

VIACELL INC  
Form 10-Q  
May 10, 2007

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
**For the quarterly period ended March 31, 2007**

**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**

*(State or Other Jurisdiction of Incorporation or  
Organization)*

**04-3244816**

*(I.R.S. Employer Identification No.)*

**245 First Street, Cambridge, MA**

*(Address of Principal Executive Offices)*

**02142**

*(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  No

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  Accelerated filer  Non-accelerated filer

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  No

As of May 6, 2007, 38,757,042 shares of the Company's common stock, \$0.01 par value, were outstanding.

**Table of Contents**

**ViaCell, Inc.**  
**Quarterly Report on Form 10-Q**  
**For the Fiscal Quarter Ended March 31, 2007**  
**NOTE ABOUT REFERENCES TO VIACELL**

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

**NOTE ABOUT TRADEMARKS**

ViaCell® and ViaCord® are registered trademarks of ViaCell, Inc. ViaCyte<sup>sm</sup> is a service mark of ViaCell, Inc. Cell Sentinel<sup>tm</sup> is a trademark of Pall Corporation. Motherhood Maternity®, A Pea in the Pod®, Mimi Maternity®, and Destination Maternity<sup>tm</sup> are trademarks of Mothers Work, 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 research and development programs, and our views as to the possible outcome of pending litigation related to our intellectual property portfolio and other disputes. 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.

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements (unaudited)</u></b>	
<u>Condensed Consolidated Balance Sheets March 31, 2007 and December 31, 2006</u>	4
<u>Condensed Consolidated Statements of Operations Three months ended March 31, 2007 and March 31, 2006</u>	5
<u>Condensed Consolidated Statements of Comprehensive Loss Three months ended March 31, 2007 and March 31, 2006</u>	6
<u>Condensed Consolidated Statements of Cash Flows Three months ended March 31, 2007 and March 31, 2006</u>	7
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	8
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	17
<b><u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	28
<b><u>Item 4. Controls and Procedures</u></b>	28
<b><u>PART II OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	29
<b><u>Item 1A. Risk Factors</u></b>	29
<b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	46
<b><u>Item 3. Defaults upon Senior Securities</u></b>	47
<b><u>Item 4. Submission of Matters to a Vote of Security Holders</u></b>	47
<b><u>Item 5. Other Information</u></b>	47
<b><u>Item 6. Exhibits</u></b>	47
<b><u>Signatures</u></b>	48
<b>EXHIBITS</b>	
<b><u>Index to Exhibits</u></b>	49
<b><u>EX-31.1 SECTION 302 CERTIFICATION OF CEO</u></b>	
<b><u>EX-31.2 SECTION 302 CERTIFICATION OF CFO</u></b>	

EX-32.1 SECTION 906 CERTIFICATION OF CEO  
EX-32.2 SECTION 906 CERTIFICATION OF CFO

**Table of Contents**

**PART I FINANCIAL INFORMATION**  
**Item 1 Financial Statements**  
**ViaCell, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(amounts in thousands except share and per share data)**  
**(unaudited)**

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,610	\$ 18,039
Short-term investments	32,808	33,206
Accounts receivable, less allowances of \$1,998 and \$1,787 at March 31, 2007 and December 31, 2006, respectively	12,471	12,616
Prepaid expenses and other current assets	2,059	2,008
Total current assets	61,948	65,869
Property and equipment, net	8,234	8,376
Goodwill	3,621	3,621
Intangible assets, net	2,571	2,621
Restricted cash	1,795	1,795
Total assets	\$ 78,169	\$ 82,282
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Current portion of long-term debt obligations	\$ 62	\$ 55
Accounts payable	1,642	960
Accrued expenses	8,804	9,550
Deferred revenue	7,785	7,300
Total current liabilities	18,293	17,865
Deferred revenue	16,089	14,666
Deferred rent	3,217	3,252
Contingent purchase price	8,155	8,155
Long-term debt obligations, net of current portion	22	27
Total liabilities	45,776	43,965
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 5,000,000 shares at March 31, 2007 and December 31, 2006, none outstanding		
Common stock, \$0.01 par value; authorized 100,000,000 shares at March 31, 2007 and December 31, 2006; issued and outstanding 38,747,919 and 38,525,036 shares at March 31, 2007 and December 31, 2006, respectively	387	385
Additional paid-in capital	232,962	232,215

