VIACELL INC
Form 10-Q
May 15, 2006

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UNITED STATES 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 March 31, 2006

OR

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. Yes þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes o No þ

As of May 12, 2006, 38,610,049 shares of the Company s common stock, $0.01 par value, were outstanding.

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ViaCell, Inc.
Quarterly Report on Form 10-Q
For the Fiscal Quarter Ended March 31, 2006

NOTE ABOUT REFERENCES TO VIACELL

Throughout this report, the words we, our, us and ViaCell refer to ViaCell, Inc. and its subsidiaries.

NOTE ABOUT TRADEMARKS

ViaCell® and ViaCord® are registered trademarks of ViaCell, Inc. ViaCyte℠ is a service mark of ViaCell, Inc.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to the potential and anticipated results of our development programs, and our views as to the possible outcome of pending litigation and actions related to our intellectual property portfolio. We have based these forward-looking statements on our current expectations about such future events. While we believe these expectations are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those discussed in this report in Part II Item 1A (Risk Factors). Given these risks and uncertainties, you are cautioned not to place substantial weight on forward-looking statements. The forward-looking statements included in this report are made only as of the date of this report. We do not undertake any obligation to update or revise any of these statements.

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PART I FINANCIAL INFORMATION
Item 1 Financial Statements
ViaCell, Inc.
Condensed Consolidated Balance Sheets
(amounts in thousands)
(unaudited)

	March 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,429	$ 33,138
Short-term investments	26,573	27,406
Accounts receivable, less allowances of $1,227 and $1,111 at March 31, 2006 and December 31, 2005, respectively	12,727	13,736
Prepaid expenses and other current assets	3,590	2,679
Restricted cash	162	162
Total current assets	74,481	77,121
Property and equipment, net	8,593	8,702
Goodwill	3,621	3,621
Intangible assets, net	2,773	2,823
Restricted cash	1,935	1,932
Other assets	31	31
Total assets	$ 91,434	$ 94,230
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt obligations	$ 1,108	$ 1,543
Accounts payable	1,110	1,141
Accrued expenses	9,080	7,706
Deferred revenue	6,148	5,785
Total current liabilities	17,446	16,175
Deferred revenue	10,858	9,930
Deferred rent	3,548	3,876
Contingent purchase price	8,155	8,155
Long-term debt obligations, net of current portion	69	84
Total liabilities	40,076	38,220
Commitments and contingencies (Note 4)		
Stockholders equity:		
Preferred stock, $0.01 par value; authorized 5,000 shares at March 31, 2006 and December 31, 2005, none outstanding	384	381

Common stock, $0.01 par value; authorized 100,000 shares at March 31, 2006 and December 31, 2005; issued and outstanding 38,361 and 38,118 shares at March 31, 2006 and December 31, 2005, respectively		
Additional paid-in capital	229,314	229,955
Deferred compensation		(1,087)
Accumulated deficit	(178,554)	(173,443)
Accumulated other comprehensive income	214	204
Total stockholders equity	51,358	56,010
Total liabilities and stockholders equity	$ 91,434	$ 94,230

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

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

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005
Processing and storage revenues	$ 11,937	$ 9,975
Grant revenues	144	165
Total revenues	12,081	10,140
Operating expenses:		
Cost of processing and storage revenues	2,328	1,953
Research and development	3,466	3,646
Sales and marketing	7,922	5,569
General and administrative	4,638	3,047
Restructuring	(181)	121
Total operating expenses	18,173	14,336
Loss from operations	(6,092)	(4,196)
Interest income (expense):		
Interest income	724	315
Interest expense	(26)	(155)
Total interest income, net	698	160
Loss from operations before cumulative effect of change in accounting principle	(5,394)	(4,036)
Cumulative effect of change in accounting principle	283	
Net loss	(5,111)	(4,036)
Accretion on redeemable convertible preferred stock		987
Net loss attributable to common stockholders	$ (5,111)	$ (5,023)
Net loss per share:		
Net loss per common share, basic and diluted	$ (0.13)	$ (0.17)
Weighted average shares used in basic and diluted net loss per share computation	38,295	29,719

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

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

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005
Net loss	$ (5,111)	$ (4,036)
Foreign currency translation adjustment	10	(42)
Comprehensive loss	$ (5,101)	$ (4,078)

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

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

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005
Cash flows from operating activities:		
Net loss	$ (5,111)	$ (4,036)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	559	514
Cumulative effect of change in accounting principle	(283)	
Stock-based compensation	711	436
Reserve for bad debt	266	58
Non-cash interest expense on related party notes		87
Tenant improvement allowance	60	
Other	2	22
Changes in assets and liabilities:		
Accounts receivable	747	(1,156)
Prepaid expenses and other current assets	(906)	1,198
Accounts payable	(51)	623
Accrued expenses	1,209	741
Deferred revenue	1,292	2,343
Deferred rent	(235)	1,222
Net cash (used in) provided by operating activities	(1,740)	2,052
Cash flows from investing activities:		
Purchases of property and equipment	(400)	(1,035)
Proceeds from maturities of investments	8,887	4,477
Purchase of investments	(8,055)	(9,579)
Net cash provided by (used in) investing activities	432	(6,137)
Cash flows from financing activities:		
Proceeds from exercise of stock options	22	622
Net proceeds from sale of common stock in initial public offering, net of offering costs		53,291
Repayments on credit facilities	(437)	(431)
Repayment of notes payable to related party, including accrued interest		(15,510)
Payments on capital lease principal	(16)	
Net cash (used in) provided by financing activities	(431)	37,972

Effect of change in exchange rates on cash		30		(105)
Net increase (decrease) in cash and cash equivalents		(1,709)		33,782
Cash and cash equivalents, beginning of period		33,138		6,746
Cash and cash equivalents, end of period	$	31,429	$	40,528

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

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

1. Organization and Nature of Business

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. The Company has a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. The Company is currently conducting a Phase 1 clinical trial of CB001, its lead umbilical cord blood-derived stem cell therapy product candidate as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In addition to the Company s therapeutic research and development programs, it has a reproductive health business that generated revenues of $11.9 million in the first quarter of 2006 and $43.8 million in 2005 from sales of ViaCord, a service offering through which expectant families can preserve their babies umbilical cord blood for possible future medical use. The Company is working to leverage its commercial infrastructure and product development capabilities by developing ViaCyte[sm], its investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs, as well as through new business development opportunities.

ViaCell was incorporated in the State of Delaware on September 2, 1994. The Company s corporate headquarters and main research facility are located in Cambridge, Massachusetts. The Company has processing and storage facilities in Hebron, Kentucky, a clinical trial manufacturing facility in Worcester, Massachusetts, and an additional research and development operation in Singapore.

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

The Company restructured its operations in September and December 2004 to reduce operating expenses and concentrate its resources on key products and product candidates, and related business initiatives (Note 5).

