able to maintain this compliance or comply with future regulatory requirements that may be imposed on us, including product standards that may be developed. 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 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 umbilical cord blood banking services, only New Jersey, New York, Maryland, Kentucky, Illinois and Pennsylvania currently require that umbilical 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 U.S. and international regulation of oocyte cryopreservation. The FDA has informed us that it will require a clinical study to support approval of the technology used in oocyte cryopreservation. Even if such a study is conducted, we cannot assure you that the FDA will find the data sufficient to grant 510(k) clearance.

If we conduct a 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 developing and commercializing this product candidate. We cannot assure you that this product candidate will receive either 510(k) clearance or PMA approval. We believe that the time to conduct a clinical study, prepare a new 510(k), and receive FDA clearance for our oocyte preservation product will take several years.

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We have not investigated the regulations for the cryopreservation of oocytes in foreign jurisdictions.
There is no assurance that we will ever be able to generate sufficient data to receive approval to market technology for the cryopreservation of oocytes.

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

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our product candidates, technologies and trade secrets. We own or have exclusive licenses to six U.S. patents and three international patents. We also own or have exclusive licenses to 14 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 U.S. PTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. The claims of our existing U.S. patents and those that may issue in the future, or those licensed to us, may not offer significant protection of our 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.

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CB001 and our other cellular product candidates and our ViaCyte product candidate 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 product candidates, the market may not accept them. Other than hematopoietic stem cell transplants, stem cell therapy is not currently a commonly used procedure. Similarly, our ViaCyte oocyte cryopreservation product candidate, if developed and cleared for commercial use, may not be accepted by the market. Market demand for our product candidates 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 and safety profile of products that compete with our product.
- our ability to supply a sufficient amount of our product to meet demand;
- our ability to build and maintain, or access through third parties, a capable sales force;
- our ability to successfully fund launch costs; and
- our ability to obtain insurance coverage and reimbursement for our cellular therapy products.

Our success will depend in part on establishing and maintaining effective strategic partnerships and collaborations.

A key aspect of our business strategy is to establish strategic relationships in order to gain access to technology and critical raw materials, to expand or complement our research, development or commercialization capabilities, or to reduce the cost of developing or commercializing products on our own. While we are currently in discussions with a number of companies, universities, research institutions, cord blood banks and others to establish additional relationships and collaborations, we may not reach definitive agreements with any of them. Even if we enter into these arrangements, we may not be able to maintain these relationships or establish new ones in the future on acceptable terms. Furthermore, these arrangements may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, or may have other terms that are burdensome to us, and may involve the acquisition of our securities. Our partners may decide to develop alternative technologies either 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

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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, we have incurred total legal expenses as of September 30, 2005 of approximately $7.0 million. Depending upon results of PharmaStem s appeal of the District Court s decision to overturn the jury verdict against us in this case, and the extent to which we are required to litigate the additional patent infringement lawsuit brought by PharmaStem and any related appeals, we estimate that we could incur at least an additional $1.0 million to $5.0 million in litigation expenses. Further, if other patent infringement suits were brought against us, our collaborators or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. In addition, payments under such licenses would reduce the earnings otherwise attributable to the related products.

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

In addition to the two PharmaStem patent infringement lawsuits we are contesting, we are aware that PharmaStem owns an additional patent, U.S. Patent No. 6,605,275, in the umbilical cord blood preservation field, which is the field in which we currently do business with our ViaCord product 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.

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We may be involved in lawsuits or other proceedings 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 U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

If we successfully develop and obtain necessary regulatory approvals, we intend to sell our lead product candidate 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

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organizations and pharmacy benefit management companies. CB001 and our other potential cellular therapy products may be relatively expensive treatments due to the higher cost of production and more complex logistics of cellular products compared with standard pharmaceuticals; this, in turn, may make it more difficult for us to obtain adequate reimbursement from third party payers, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payers may also deny coverage or offer inadequate levels of reimbursement for CB001 or any of our other potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate. In the countries of the European Union and in some other countries, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control.

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

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

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

We currently produce limited quantities of stem cells using our Selective Amplification and USSC technologies. We have not built commercial scale manufacturing facilities, and have no experience in manufacturing cellular products in the volumes that will be required for later stage clinical studies or commercialization. If we successfully obtain marketing approval for any products, we may not be able to produce sufficient quantities of our products at an acceptable cost. Commercial-scale production of therapies made from live human cells involves production in small batches and management of complex logistics. Cellular therapies are inherently more difficult to manufacture at commercial-scale than chemical pharmaceuticals, 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

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manufacturers, and we need to establish relationships with other suppliers to manufacture cGMP grade products for commercial sale. We are dependent on our suppliers for such components such as SCF, Flt-3, Tpo mimetic and cGMP grade antibodies conjugated with magnetic particles. Some of these components are currently supplied to us by Amgen, GlaxoSmithKline and Miltenyi Biotec, who are currently single-source suppliers. 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 whom we do not have relationships. In order to continue our clinical trials and commercialize our Selective Amplification product candidates, 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 product candidates. 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 product candidates may be delayed and we may not be able to complete development of or market our stem cell product candidates.

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 dependent on them for supply of cGMP grade components. If we are unable to obtain cGMP grade biological components for our product candidates, we may not be able to market our stem cell product candidates.

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 umbilical 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 have built 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

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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 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. To manage future growth, we would need to hire, train and manage additional employees, particularly a specially-trained sales force. Concurrent with expanding our reproductive health activities, we also plan to increase our research and development activities.