Edgar Filing: VIACELL INC - Form 10-Q

Accumulated deficit	(201,174)	(194,490)
Accumulated other comprehensive income	218	207
Total stockholders' equity	32,393	38,317
Total liabilities and stockholders' equity	\$ 78,169	\$ 82,282

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

4

---

**Table of Contents**

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

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Processing and storage revenues	\$ 14,362	\$ 11,937
Grant revenues	95	144
Total revenues	14,457	12,081
Operating expenses:		
Cost of processing and storage revenues	2,639	2,328
Research and development	3,278	3,466
Sales and marketing	11,121	7,922
General and administrative	4,800	4,638
Restructuring		(181)
Total operating expenses	21,838	18,173
Loss from operations	(7,381)	(6,092)
Interest income (expense):		
Interest income	698	724
Interest expense	(1)	(26)
Total interest income, net	697	698
Loss from operations before cumulative effect of change in accounting principle	(6,684)	(5,394)
Cumulative effect of change in accounting principle		283
Net loss	\$ (6,684)	\$ (5,111)
Net loss per share:		
Basic and diluted net loss per common share before cumulative effect of change in accounting principle	\$ (0.17)	\$ (0.14)
Cumulative effect of change in accounting principle		0.01
Basic and diluted net loss per common share	\$ (0.17)	\$ (0.13)
Weighted average shares used in basic and diluted net loss per share computation	38,669	38,295

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



**Table of Contents**

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

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Net loss	\$ (6,684)	\$ (5,111)
Foreign currency translation adjustment	11	10
Comprehensive loss	\$ (6,673)	\$ (5,101)

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

**Table of Contents**

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

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Cash flows from operating activities:		
Net loss	\$ (6,684)	\$ (5,111)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	577	559
Cumulative effect of change in accounting principle		(283)
Stock-based compensation	613	711
Reserve for bad debt	331	266
Tenant improvement allowance		62
Changes in assets and liabilities:		
Accounts receivable	(186)	747
Prepaid expenses and other current assets	(52)	(906)
Accounts payable	681	(51)
Accrued expenses	(759)	1,209
Deferred revenue	1,908	1,292
Deferred rent	(89)	(235)
Net cash used in operating activities	(3,660)	(1,740)
Cash flows from investing activities:		
Purchases of property and equipment	(306)	(400)
Proceeds from maturities of investments	17,128	8,887
Purchases of investments	(16,730)	(8,055)
Net cash provided by investing activities	92	432
Cash flows from financing activities:		
Proceeds from exercise of stock options	136	22
Repayments on credit facilities		(437)
Payments of capital lease principal	(10)	(16)
Net cash provided by (used in) financing activities	126	(431)
Effect of change in exchange rates on cash	13	30
Net decrease in cash and cash equivalents	(3,429)	(1,709)
Cash and cash equivalents, beginning of period	18,039	33,138
Cash and cash equivalents, end of period	\$ 14,610	\$ 31,429

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



**Table of Contents**

**ViaCell, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Organization and Nature of Business**

ViaCell is a biotechnology company dedicated to enabling the widespread application of human cells as medicine. The Company has a reproductive health business that generates revenues from sales of ViaCord, a service offering through which expectant families can preserve their baby's umbilical cord blood for possible future medical use. Stem cells from umbilical cord blood are a treatment option today for over 40 diseases, including certain blood cancers and genetic diseases. The Company is also working to leverage its commercial infrastructure and product development capabilities by developing ViaCyte<sup>sm</sup>, a product candidate being studied for its potential to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs. The Company's other research and development efforts are focused on investigating the potential for new therapeutic uses of umbilical cord blood-derived stem cells and on technology for expanding populations of these cells. The Company is concentrating these efforts in the areas of cancer, cardiac disease, and diabetes.