On January 26, 2005, the Company completed its initial public offering (IPO). The Company issued 8,625,000 shares at $7.00 per share resulting in net proceeds to the Company of approximately $53,249,000 after underwriters discounts and offering expenses. As a result of the IPO, all shares of the Company s preferred stock immediately converted into 25,810,932 shares of common stock. On January 26, 2005, the Company paid in full a related party note of $15,509,760, which included all outstanding principal and interest owed at that date.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements as of March 31, 2006 and for the three months ended March 31, 2006 and 2005, and related notes, are unaudited but in management s opinion include all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary

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

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 U.S. The Company s accounting policies are described in the Notes to the Consolidated Financial Statements in the Company s 2005 Annual Report on Form 10-K and updated, as necessary, in this Form 10-Q. Results for the three months ended March 31, 2006 are not necessarily indicative of results for the entire fiscal year or future periods. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

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

Stock-Based Compensation

The ViaCell, Inc. Amended and Restated 1998 Equity Incentive Plan (the Plan) provides for the granting of incentive and nonqualified stock options to employees, consultants and directors of the Company. The number of shares of common stock available for issuance under the Plan as of March 31, 2006 was 7,200,000. Incentive stock options may only be granted to employees of the Company. The exercise price of each option is determined by the Board of Directors. The exercise price of each incentive stock option, however, may not be less than the fair market value of the stock on the date of grant, as determined by the Board of Directors. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R Share-Based Payment (SFAS 123R) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation expense is measured using the Black-Scholes option pricing model at the grant date based on the value of the award and is recognized as expense on a straight-line basis over the requisite service period. Previously, the Company had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee share options at their intrinsic value in the consolidated financial statements.

The Company recognized the full impact of its share-based payment plan of $0.7 million in the condensed consolidated statement of operations for the three month period ended March 31, 2006 under SFAS 123R. The following table presents stock-based compensation expense for continuing operations included in the Company s unaudited condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005 (pro forma)
Cost of processing and storage revenues	$ 15	$ 11
Research and development	104	172
Sales and marketing	57	194
General and administrative	535	701
Total stock-based compensation expense	$ 711	$ 1,078

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

The Company has recognized compensation expense for its stock option grants. Upon adoption of SFAS 123(R), using the modified prospective method, the Company recognized a benefit of $0.3 million as a cumulative effect of a change in accounting principle resulting from the adjustment to estimate forfeitures of the Company s stock option grants at the date of grant instead of recognizing them as incurred. The cumulative benefit increased both basic and diluted earnings per share by approximately $0.01 for the three months ended March 31, 2006. The estimated forfeiture rate was applied to the previously recorded stock-based compensation expense of the Company s unvested stock options in determining the cumulative effect of a change in accounting principle. The impact to the Company of adopting SFAS 123(R) for the three months ended March 31, 2006 was an increase to loss from operations of $0.7 million, an increase to net loss of $0.4 million, an increase to cash flow from operating activities of $0.4 million, and an increase in net loss per basic and diluted share of $0.01.

The Company had previously adopted the provisions of SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, through disclosure only. The following table illustrates the effect on net loss and earnings per share for the three month period ended March 31, 2005 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee awards.

(in thousands except per share data)		**Three Months ended March 31, 2005**
Net loss attributable to common stockholders as reported	$	(5,023)
Add: employee stock-based compensation expense included in reported net loss		434
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards		(1,078)
Pro forma net loss attributable to common stockholders	$	(5,667)
Basic and diluted net loss per share as reported	$	(0.17)
Pro forma basic and diluted net loss per share	$	(0.19)

The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model.

The Company s expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. For stock option grants issued during the three-month period ended March 31, 2006, the Company used a weighted-average expected stock-price volatility of 65%.

The Company determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three month period ended March 31, 2006, the Company used a weighted average expected option life assumption of 4.57 years.

The risk-free interest rate used for each grant is equal to the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

	Three Months Ended March 31, 2006	**Three Months Ended March 31, 2005**

Option life	4.57 years	5.00 years
Risk-free interest rate	4.61%	4.17%
Stock volatility	65%	100%
Dividend rate	0%	0%

As of March 31, 2006, there remained approximately $6.9 million of compensation costs related to non-vested stock options to be recognized as expense over a weighted-average period of approximately 1.8 years.

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

Presented below is the Company s stock option activity for the three months ended March 31, 2006

	Number of Options Outstanding	Weighted Average Exercise Price
Outstanding, December 31, 2005	3,930,694	$ 2.77
Granted	240,625	5.21
Exercised	(35,051)	0.65
Canceled	(17,072)	6.17
Outstanding, March 31, 2006	4,119,196	$ 2.91
Exercisable, March 31, 2006	2,178,044	
Weighted average fair value of options granted		$ 2.93

	Options Outstanding at March 31, 2006			Options Exercisable at March 31, 2006	
Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$ 0.30	1,380,043	4.13	$ 0.30	1,080,043	$ 0.30
0.75	34,700	4.84	0.75	34,700	0.75
0.95	125,986	5.12	0.95	125,986	0.95
2.00	728,925	5.72	2.00	202,925	2.00
4.00	51,775	6.02	4.00	46,400	4.00
5.00	1,230,174	7.65	5.00	598,769	5.00
5.21	240,375	9.92	5.21	779	5.21
5.31	138,281	9.48	5.31	17,304	5.31
5.62	9,781	9.69	5.62	857	5.62
7.25	25,000	9.07	7.25	6,250	7.25
8.17	97,781	8.78	8.17	50,848	8.17
9.00	7,125	8.86	9.00	1,875	9.00
10.89	40,000	9.28	10.89	10,000	10.89
11.10	9,250	9.28	11.10	1,308	11.10
	4,119,196	6.26	$ 2.91	2,178,044	$ 2.18
		6.26			5.56

Weighted-average remaining contractual term
(Years)

The aggregate intrinsic value of outstanding and exercisable options as of March 31, 2006 was $2.6 million. The intrinsic value of options exercised during the three months ended March 31, 2006 and 2005 was $0.2 million and $2.4 million, respectively. Since the Company has federal, state and foreign net operating loss carryforwards, the adoption of SFAS 123(R) did not result in any windfall tax benefits.

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Notes to Condensed Consolidated Financial Statements
(unaudited)

Net Loss Per Common Share

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

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

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005
Basic and diluted net loss per share		
Net loss attributable to common stockholders	$ (5,111)	$ (5,023)
Weighted average number of common shares outstanding	38,295	29,719
Basic and diluted net loss per share	$ (0.13)	$ (0.17)

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

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005
Options	4,119,196	4,085,046
Warrants	1,430,833	1,420,833

3. Accrued Expenses

At March 31, 2006 and December 31, 2005, accrued expenses consisted of the following (in thousands):

	March 31, 2006	December 31, 2005
Payroll and payroll related	$ 1,313	$ 1,541
Management incentive	324	881
Professional fees	1,887	1,206
Accrued marketing	1,798	1,260
Accrued restructuring (Note 5)	632	632
Deferred rent, current	786	619
Accrued taxes	475	537
Other	1,865	1,030

Accrued expenses	$ 9,080	$ 7,706

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4. 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. For the three months ended March 31, 2006 and 2005, the Company had paid $0 and $700,000, respectively relating to the development of the product, and is recognizing expense as the work is performed over the development period. The remaining payment of $250,000 relates to a milestone to be paid upon filing the master files for the cell separation kits with the FDA. The Company recognized $950,000 of expense related to this development agreement in 2005. 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 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 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 $269,000 and $296,000 of research and development in Singapore during the three months ended March 31, 2006 and 2005, respectively, and recorded grant revenues of approximately $144,000 and $165,000 during the three months ended March 31, 2006 and 2005, respectively.