Prior to completing our initial public offering in January 2005, 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 have increased the number of our accounting and finance personnel and have taken steps to proactively monitor our networks and to improve our financial, accounting and information systems and internal controls in order to fulfill our responsibilities as a public company and to support growth in our business. We cannot assure you that our current and

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planned personnel, systems procedures and controls will be adequate to support our anticipated growth or that management will be able to hire, train, retain, motivate and manage required personnel. Our failure to manage growth effectively could limit our ability to achieve our research and development and commercialization goals or to satisfy our reporting and other obligations as a public company.

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

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

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 paid to our German subsidiary in 2003 and 2004. In March 2005, following cessation of our operations, 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 further discussions with the grant authorities, we believed it was probable that the grant authorities would request additional repayment of grant funds related to these fixed asset expenditures. As a result of these discussions, we estimated the total repayment necessary would be approximately $340,000. In September 2005, after additional correspondence with the grant authorities we were further notified that our potential liability would be approximately $500,000 and we accrued an additional $155,000 to account for our estimated total 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. Because we consider this possibility to be remote, and therefore have not established a reserve for additional operating expenses, 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 September 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,

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Osiris Therapeutics and StemCells. We also face competition in the cell therapy field from academic institutions and governmental agencies. We are also aware that some larger pharmaceutical and biopharmaceutical companies have programs in the cell therapy area. Some of these competitors, and future competitors, may have similar or better product candidates or technologies, greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities. Specifically, Gamida-Cell, a private company based in Israel, is developing a hematopoietic 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 in fiscal year 2004 and up to $30 million in fiscal year 2005 for a national system of public cord blood banks and to encourage cord blood donations 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.

The private umbilical cord banking business is highly competitive. In private umbilical cord blood banking, we compete with companies such as CBR Systems, Cryo-Cell International, Inc., CorCell, Inc. and LifeBank USA. Any of these companies may choose to invest more in sales, marketing, research and product development than we have. In cord blood banking, we also compete with public cord blood banks such as the New York Blood Center (National Cord Blood Program), University of Colorado Cord Blood Bank, Milan Cord Blood Bank, Düsseldorf Cord Blood Bank, and 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 and Extend Fertility is offering related services, which may make it more difficult for us to establish our product candidate 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

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characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our product candidates obsolete.

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

Our cord blood preservation product is an activity in which our reputation among clients and the medical and birthing services community is 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 problems. Like family cord blood banks generally, we face the risk that a customer s cord blood unit could be lost or damaged while in transit from the collection site to our storage facility, including while the unit is in the possession of third party commercial carriers used to transport the units. There is also risk of loss or damage to the unit during the preservation or storage process. Any such problems, particularly if publicized in the media or otherwise, could negatively impact our reputation, which could adversely affect our business and business prospects.

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

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

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

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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 and product candidates, thereby reducing demand for our products and product candidates.

The use of embryonic stem cells for research and stem cell therapy has been the subject of debate regarding related ethical, legal and social issues. Although we do not currently use embryonic stem cells as a source for our research programs, the use of other types of human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with embryonic stem cells. The commercial success of our product candidates will depend in part on public acceptance of the use of stem cell therapy, in general, for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that stem cell therapy is unsafe, and stem cell therapy may not gain the acceptance of the public or the medical community. Adverse events in the field of stem cell therapy that may occur in the future also may result in greater governmental regulation of our product candidates and potential regulatory delays relating to the testing or approval of our product candidates. In the event that our research becomes the subject of adverse commentary or publicity, the market price for our common stock could be significantly harmed.

Our business involves the use of hazardous materials that could expose us to environmental and other liability.

We have facilities in Massachusetts, Kentucky, and Singapore that are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. In the 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

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have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

Volatility of Our Stock Price

The market price for our common stock is highly volatile, and likely will continue to fluctuate due to a variety of factors, including:

- material public announcements
- the data, positive or negative, generated from the development of our product candidates
- setbacks or delays in any of our development programs
- the outcome of material litigation
- the financial results achieved by our cord blood preservation business
- the impact of competition
- unusual or unexpectedly high expenses
- developments related to patents and other proprietary rights
- market trends affecting stock prices in our industry
- economic or other external factors

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.

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.

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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 September 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 September 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

The section entitled Litigation in Notes to Condensed Consolidated Financial Statements in Part I of this Quarterly Report on Form 10-Q is incorporated into this item by reference.

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

Changes in Securities

On August 29, 2005, we issued a warrant to Amgen, Inc. to purchase 200,000 shares of our common stock at an exercise price of $7.85 per share. This warrant was issued in connection with the amendment of an existing license and collaboration agreement between us and Amgen to include a nonexclusive license to patent rights covering an additional Amgen growth factor. The warrant will vest upon the successful treatment of a human in a Phase II clinical trial utilizing the specific growth factor that is the subject of the amendment. The term of the warrant is seven years from the effective date of the amendment. In issuing this warrant, we relied upon the exemption from securities registration afforded by Section 4(2) of the Securities Act of 1933, as amended.

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.

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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 nine months ended September 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;

- approximately $12,805,000 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 $24,985,000 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

None.

ITEM 5. OTHER INFORMATION

None.

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.

November 14, 2005

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

November 14, 2005

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

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EXHIBIT INDEX

No.	Item
10.1	Amendment No. 1 to Collaboration Agreement, dated August 29, 2005, between ViaCell, Inc. and Amgen Inc.*
10.2	Warrant Purchase Agreement, dated August 29, 2005, between ViaCell, Inc. and Amgen Inc.
10.3	Purchase Warrant, dated August 29, 2005.
10.4	Exclusive License Agreement among the Johns Hopkins University, Zhejiang University and ViaCell, Inc. dated August 29, 2005.*
10.5	Letter Agreement dated August 1, 2005 between ViaCell, Inc. and Anne Marie Cook**
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

* This exhibit has been filed separately with the Commission pursuant to an application for confidential treatment. The confidential portions of this exhibit have been omitted and are marked by an asterisk.

** Indicates a management contract.