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 a processing and storage facility in Hebron, Kentucky.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying condensed consolidated financial statements as of March 31, 2007 and for the three months ended March 31, 2007 and 2006, and related notes, are unaudited but in management's opinion include all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary for fair statement of the interim periods presented. The Company has prepared its unaudited, condensed 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. (GAAP). The Company's accounting policies are described in the Notes to the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and updated, as necessary, in this Form 10-Q. Results for the three months ended March 31, 2007 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. The year-end condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

***Use of Estimates***

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

**Table of Contents****Stock-Based Compensation**

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards 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 condensed 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. The Company had previously 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. Employee stock-based compensation expense was \$0.6 million and \$0.7 million for the three months ended March 31, 2007 and March 31, 2006, respectively.

The Company recognized the full impact of its share-based payment plan in the condensed consolidated financial statements for the three months ended March 31, 2007 and March 31, 2006 under SFAS 123R and did not capitalize any such costs on the condensed consolidated balance sheets, as the costs that qualified for capitalization were not material. Expense recognized in connection with the adoption of SFAS 123R increased the Company's net loss for the three months ended March 31, 2007 and March 31, 2006 by \$0.6 million and \$0.7 million, respectively, and increased basic and diluted net loss per share by \$0.02 for both the three months ended March 31, 2007 and March 31, 2006. There was no impact in the three months ended March 31, 2007 and March 31, 2006 on the Company's cash flows from operating, investing or financing activities in connection with recognition of stock-based compensation expense under SFAS 123R.

The following table presents stock-based compensation expense included in the Company's unaudited condensed consolidated statements of operations (in thousands):

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Cost of processing and storage revenues	\$ 14	\$ 15
Research and development	50	104
Sales and marketing	80	57
General and administrative	469	535
Total stock-based compensation expense	\$ 613	\$ 711

The fair value of stock options as of their respective grant dates was estimated using the Black-Scholes option-pricing model.

**Table of Contents**

Presented below is the Company's stock option activity for the three months ended March 31, 2007 and March 31, 2006, respectively:

	Three Months Ended March 31, 2007		Three Months Ended March 31, 2006	
	Number of Options Outstanding	Weighted Average Exercise Price	Number of Options Outstanding	Weighted Average Exercise Price
Outstanding at beginning of period	3,991,327	\$3.02	3,930,694	\$2.77
Granted	415,145	4.79	240,625	5.21
Exercised	(35,446)	3.84	(35,051)	0.65
Canceled	(33,037)	5.44	(17,072)	6.17
Outstanding at end of period	4,337,989	3.16	4,119,196	2.91
Exercisable at end of period	2,465,551		2,178,044	
Weighted average fair value of options granted		2.28		2.93

**Net Loss Per Common Share**

Basic net loss per share is computed by dividing net loss 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 for the period by the weighted average number of common and potentially dilutive shares of common stock outstanding during the period. Potentially dilutive shares of common stock consist of shares of common stock issuable upon the exercise of stock options and warrants. Potentially dilutive shares of common stock 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, 2007	Three Months Ended March 31, 2006
Basic and diluted net loss per share:		
Net loss	\$ (6,684)	\$ (5,111)
Weighted average number of common shares outstanding	38,669	38,295
Basic and diluted net loss per share	\$ (0.17)	\$ (0.13)

The following reflects the weighted average of potentially dilutive securities that were excluded from the calculation of basic and diluted net loss per share because their effect was antidilutive:

	Three Months Ended March 31, 2007	Three Months Ended March 31, 2006
Stock Options	4,031,549	3,958,946
Warrants	1,262,777	1,837,291



**Table of Contents*****In-Process Research and Development Expense***

As part of the Company's acquisition of Kourion Therapeutics in September 2003, the Company is obligated to make up to four future payments ( milestone payments ) of \$3.0 million each to former shareholders of Kourion Therapeutics if certain product development goals are achieved within specified timeframes. These milestone payments are payable in cash or stock, valued at its fair market value at the time of issuance, at the election of each former Kourion shareholder. On December 31, 2006, the first of these milestone payments expired and was not paid since the related development goal was not met within the required timeframe. As of March 31, 2007, the Company has \$8.2 million in contingent purchase price classified as long-term liabilities on its condensed consolidated balance sheet associated with the remaining outstanding milestone payments, which was originally recorded as an offset to the amount of negative goodwill associated with the acquisition of Kourion Therapeutics. Of the remaining \$9.0 million of potential milestone payments, an additional \$3.0 million will expire and never be paid if certain development goals are not met by June 30, 2007. The Company currently expects that these development goals will not be met and that its long-term liabilities will therefore be reduced to \$6.0 million as of June 30, 2007 to reflect the two remaining milestone payments that will remain outstanding. Should this occur, the reduction in long-term liabilities is expected to result in a credit to in-process research and development expense of \$2.2 million in the quarter ended June 30, 2007.

**Recent Accounting Pronouncements**

In February 2007, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* Including an amendment of FASB Statement No. 115 ( SFAS 159 ), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 will be effective for the first fiscal year that begins after November 15, 2007. The Company has not yet completed its evaluation of the impact of adoption of SFAS 159 on its financial condition or results of operations.

In September 2006, FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ( SFAS No. 157 ), which defines fair value under GAAP, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. Where applicable, SFAS No. 157 simplifies and codifies related guidance within GAAP and does not require any new fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company does not expect the adoption of SFAS No. 157 to have a significant immediate effect on its financial condition or results of operations.



**Table of Contents****3. Accrued Expenses**

At March 31, 2007 and December 31, 2006, accrued expenses consisted of the following (in thousands):

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
Payroll and payroll-related	\$ 1,605	\$ 1,904
Management incentive	426	1,047
Professional fees	2,004	1,829
Accrued marketing	1,878	2,079
Deferred rent, current	357	345
Accrued taxes	518	459
Other	2,016	1,887
Accrued expenses	\$ 8,804	\$ 9,550

**4. Income Taxes**

On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes ( FIN 48 ), an interpretation of FASB Statement No. 109 ( SFAS 109 ). FIN 48 establishes a single model to address accounting for uncertain tax positions. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before it can be recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement clarification, interest and penalties, accounting in interim periods, disclosure and transition. Upon adoption of FIN 48, the Company recognized no material adjustment in its liability for unrecognized income tax benefits.

As of January 1, 2007, the Company had net deferred tax assets of approximately \$61.0 million representing unrecognized tax benefits. The Company has recorded a full valuation allowance against its deferred tax assets. Due to the weight of available evidence, the Company believed it was more likely than not that the deferred tax assets will not be realized. There have been no significant changes to these amounts during the quarter ended March 31, 2007.

In many cases, the Company's uncertain tax positions are related to tax years that remain subject to examination by the relevant tax authorities. Currently, all of the Company's tax years remain open to examination by the major taxing jurisdictions in which the Company has federal and state net operating loss ( NOL ) carryforwards.

The Company conducts business in the U.S. and Singapore, and previously conducted business in Germany. The Company is subject to examination in the normal course of business by taxing authorities in all of these jurisdictions. As of March 31, 2007, no examinations related to income taxes have occurred.