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, typically with business partners, licensors and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the party s activities. Certain indemnification provisions survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date, the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. The Company has approximately $51,000 recorded for these agreements as of March 31, 2006 and December 31, 2005.

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

Litigation

In 2002, PharmaStem Therapeutics, Inc. filed suit against the Company and several other defendants in the U.S. 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 these 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 finding that the patents were valid and enforceable, and that the defendants infringed the patents. A judgment was entered against the Company 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 in the case overturned the jury s verdict stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge s decision. The Company has appealed the jury s finding as to validity of the patents. A hearing on the appeal took place on April 4, 2006.

In July 2004, PharmaStem filed a second complaint against the Company. The second complaint was filed in the U.S. 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. The Company believes that the patents in this new action are invalid and/or that the Company does not infringe them. 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 been consolidated in Delaware.

The U.S. Patent and Trademark Office (U.S. PTO) has ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and 427 patents at issue in the second case based on prior art. A second re-examination of the 427 patent was ordered in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010. In April 2006, the U.S. PTO issued office actions rejecting all of the claims of the 645 and 681 patents. The U.S. PTO ruled that PharmaStem s patent claims are unpatentable over prior art. The office actions issued by the U.S. PTO are not final determinations. PharmaStem will have the right to respond to the office actions by either amending the claims of the patents to try to avoid the prior art or by challenging the U.S. PTO s decision. PharmaStem will also have recourse through the Board of Appeals on the office actions. In early 2005, the U.S. PTO issued an initial office action rejecting all the claims of the 553 patent. PharmaStem subsequently cancelled certain of the claims and argued for patentability of the remaining claims. The U.S. PTO has not yet issued a final office action on the 553 patent. An office action on the 427 patent re-examination has not yet been issued.

On October 6, 2005, the Delaware court granted the Company s motion to stay all discovery in the second lawsuit pending decisions from the Federal Circuit on PharmaStem s appeal of the District Court s ruling of non-infringement in the original case and from the U.S. PTO on the patent re-examinations.

In either of the pending cases, if the Company is ultimately found to infringe valid claims of the PharmaStem patents, the Company could have a significant damages award entered against it. If the Company is found to infringe at any time during the course of either case, including if the court of appeals were to overturn the district court s non-infringement ruling, the Company could also face an injunction which could prohibit the Company from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant

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

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 the Company is not able to obtain a license under the disputed patents on economically reasonable terms or at all and the Company cannot operate under an equitable doctrine known as intervening rights, the Company could 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 the Company. The complaint alleged that the defendants made fraudulent claims in connection with the marketing of their cord blood banking services and sought restitution for those affected by such marketing, injunctive relief precluding the defendants from continuing to abusively and fraudulently market their services and requiring them to provide certain information and refunds to their customers, unspecified punitive and exemplary damages and attorney s fees and costs. Subsequently, the Company received a Notice of Ex Parte Application for Leave to Intervene filed on behalf of the Cord Blood Foundation by the same individual and seeking similar relief. On October 7, 2004, the Court orally granted a motion to strike the complaint under the California anti-SLAPP statute and dismissed the complaint as to all defendants without leave to amend. Judgment has been entered, dismissing the complaint, and plaintiff has filed a notice of appeal and a 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 the Company. 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 U.S. 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 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. On March 31, 2006, the Court dismissed all claims with prejudice at the request of the parties.

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. It is not possible based on the current available information to reasonably estimate the scope of any potential liability.

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

5. Restructuring

In December 2004, the Company restructured its German operations and sublet its laboratory facility in Germany to a third party effective January 1, 2005. As a result, the Company recorded a 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.

In November 2005, the sub-lessee verbally gave notice of their intent to not extend the sublease past December 31, 2006. The sub-lessee has prepaid rent through December 2006. In March 2006, the Company executed an agreement with the sub-lessee under which the sub-lessee made a one-time payment to the Company of approximately $181,000 for giving notice of termination prior to the termination of the first period of the sublease agreement.

The Company is finalizing discussions with the German grant authorities regarding repayment of part of certain grants made to Kourion, our German subsidiary, in 2003 and 2004.

The Company was 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 $410,000 during the year ended December 31, 2005 for its estimated liability under this grant. The additional reserves resulted in reversals of grant revenue of approximately $105,000 for the year ended December 31, 2005. In addition, the Company reclassified approximately $200,000 of accrued restructuring reserves to reduce outstanding grants receivable. In February 2006, the Company was notified by the State of North-Rhine-Westfalia, Germany that it plans on performing an audit of the State s economic grants granted throughout its territory, including the grant to Kourion. It is 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, as of March 31, 2006, the Company considers this possibility to be remote in light of the current outcome of the audit. Only minor deviations from the grant policies have been identified. As of March 31, 2006, the Company had received approximately $3.6 million in cumulative grant proceeds from the German grant authorities. The Company s restructuring accrual was $0.6 million at March 31, 2006 and December 31, 2005.

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

The following discussion and analysis by our management of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes appearing in Item 1 of this report. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part II Item 1A (Risk Factors) section of this report.

Overview

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. We have a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. We are currently conducting a Phase 1 clinical trial of CB001, our lead umbilical cord blood-derived stem cell therapy product candidate as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In addition to our therapeutic research and development programs, we have a reproductive health business unit that generated revenues of $11.9 million in the first quarter of 2006 and $43.8 million in 2005 from sales of ViaCord, a product offering through which expectant families can preserve their baby s umbilical cord blood for possible future medical use. We are working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte[sm], our investigational product candidate intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs.

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 U.S., and the majority of our long-lived assets are located in the U.S.

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 cord blood banking has gained increased 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. The majority of our customers pay their fees directly to us; accordingly 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 March 31, 2006.

We are in ongoing litigation with PharmaStem Therapeutics, Inc. 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 the lawsuit. As a result of this ruling, we do not expect the PharmaStem litigation to have a materially adverse impact on

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our net sales, revenues or income from continuing operations. However, PharmaStem has appealed the court s decision and has also filed a second suit claiming that we infringe additional patents. Should we ultimately lose the appeal, or the additional ongoing litigation with PharmaStem, it could have a material adverse effect on our net sales, revenues or income from continuing operations, including, possibly, resulting in an injunction preventing us from operating our cord blood preservation business.

In addition to the revenues generated by our ViaCord service, we recorded revenues in the periods presented from grant agreements with both the Governments of Singapore and Germany. We maintain a research facility in Singapore. We closed our German research facility in December 2004, and have transitioned the research activities performed there to the U.S. As a result, revenues from grants in Germany 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. Our cost of processing and storage revenues also includes expenses charged by third party vendors relating to the transportation of cord blood to our processing facility and certain assay testing performed by a third party 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.