At December 31, 2006, the Company had federal and state NOL carryforwards of approximately \$87.8 million and \$93.3 million, respectively, which begin to expire in 2009 and 2007, respectively, and

**Table of Contents**

federal and state research and development ( R&D ) credit carryforwards of \$3.4 million and \$1.6 million, respectively, which begin to expire in 2009 and 2013, respectively. The Company had foreign NOL carryforwards of \$14.8 million. These carryforwards expire through 2024 and are subject to review and possible adjustment by the local tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state and foreign provisions, utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation in the event of ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that the Company can utilize annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition.

The Company has not currently completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since its formation due to the significant complexity and cost associated with such a study and that there could be additional changes of control in the future. If the Company has experienced a change of control at any time since Company formation, utilization of its NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the Company's NOL or R&D credit carryforwards before utilization. Until the Company completes a study and any limitations are known, no amounts are being presented as an uncertain tax position under FIN 48.

The Company has elected to recognize interest and penalties related to uncertain tax positions in income tax expense on its condensed consolidated statements of operations. As of March 31, 2007, the Company has not accrued any interest or penalties related to uncertain tax positions.

**5. Commitments and Contingencies*****Agreements***

In August 2006, the Company entered into a data license and marketing services agreement with Mothers Work, Inc., the world's largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as Motherhood Maternity<sup>®</sup>, A Pea in the Pod<sup>®</sup>, Mimi Maternity<sup>®</sup>, and Destination Maternity<sup>™</sup>. Under the terms of the agreement, Mothers Work has granted the Company an exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. Under the terms of the agreement, the Company will pay Mothers Work \$5.0 million per year over the three-year term of the agreement which began on January 1, 2007 and, unless earlier terminated, ends on December 31, 2009. Under certain circumstances, the Company will also be obligated, at the beginning of 2009, to issue Mothers Work a warrant to purchase 100,000 shares of the Company's common stock with an exercise price of \$6.29, which represents a 30% premium to the average closing price of the Company's common stock over the ten trading days immediately preceding January 1, 2007. The warrant would be exercisable for a one year period beginning on January 1, 2010. The fair market value of the warrant will be remeasured at each reporting period and recognized over the three year term of the agreement. The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work's commitment to the Company. The dispute between Mothers Work and the

**Table of Contents**

third party is the subject of an ongoing arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. The arbitrator has denied a challenge to his ruling by the third party. While there is no assurance that the third party will not again challenge the ruling, the Company believes that reversal of this ruling is unlikely and that the termination rights under its agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, the Company agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with the Company. The Company also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. The Company's potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on the Company's assessment of the low likelihood that it might have to pay damages or legal fees given the arbitrator's ruling, the Company concluded the fair value of its indemnification obligation is not material and has not recorded a liability as of March 31, 2007.

In June 2006, the Company entered into a research collaboration agreement with the Stem Cell Internal Venture ( SCIV ) of Centocor Research and Development, Inc. to evaluate ViaCell's proprietary cord blood-derived multi-potent stem cells in preclinical testing as a potential treatment for cardiac disease. The collaboration is also supported by the Biologics Delivery Systems Group of Cordis Corporation, and is focused on dosing, delivery and targeting of ViaCell's expanded proprietary cord blood stem cells using Cordis' NOGA XP delivery system. Under the terms of the agreement, ViaCell received an initial up-front payment of \$350,000 which it recorded as a liability and is amortizing as a reduction of research and development expense, as work is performed. SCIV will be responsible for its own costs under the collaboration and will pay 50% of the research costs that ViaCell incurs under the collaboration, consistent with the agreed upon budget. As of March 31, 2007, SCIV has reimbursed the Company approximately \$0.2 million of these costs. In addition, the agreement provides SCIV with the first right to negotiate a collaboration with ViaCell on the clinical development and commercialization of a cardiac product offering based on ViaCell's proprietary cord blood stem cells.

In January 2005, the Company entered into a supply agreement with Miltenyi Biotec GmbH ( Miltenyi ). The supply agreement with Miltenyi provides for the exclusive supply by Miltenyi to ViaCell of cell separation kits for ViaCell consisting of various antibodies conjugated with magnetic particles to be used in Selective Amplification, ViaCell's proprietary technology for the expansion of stem cell populations for the development and commercialization of certain of ViaCell's proprietary cellular therapy product candidates. The initial term of the supply agreement is seven years. The Company purchased \$1.3 million of cell separation kits in 2006. The Company purchased \$0.1 million of kits in the first quarter of 2007 and has a firm order to purchase an additional \$0.2 million of cell separation kits in 2007. Since the Company has decided not to advance CB001 into further clinical trials, the Company intends to use these cell separation kits in its other research and development activities.

In addition to the revenues generated by the Company's ViaCord service offering, the Company recorded revenues in the periods presented from a grant agreement with the Economic Development Board ( EDB ) of the Government of Singapore. The Company maintains a research facility in Singapore. In April 2007, the Company reached a tentative agreement ( Agreement ) with the EDB with respect to the conclusion of the grant, which expires in May 2007, resolving a dispute related to the impact of a prior period increase in the EDB's cost reimbursement percentage on the cost reimbursement percentage provisions of the grant, and a related dispute concerning an assertion by the EDB that the Company had not fulfilled a commitment to employ a specified number of people in Singapore which was an original condition of the grant. The Company recorded a reduction of grant revenues of approximately \$0.2 million during the fourth quarter of 2006 to reflect the estimated potential settlement costs. As a result of the Agreement, the Company revised its settlement estimate resulting in the recognition of \$0.1 million of grant revenues in the quarter ended March 31, 2007. The Company expects

**Table of Contents**

to finalize the Agreement in the quarter ended June 30, 2007. As of March 31, 2007, the Company had received grant payments from EDB totaling approximately \$1.9 million and had recognized cumulative grant revenues of approximately \$1.8 million. The Company plans to cease operations in Singapore in the quarter ended June 30, 2007. As a result, the Company expects to record a restructuring charge in the range of \$0.2 million to \$0.3 million related to employee severance and facility-related costs in the quarter ended June 30, 2007.

***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., a subsidiary of Cord Blood America 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 and entered judgment in the Company's favor and against PharmaStem, stating that PharmaStem had failed to prove infringement, consequently the Company has not recorded a liability as of March 31, 2007. 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 was held at the U.S. Court of Appeals for the Federal Circuit, on April 4, 2006 and a final ruling has not been issued.

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 in any event. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That motion is currently stayed. The Company believes the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, the Company filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, the Company's request was granted. The cases have been consolidated in Delaware.

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 of Delaware's ruling in the original case and from the U.S. Patent and Trademark Office ( U.S. PTO ) on the patent re-examinations described below.

In late 2006, the U.S. PTO issued final decisions in the existing 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. The U.S. PTO had ordered a second re-examination of the 427 patent in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO issued notice of its intent to allow the remaining claims of all of the patents.

**Table of Contents**

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 it from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant the Company a license or to do so on economically reasonable terms, and previously informed the Company that it would not do so after October 15, 2004. While the Company does not believe this outcome is likely, in the event of an injunction, if 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.

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.

**Table of Contents****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 unaudited consolidated financial statements and the accompanying notes appearing at the beginning 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) of this report.

**Overview**

ViaCell is a biotechnology company dedicated to enabling the widespread application of human cells as medicine. We have a reproductive health business that generated revenues of \$14.4 million in the first quarter of 2007 and \$54.1 million in 2006 from sales of ViaCord, a service offering through which expectant families can preserve their baby's umbilical cord blood for possible future medical use. Stem cells from umbilical cord blood are a treatment option today for over 40 diseases, including certain blood cancers and genetic diseases. We are also working to leverage our commercial infrastructure and product development capabilities by developing ViaCyte, our product candidate being studied for its potential to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs. Our other research and development efforts are focused on investigating the potential for new therapeutic uses of umbilical cord blood-derived stem cells and on technology for expanding populations of these cells. We are concentrating these efforts in the areas of cancer, cardiac disease and diabetes.