In 2003, we recorded a royalty expense of $3.3 million following an unfavorable jury verdict in the PharmaStem litigation. In 2004, the District Court overturned the jury verdict. Based on the court s ruling, we reversed the entire royalty accrual in 2004 and have not recorded any royalties since such date. PharmaStem has appealed the District Court s ruling. PharmaStem has also filed a second lawsuit claiming that we infringe additional patents. Pending a decision on the appeal and further action by the court on the second lawsuit, 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 lawsuits 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 the continued development of our lead stem cell product candidate, CB001, our expansion technologies, including Selective Amplification, our other cellular therapy product candidates and ViaCyte, our oocyte cryopreservation candidate. 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 services, 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 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.

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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, may 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 to our ViaCell Reproductive Health business. The majority of these costs relate to our sales force and support personnel, marketing expenses and 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, business development, investor relations 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 advisors, 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.

In December 2004, we restructured our German operations and sub-leased our German facility to a third party. As a result we recorded a restructuring charge of $1.2 million in the fourth quarter of 2004, including facility costs of $1.1 million and $0.1 million related to a contract termination fee. The majority of the facility related costs consists of the write off of the leasehold improvements and fixed assets in our German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future lease payments receivable from the sub-lessee, as described in Results of Operations - Restructuring .

We are finalizing discussions with the German grant authorities regarding repayment of part of certain grants made to Kourion, our German subsidiary, in 2003 and 2004. We were 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 $410,000 during the year ended December 31, 2005 for our estimated liability under this grant. The additional reserves resulted in reversals of grant revenue of approximately $105,000 for the year ended December 31, 2005. In addition, we reclassified approximately $200,000 of accrued restructuring reserves to reduce outstanding grants receivable. In February 2006, we were notified by the State of North-Rhine-Westfalia, Germany that it plans on performing an audit of the State s economic grants throughout its territory, including the grant to Kourion. It is 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, as of March 31, 2006, we consider this possibility to be remote in light of the current outcome of the audit. Only minor deviations from the grant policies have been identified. As of March 31, 2006, we had received approximately $3.6 million in cumulative grant proceeds from the German grant authorities.

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Results of Operations

Three Months Ended March 31, 2006 and 2005 (table amounts in thousands)

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change	% Change
Processing revenues	$ 9,610	$ 8,319	$ 1,291	16%
Storage revenues	2,327	1,656	671	41%
Total processing and storage revenues	11,937	9,975	1,962	20%
Grant revenues	144	165	(21)	(13)%
Total revenues	$ 12,081	$ 10,140	$ 1,941	19%

The increase in processing revenues of $1.3 million, or 16%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was due primarily to an increase in the total number of umbilical cords processed, offset by a slight decrease in the average selling price for processing. The increase in storage revenues of $0.7 million, or 41%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was due primarily to increases in the number of umbilical cords stored, as well as a slight increase in the average selling price for storage.

The slight decrease in grant revenues of $0.02 million, or 13%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was primarily due to a slight decrease in grant revenues recognized from the Government of Singapore.

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change	% Change
Cost of processing and storage revenues	$ 2,328	$ 1,953	$ 375	19%

The increase in cost of processing and storage revenues of $0.4 million, or 19%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was due primarily to increases in variable expenses related to the increased number of umbilical cords processed and an increase in the number of umbilical cords stored. These variable expenses relate to transportation of the cord blood and materials for related collection and testing of the umbilical cord blood.

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change 2005 to 2006	% Change 2005 to 2006
Research and development	$ 3,466	$ 3,646	$ (180)	(5%)

During the three months ended March 31, 2006 and 2005, our research and development expenses primarily related to our CB001, cardiac and diabetes programs, as well as our basic research programs. The decrease in costs associated with research and development of $0.2 million, or 5%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was primarily due to a decrease in outside services related to certain program studies, as well as reduction in employee-related expenses.

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	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change	% Change
Sales and marketing	$ 7,922	$ 5,569	$ 2,353	42%

The increase in sales and marketing expenses of $2.4 million, or 42%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was primarily related to increased staffing within both the internal and external sales organization and increased external marketing expenses to strengthen our market presence.

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change	% Change
General and administrative	$ 4,638	$ 3,047	$ 1,591	52%

The increase in general and administrative expenses of $1.6 million, or 52%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 was primarily due to increased accounting fees and outside service fees of approximately $0.4 million associated with compliance of the Sarbanes-Oxley Act of 2002, increased employee related expenses of $0.3 million, an increase of $0.3 million in stock-based compensation expense related to our adoption of Statement of Financial Accounting Standards No. 123R Share-Based Payment (SFAS 123R), increased bad debt expense of $0.2 million reflecting higher processing and storage revenues, as well as certain other expenses related to being a public company.

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change	% Change
Restructuring	$ (181)	$ 121	$ (302)	(250)%

In December 2004, we restructured our German operations and sub-leased our German facility to a third party. As a result we recorded a restructuring charge of $1.2 million in the fourth quarter of 2004, including facility costs of $1.1 million and $0.1 million related to a contract termination fee. The majority of the facility related costs consisted of the write off of the leasehold improvements and fixed assets in our German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future lease payments receivable from the sub-lessee.

In November 2005, the sub-lessee verbally gave notice of their intent to not extend the sublease past December 31, 2006. The sub-lessee has prepaid rent through December 2006. In March 2006, we executed an agreement with the sub-lessee under which the sub-lessee made a one-time payment to us of approximately $181,000 for giving notice of termination prior to the termination of the first period of the sublease agreement.

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In 2005, we were notified that approximately $0.5 million 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 recorded restructuring expense of $0.3 million in 2005 to reserve for this liability. In February 2006, we were notified by the State of North-Rhine-Westfalia, Germany that it plans on performing an audit of the state s economic grants granted throughout its territory, including the grant to Kourion. It is also possible that the German grant authorities could request additional repayment of grant funds related to certain operating expenses that were previously funded by them for research performed in Germany, however, as of March 31, 2006, we consider this possibility to be remote in light of the current outcome of the audit. Only minor deviations from the grant policies have been identified. As of March 31, 2006, we had received approximately $3.6 million in grant proceeds from the German grant authorities.

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change	% Change
Interest income	$ 724	$ 315	$ 409	130%
Interest expense	(26)	(155)	(129)	(83)
Total interest income, net	$ 698	$ 160	$ 538	336%

Interest income is earned primarily from the investment of our cash in short-term securities and money market funds. The increase in interest income of $0.4 million, or 130%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 primarily relates to increased average investment balances resulting from a higher cash balance available for investment following our initial public offering in January 2005, as well as an increase in interest rates. The decrease in interest expense of $0.1 million, or 83%, from the three months ended March 31, 2005 to the three months ended March 31, 2006 relates primarily to the reduction of interest on the related party notes payable, which were paid in full following the closing of our Initial Public Offering (IPO) in January 2005.

Liquidity and Capital Resources

From inception through March 31, 2006, we have raised $192.0 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 of $14.0 million, and accrued interest thereon of $1.5 million. As of March 31, 2006, we had approximately $58.0 million in cash, cash equivalents and investments, which we believe is sufficient to meet our anticipated liquidity needs for at least the next three years.

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Table excerpted from our Condensed Consolidated Statements of Cash Flows (in millions):

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	$ Change
Net cash provided by (used in) operating activities	$ (1.7)	$ 2.1	$ (3.8)
Net cash provided by (used in) investing activities	0.4	(6.1)	6.5
Net cash provided by (used in) financing activities	(0.4)	38.0	(38.4)
Cash and cash equivalents, end of period	$ 31.4	$ 40.5	$ (9.1)

Net cash used in operating activities was $1.7 million for the three months ended March 31, 2006, a decrease of $3.8 million from the $2.1 million net cash provided by operating activities in the three months ended March 31, 2005. For the three months ended March 31, 2006, the $1.7 million cash used by operations was primarily due to our net loss of $5.1 million, reduced by non-cash expenses of $1.3 million, net increases in deferred revenue of $1.3 million, and a net decrease in working capital (accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses) of $1.0 million, offset by a decrease in deferred rent of $0.2 million. The increase in deferred revenue of $1.3 million related to sales of long-term pre-paid storage contracts. For the three months ended March 31, 2005, the $2.1 million in cash provided by operating activity was due to our net loss of $4.0 million, offset by a decrease in working capital of $1.4 million, an increase in non-cash expenses of $1.1 million, and an increase in deferred revenue related to increases in long-term pre-paid storage contracts and volumes of cords stored and deferred rent of $3.6 million.

Net cash provided by investing activities for the three months ended March 31, 2006 was $0.4 million as compared to net cash used in investing activities of $6.1 million for the three months ended March 31, 2005. For the three months ended March 31, 2006, $8.9 million of U.S. Government and high-rated corporate securities matured and $8.1 million were invested in similar securities. We also invested approximately $0.4 million in property and equipment for the three months ended March 31, 2006. For the three months ended March 31, 2005, $4.5 million of U.S. Government and high-rated corporate securities matured and $9.6 million was invested in similar securities. We also invested approximately $1.0 million in property and equipment for the three months ended March 31, 2005.

Net cash used in financing activities for the three months ended March 31, 2006 was $0.4 million as compared to net cash provided by financing activities of $38.0 million for the three months ended March 31, 2005. For the three months ended March 31, 2006, the net cash used in financing activities was principally related to repayments of $0.4 million on our long-term debt obligations. For the three months ended March 31, 2005, the net cash provided by financing activities included net proceeds from our IPO of $53.3 million and proceeds of $0.6 million relating to stock options exercised. These proceeds were partially reduced by cash used to repay a related party note related to the acquisition of Kourion Therapeutics of $15.5 million and repayment of $0.4 million relating to our credit facility with General Electric Capital Corporation.

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

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Other than outstanding warrants exercisable for up to 1,430,833 shares of our common stock at March 31, 2006, we have no off balance sheet arrangements , as defined by Item 303(a)(4) of the SEC s Regulation S-K.

Commitments and Contingencies

Legal Proceedings

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the U.S. 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. 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 finding that the patents were valid and enforceable, and that the defendants infringed the patents. 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 in the case overturned the jury s verdict stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge s decision. We appealed the jury s finding as to validity of the patents. A hearing on the appeal took place on April 4, 2006.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the U.S. 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. We believe that the patents in this new action are invalid and/or 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 been consolidated in Delaware.

The U.S. Patent and Trademark Office (U.S. PTO) has ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and 427 patents at issue in the second case based on prior art. A second re-examination of the 427 patent was ordered in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010. In April 2006, the U.S. PTO issued office actions rejecting all of the claims of the 645 and 681 patents. The U.S. PTO ruled that PharmaStem s patent claims are unpatentable over prior art. The office actions issued by the U.S. PTO are not final determinations. PharmaStem will have the right to respond to the office actions by either amending the claims of the patents to try to avoid the prior art or by challenging the U.S. PTO s decision. PharmaStem will also have recourse through the Board of Appeals on the office actions. In early 2005, the U.S. PTO issued an initial office action rejecting all the claims of the 553 patent. PharmaStem subsequently cancelled certain of the claims and argued for patentability of the remaining claims. The U.S. PTO has not yet issued a final office action on the 553 patent. An office action on the 427 patent re-examination has not yet been issued.

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On October 6, 2005, the Delaware court granted our motion to stay all discovery in the second lawsuit pending decisions from the Federal Circuit on PharmaStem s appeal of the District Court s ruling of non-infringement in the original case and from the U.S. PTO on the patent re-examinations.

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against us. If we are found to infringe or at any other time during the course of either case, including if the court of appeals were to overturn the district court s non-infringement ruling, we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. 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. 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 could 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. 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, 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 alleged that the defendants made fraudulent claims in connection with the marketing of their cord blood banking services and sought 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 U.S. 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. On March 31, 2006, the Court dismissed all claims with prejudice at the request of the parties.

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

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liability, although we also believe that the present classifications can be supported and defended. It is not possible based on the current available information to reasonably estimate the scope of any potential liability.

Critical Accounting Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies include:

Accounting for Stock-Based Compensation. We have one stock-based employee compensation plan. On January 1, 2006, we adopted SFAS 123R using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the condensed consolidated financial statements going-forward (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation expense is measured using the Black-Scholes option pricing model at the grant date based on the value of the award and is recognized as expense on a straight-line basis over the requisite service period. Stock-based employee compensation expense was $0.7 million for the three months ended March 31, 2006. Previously, we had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee stock options at their intrinsic value in the condensed consolidated financial statements.

We were required to make significant estimates related to the adoption of SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. For stock option grants issued during the three month period ended March 31, 2006, we used a weighted-average expected stock-price volatility of 65%. We also determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three month period ended March 31, 2006, we used a weighted-average expected option life assumption of 4.57 years.

We recognized the full impact of our share-based payment plan in the condensed consolidated statement of operations for the three month period ended March 31, 2006 under SFAS 123R and did not capitalize any such costs on the condensed consolidated balance sheets. We have recognized compensation expense for our stock option grants. Upon adoption of SFAS 123R, using the modified prospective method, we recognized a benefit of $0.3 million as a cumulative effect of a change in accounting principle resulting from the requirement to estimate forfeitures of our stock option grants at the date of grant instead of recognizing them as incurred. The estimated forfeiture rate was applied to the previously recorded stock-based compensation expense of our unvested stock options in determining the cumulative effect of a change in accounting principle.

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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 equity. 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 U.S government and its agencies, investment grade corporate and money market instruments. These investments are denominated in U.S. dollars. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

ITEM 4. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2006 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 March 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The section entitled Litigation in Note 4 Commitments and Contingencies of the 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 1A. RISK FACTORS

NOTE ABOUT FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to the potential and anticipated results of our development programs, and our views as to the possible outcome of pending litigation and actions related to our intellectual property portfolio. We have based these forward-looking statements on our current expectations about such future events. While we believe these expectations are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those discussed in this report under this heading Risk Factors . Given these risks and uncertainties, you are cautioned not to place substantial weight on forward-looking statements. The forward-looking statements included in this report are made only as of the date of this report. We do not undertake any obligation to update or revise any of these statements.

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

We have generated operating losses since our inception. As of March 31, 2006, we had cumulative net losses of approximately $178.6 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately $105.1 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 research, clinical trials, submissions for regulatory approvals, and the expansion of clinical and commercial scale manufacturing facilities. Furthermore, we expect to make additional sales and marketing investments in the near term in our ViaCell Reproductive Health business, 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 increase sales of our ViaCord product offering particularly in the face of significant competition, and our ability to establish the safety and efficacy of our product candidates, obtain necessary regulatory approvals for such product candidates and successfully commercialize the resulting products. We cannot assure you that we will ever become profitable. Factors that may affect our ability to become profitable are described in more detail elsewhere in this Risk Factors Section.

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

Revenues from sales of ViaCord have grown significantly over the past several years, from $7.1 million in 2001, to $20.1 million, $30.9 million, $36.8 million, and $43.8 million in 2002, 2003, 2004, and 2005, respectively. In the first quarter of 2006, we had revenues from sales

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of ViaCord of $11.9 million, an increase of 20% over the first quarter of 2005. We believe that this revenue growth 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 revenues. The principal factors that may adversely affect our revenues include competition from other private cord blood banks, the risks of associated litigation, in particular, the pending PharmaStem litigation, the risks of operational issues and the risks of reputational damage. These and other risks that may affect our future revenues are described in more detail elsewhere in this Risk Factors section. If we are unable to sustain our revenues, we may need to reduce our product development activities or raise additional funds earlier than anticipated or on unfavorable terms, and our stock price may be adversely affected.

If we do not prevail in the PharmaStem litigation, we may be prevented from selling our ViaCord product offering, or may have to incur significant expenses.

In 2002, PharmaStem Therapeutics, Inc. filed suit against us and several other defendants in the U.S. 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 finding that the patents were valid and enforceable, and that the defendants infringed the patents. 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 in the case overturned the jury s verdict and entered judgment in our favor and against PharmaStem, stating that PharmaStem had failed to show infringement. PharmaStem has appealed the judge s decision. We have appealed the jury s finding as to validity of the patents. A hearing on the appeal was held on April 4, 2006.

In July 2004, PharmaStem filed a second complaint against us. The second complaint was filed in the U.S. 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. We believe that the patents in this new action are invalid and/or 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 been consolidated in Delaware.

The U.S. PTO has ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and the 427 patents at issue in the second case based on prior art. A second re-examination of the 427 patent was ordered in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. In April 2006, the U.S. PTO issued office actions rejecting all of the claims of the 645 and 681 patents. The U.S. PTO ruled that PharmaStem s patent claims are unpatentable over prior art. The office actions issued by the U.S. PTO are not final determinations. PharmaStem will have the right to respond to the office action by either amending the claims of the patents to try to avoid the prior art or by challenging the U.S. PTO s decision. PharmaStem

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will also have recourse through the Board of Appeals on the office actions. In early 2005, the U.S. PTO issued an initial office action rejecting all the claims of the 553 patent. PharmaStem subsequently cancelled certain of the claims and argued for patentability of the remaining claims. The U.S. PTO has not yet issued a final office action on the 553 patent. An office action on the 427 patent re-examination has not yet been issued.

On October 6, 2005, the Delaware court granted our motion to stay all discovery in the second lawsuit 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.

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against us. If we are found to infringe or at any other time during the course of either case, including if the court of appeals were to overturn the district court s non-infringement ruling, we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. 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. 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 could 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.

A loss in either of the PharmaStem lawsuits could have a material adverse effect on our ability to generate revenues from our ViaCord product offering, which is currently our only commercialized product, and would have a significant adverse impact on our business, results of operations and stock price. Even if we ultimately prevail, we are likely to incur significant legal expenses during the course of the cases.

If we are not able to successfully develop and commercialize new products, we may not generate sufficient revenues to continue our business operations.

No company has yet been successful in its efforts to develop and commercialize a stem cell product. Stem cell products in general 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.

Our cellular therapy product candidates are in the early stages of development. Only one of our therapeutic product candidates, CB001, has entered human clinical trials. CB001 consists of a highly enriched population of hematopoietic stem cells which are expanded from umbilical cord blood using our Selective Amplification technology. While stem cell populations expanded using our Selective Amplification technology have shown promising results in preclinical research, those results have not been obtained in humans and may not be indicative of results we may encounter in clinical trials. We may discover that manipulation of stem cells using Selective Amplification or any of our other expansion technologies changes the biological characteristics of the 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

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achieve benefits or a safety profile that is acceptable and better or equal to existing therapies.

Drug development in general involves a high degree of risk. We are likely to encounter hurdles and unexpected issues as we proceed in our development of any particular product candidate. For example, in the second half of 2005, the FDA put our Phase 1 clinical trial of CB001 on clinical hold while we assessed two cases of Grade IV aGVHD, a potential and sometimes fatal side effect of transplantation. The FDA lifted the clinical hold in December 2005. However there is no assurance that we will not encounter additional safety issues that may cause us to further delay or discontinue the trial, including additional cases of aGVHD. Several other factors could also prevent completion or cause further delay in this trial, or cause us to decide to end the trial early without enrollment of the remaining two patients, including if we are unable to enroll the final two patients in a timely manner and prior to expiration of the lease to our Worcester manufacturing facility. To date, enrollment in our Phase 1 clinical trial for CB001 has been slower than anticipated and we cannot predict whether or when we will be able to enroll the final patients to complete the trial. We are currently manufacturing CB001 for our Phase 1 clinical trial at our Worcester facility and plan to transfer our existing manufacturing operations from the Worcester facility to our Cambridge manufacturing facility after completion of the CB001 Phase 1 clinical trial. We expect that our access to the Worcester facility will terminate in September 2006. If the CB001 trial has not been completed by that time, we expect that we will have to either transition CB001 manufacturing to our Cambridge facility prior to completion of the CB001 trial which could take several months or more or stop the CB001 trial early and complete analysis with the number of patients who have been treated as of such date. The success of any transition of CB001 manufacturing for the Phase 1 clinical trial to our Cambridge facility is subject to a number of risks and uncertainties, including the complexity of such a transition and the amount of time and resources it takes to complete such a transition. The FDA would need to be notified of our intent to transition the CB001 process and we would need to file an amendment to our IND. There is no guarantee that the FDA would find this change and proposed comparability studies acceptable during our trial. Transitioning the manufacturing to our Cambridge facility prior to completion of the Phase 1 trial could result in a supply disruption and delay in completion of the trial. As noted above, we may elect instead to complete the trial with fewer than ten patients which, given the smaller sample size, could have an impact on the overall trial results.

We also may encounter hurdles related to the clinical path for CB001. For example, in improving our Selective Amplification process for CB001, the resulting product candidate may be viewed by the FDA as sufficiently different from the product candidate being used in our current Phase 1 clinical trial. If so, the FDA may require that we conduct new Phase 1 clinical trials using the product candidate manufactured using the improved process to generate appropriate safety data to support later stage clinical 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 1 trials. If we need to redesign trials for CB001 that incorporate mini-transplants, it could require repeating earlier trials. Repeating clinical trials for any reason would significantly delay our development efforts related to CB001.

As we obtain results and safety information from preclinical or clinical trials of our product candidates, we may elect to discontinue development or delay additional preclinical studies or clinical trials in order to focus our resources on more promising product candidates. There is no assurance, for example, that the results of the CB001 Phase 1 clinical trial will warrant further clinical development or ultimately prove to be safe and effective. We may also change the indication being pursued for a particular product candidate or otherwise revise the development plan for that candidate. Moreover,

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product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical testing.

We cannot market any product candidate until regulatory agencies grant marketing approval or licensure. 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 our stem cell-based product candidates, including CB001, may be more complex and lengthy than the pathway for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the U.S., we will need to submit clinical data concerning our products and receive regulatory approval from the appropriate governmental agencies. Standards for approval outside the U.S. 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.

The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never gain necessary approvals. Any difficulties that we encounter in developing our product candidates and in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly. If we are not able to successfully develop our product candidates and obtain regulatory approval, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

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 approvals.

We may not be able to successfully develop our ViaCyte oocyte cryopreservation product candidate.

We are in discussions with the FDA on an IDE to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. In response to the original 510(k) application filed by our media supplier, the FDA indicated that the media supplier had not demonstrated substantial equivalence of the media to a predicate device and, as a result, the FDA could not clear the media for commercial use. The FDA indicated that the 510(k) application could be re-submitted when additional data supporting substantial equivalence of the media to a predicate device were available. The FDA has indicated that we will need to conduct a clinical study of ViaCyte in oocyte cryopreservation that produces pregnancy and birth rate data to support the application. We are in discussions with the FDA related to the IDE and, in particular, the design and size of the trial. However, there is no assurance that we will be able to reach agreement with the FDA on a trial design or size that is feasible and acceptable to both the FDA and us. In addition, even if we undertake the clinical trial, there is no assurance that we will be able to show that our ViaCyte cryopreservation product is safe and effective for its intended use. While methods for preserving sperm and embryos are well-established and have been utilized in *in vitro* fertilization procedures for the past three decades, methods for cryopreserving oocytes have not been widely employed due to difficulties encountered in freezing this cell. The oocyte is the largest cell in the body and, due to its large liquid volume, tends to form ice crystals during the freezing process. Formation of ice crystals can damage this cell, making it unsuitable to develop into a healthy embryo. These obstacles represent a significant barrier to the cryopreservation of oocytes. There is no assurance that we will be able to generate the number of live births needed to show that our product candidate is effective. We may also encounter unexpected safety issues. Even if we are successful in our efforts to reach agreement with the FDA on a clinical trial design and size and the results of such trial are favorable,

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there is no assurance that the FDA will agree that we have met the standards for 510(k) clearance. The FDA could at any time determine that some or all of the components used to cryopreserve the oocytes will require pre-market approval, or PMA, and additional trials, which would involve additional time and expense. Even if we are successful in our efforts to develop and gain approval for the ViaCyte oocyte cryopreservation product candidate, the FDA could ask for post-approval safety monitoring which would entail additional expense.

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

As of March 31, 2006, we had approximately $58.0 million in cash, cash equivalents and short-term investments. In order to develop and bring our new products 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 sales of our ViaCord product offering;

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;

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;

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.

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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.

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 U.S. 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. While Selective Amplification is covered by issued patents and we are not aware of any challenges to the validity of these patents, 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, or 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. Interference proceedings brought by the U.S. PTO 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.

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 invalid or 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. 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

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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.

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 issued patents on Selective Amplification will expire in 2015. 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 2015. 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. 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 U.S.

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 U.S., 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 patent applications of which we are unaware that will result in issued patents in our field, and avoiding patent infringement may be difficult. We may inadvertently infringe third party patents or patent applications. These third parties could bring claims against us, our collaborators or our licensors that, even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. For example, 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 believe 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 Flt3-L 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 or be required to repeat earlier clinical trials, which would be costly and time consuming.

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We may be required to pay substantial damages to a patent holder in an infringement case in the event of a finding of infringement. Under some circumstances in the U.S., 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. Further, if patent infringement suits are 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.

Patent infringement cases often involve substantial legal expenses. For example, we are involved in two patent infringement lawsuits filed against us by PharmaStem. As of March 31, 2006, we have incurred total legal expenses of approximately $7.3 million related to these cases. Depending upon the 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 second 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.

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 potentially might relate to our CB001 product candidate, if approved and commercialized. 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. There is no assurance, 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 by us based on similar technology and may also delay the regulatory approval process for future product candidates. 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 may harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

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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 continually 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.

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

Cord blood preservation. The FDA has adopted good tissue practice, or 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 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 PMA or 510(k) clearance for the collection kits, or new drug application supplement, or sNDA, approval for a drug component of the kits or to file an IND/BLA and seek approval for the cell product. Securing any necessary medical device 510(k) clearance or PMA for the cord blood collection kits, or sNDA approval for a drug component of the kits or BLA, 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 for the kits or sNDA approval of a drug component of the kits or BLA approval prior to further distribution of the kits.

Of the states in which we provide cord blood banking services, only New Jersey, New York, Maryland, Kentucky, Illinois and Pennsylvania currently require that cord blood services be licensed, permitted or registered. We are currently licensed, permitted or registered to operate in all of these states. If other states adopt requirements for the licensing, permitting or registration of cord blood preservation services, we would have to obtain licenses, permits or registration 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

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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 a PMA. 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. We believe that the time to conduct a clinical study, prepare a new 510(k), and receive FDA clearance for our oocyte cryopreservation product candidate, will take several years.

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 have only limited experience manufacturing cell therapy product candidates, and we may not be able to manufacture our product candidates in quantities sufficient for 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.

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 maintain supply agreements with third parties who manufacture these components to cGMP standards. 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.

Certain antibodies, growth factors and other reagents are critical components used in our stem cell production process. Our Selective Amplification process currently uses components sold to us by certain manufacturers, and we need to establish relationships with other suppliers to manufacture cGMP grade products for commercial sale. We are dependent on our suppliers for such components as SCF, Flt3-L,

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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 1 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.

If our cord blood processing and storage facility or our clinical manufacturing facilities are damaged or destroyed or we are no longer able to use our leased clinical manufacturing facilities, our business, programs and prospects could 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 from our cord blood banking customers and could affect our ability to continue to provide umbilical cord blood banking services.

We lease a clinical manufacturing facility located in Worcester, Massachusetts that is capable of producing stem cells for Phase 1 and 2 clinical trials. We have built out, but not yet completed validation of, a facility in Cambridge, Massachusetts that we intend to replace our Worcester facility and to be capable of producing stem cells for Phase 1, Phase 2 and 3 clinical trials and initial commercialization. We are currently manufacturing CB001 for our Phase 1 clinical trial at our Worcester facility and plan to transfer our existing manufacturing operations from the Worcester facility to our Cambridge manufacturing facility after completion of the CB001 Phase 1 clinical trial. We expect that our access to the Worcester facility will terminate in September 2006. If the CB001 trial has not been completed by that time, we expect that we will have to either transition CB001 manufacturing for the Phase 1 clinical trial to our Cambridge facility prior to the completion of the CB001 trial which could take several months or more or stop the CB001 trial early and complete analysis with the number of patients who have been treated as of such date. The success of any transition of CB001 manufacturing to our Cambridge facility is subject to a number of risks and uncertainties, including the complexity of such a transition and the amount of time and resources it takes to complete such a transition. The FDA would need to be notified of our intent to transition the CB001 process and we would need to file an amendment to our IND. There is no guarantee that the FDA would find this change and proposed comparability studies acceptable during our trial. Transitioning the manufacturing to our Cambridge facility prior to completion of Phase 1 clinical trial could result in a supply disruption and

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a delay in completion of the trial. As noted above, we may elect instead to complete the trial with fewer than ten patients which, given the smaller study sample size, could have an impact on the overall trial results.

If we are able to successfully validate the Cambridge facility and transfer existing manufacturing operations to the facility, we expect to manufacture all of our stem cell product candidates in the facility for the next several years. If the Cambridge facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. In the event of a temporary or protracted loss of this facility or equipment, we may be able to transfer manufacturing to a third party, but the shift would likely be expensive, and the timing would depend on availability of third party resources and the speed with which we could have a new facility approved by the FDA.

While we believe that we have insured against losses from damage to or destruction of our facilities consistent with typical industry practices, if we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies. Currently, we maintain insurance coverage totaling $21.9 million against damage to our property and equipment, and an additional $19.0 million to cover incremental expenses and loss of profits resulting from such damage.

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 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 Stem Cell Therapeutic Act, 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 antigens, or HLA, typing advances, then unrelated cord blood transplantation may become safer and more efficacious, similarly reducing the clinical advantage of related cord blood transplantation.

The pharmaceutical and biotechnology businesses are also 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 Therapeutics, Inc., Celgene Corporation, Cytori Therapeutics, Inc., Gamida-Cell, Genzyme Corporation, Bioheart, Inc., and Osiris Therapeutics, Inc. 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 1/2

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trial. Enrollment for this trial was completed in August 2004. This product candidate, 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 Stem Cell Therapeutic Act provides financing for a national system of public cord blood banks to encourage cord blood donations from an ethnically diverse population. An increase in the number and diversity of publicly-available cord blood units from public banks could diminish the necessity for cord blood-derived therapeutics produced with our Selective Amplification technology.

In oocyte cryopreservation, if our ViaCyte product candidate is successfully developed and approved, we expect to compete with 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 cryopreservation 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 cryopreservation markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our 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 reputation among clients and the medical and birthing services community is extremely important to the commercial success of our ViaCord product offering. This is due in significant part to the nature of the product and service we provide. For instance, as part of our ViaCord product offering, 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. 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, and if we are found liable, whether our insurance coverage will be sufficient to cover such damages.

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The manufacture and sale of 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 our products or product candidates 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 additional products. We may not be able to obtain insurance with adequate coverage for potential liability arising from any such potential products on acceptable terms 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.

If we are not able to recruit and retain qualified management and other 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 employees with scientific or other skills 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 business and our research and development activities. 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.

Prior to completing our IPO in January 2005, we maintained a small finance and accounting staff because we were a private company. Our reporting obligations as a public company, as well as our need to comply with the requirements of the Sarbanes-Oxley Act of 2002, the rules and regulations of the Securities and Exchange Commission and the NASDAQ National Market, 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 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.

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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 the transactions may be dilutive and we may be 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 increase our net loss.

The successful commercialization 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 for our therapeutic product candidates, we intend to sell such products initially in the U.S. and the European Union. In the U.S., the market for many pharmaceutical products is affected by the availability of reimbursement from third party payers such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. Our 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 our 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 U.S. 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 are not reimbursed by the government or third party insurers, the market for those products would be limited. We cannot be sure

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

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

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

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with the standards prescribed by these regulations, we cannot assure you that accidental contamination or injury to employees and third parties from these materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

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; and

economic or other external factors.

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

Sales of Unregistered Securities

During the first quarter of 2006, we issued 208,744 shares of common stock to a former employee and warrant holders upon an option exercise for compensation by the former employee for services provided and warrant exercises in connection with our Series J preferred stock. In lieu of using cash to pay the exercise price, the option holder and warrant holders utilized a cashless exercise procedure in which they forfeited common shares and/or warrants to purchase the shares of common stock that we issued to them. There were no underwriters employed in connection with any of these transactions. The option grant and related stock issuance were exempt from registration under the Securities Act of 1933, as amended, or the Securities Act, under Rule 701 promulgated thereunder, because the securities were offered and sold pursuant to either a written compensatory plan or a written contract relating to compensation and made pursuant to an offer made prior to our initial public offering. The warrant issuances and related stock issuances were exempt from registration under the Securities Act under Regulation D and Section 4(2) thereunder because the issuances and exercises did not involve a public offering.

Use of Proceeds from Registered Securities

We registered shares of our common stock in connection with our initial public offering, or IPO, under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-114209) in connection with our IPO was declared effective by the SEC on January 19, 2005. The IPO commenced as of January 20, 2005 and was

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completed on January 26, 2005. Credit Suisse and UBS Investment Bank were the managing underwriters.

All 8,625,000 shares of our common stock registered in the offering were sold, with an IPO price per share of $7.00. The aggregate purchase price of the IPO was $60,375,000, of a maximum potential registered aggregate offering price of $92,000,000. The net offering proceeds to us after deducting total related expenses were approximately $53,300,000.

No payments for the above expenses or other payments of proceeds were made directly or indirectly to (i) any of our directors, officers or their associates, except as described below (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds of the IPO, after payment of approximately $15.5 million for all outstanding principal and interest on promissory notes held by funds affiliated with MPM Asset Management LLC, the manager of which served on our board of directors until June 9, 2005, are invested in investment grade securities with the weighted average days to maturity of the portfolio less than six months and no security with an effective maturity in excess of 12 months. To date, apart from the payment of promissory notes of $15.5 million, we have not used any of the net proceeds from the IPO and there has been no material change in the planned use of proceeds from the IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act.

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.

May 15, 2006

/s/ Marc D. Beer

Marc D. Beer
Chief Executive Officer
(Principal Executive Officer)

May 15, 2006

/s/ Stephen G. Dance

Stephen G. Dance
Chief Financial Officer
(Principal Financial Officer)

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EXHIBIT INDEX

No.	Item
10.1 (1)	First Amendment dated February 14, 2006 to Lease Agreement dated December 22, 2003 between ViaCell, Inc. and MA-Riverview/245 First Street, LLC
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to our annual report on Form 10-K (No. 0-51110) filed with the SEC on March 31, 2006.