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 processing and storage of a child's umbilical cord blood stem cells collected at birth. These fees consist of an initial fee for collection, processing and freezing of the umbilical cord blood stem cells and an annual storage fee. The annual storage fee provides a growing annuity of future revenue as the number of stored umbilical cord blood stem cells increases. Our revenues are recorded net of discounts and rebates that we offer our customers from time to time under certain circumstances. 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 long-term future revenues from our umbilical cord blood preservation 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 as of March 31, 2007.

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

**Table of Contents**

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 umbilical cord blood preservation business.

***Operating Expenses***

Cost of processing and storage revenues reflects the cost of transporting, testing, processing and storing umbilical cord blood stem cells at our processing facility in Hebron, Kentucky. Our cost of processing and storage revenues includes expenses incurred by third party vendors relating to the transportation of cord blood stem cells 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 revenues. 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. In July 2004, PharmaStem filed a separate lawsuit claiming that we infringed additional patents. Pending a decision on the appeal and further action by the court in this litigation, we do not intend to record a royalty expense in future periods, since we believe PharmaStem's claims are without merit. It is possible that the final outcome of our litigation with PharmaStem could result in us being required to pay damages to PharmaStem at a higher or lower amount than previously awarded by the jury in Delaware. Should this occur, our financial condition 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 to PharmaStem, or what those amounts might be.

Our research and development expenses consist primarily of costs associated with development of our product candidates, including the Phase 1 clinical trial of our expanded umbilical cord blood product candidate, CB001, development of ViaCyte, our oocyte cryopreservation product candidate, and our preclinical research evaluating our proprietary cord blood-derived multi-potent stem cells as a potential treatment for cardiac disease. These expenses represent preclinical and clinical development costs, and costs associated with non-clinical support activities such as toxicological testing, manufacturing, process development and regulatory services. The cost of our research and development staff is the most significant category of expense, however we also incur expenses for external service providers, including those involved in preclinical studies, consulting expenses, and lab supplies. The major outside expenses relating to our CB001 clinical trial included 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 included site costs and the cost of the cord blood. In February 2007, we announced that, based on the results of the Phase 1 trial, we would not advance CB001 in further clinical trials.

We expect that our research and development expenses will continue to increase over the next several years as a result of increased costs and expenses associated with our ViaCyte clinical trial and possible future clinical trials of other product candidates, including the product candidate that we are studying in preclinical trials as a potential treatment for cardiac disease, if preclinical data supports moving forward. Future research and development expenses may also include costs associated with product candidates that we might license or acquire, and, if our programs are successful, costs and expenses associated with submissions for regulatory approvals and the expansion of clinical and commercial scale manufacturing

**Table of Contents**

facilities. The amount of these increases is difficult to predict due to the uncertainty inherent in our research, development and manufacturing programs and activities, the timing and scope of our clinical trials, the rate of patient enrollment in our clinical trials, and the detailed design of future clinical trials. In addition, the results from our clinical trials, as well as the results of trials of similar therapeutics under development by others, will influence the number, size and duration of planned and unplanned trials. On an ongoing basis, we evaluate the results of our product candidate programs, all of which, other than ViaCyte, are currently in early stages. Based on these assessments, we consider options for each program, 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 reproductive health business and, specifically, our ViaCord service offering. 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. However, we may, from time to time, implement additional promotions and other marketing programs that may increase sales and marketing expenses, and augment our internal marketing efforts with external relationships such as the data license and marketing services agreement we entered into with Mothers Work, Inc. in August 2006. For a description of our agreement with Mothers Work, including the risks related thereto, see *Commitments and Contingencies - Other Arrangements*.

Our general and administrative expenses include 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.

**Results of Operations**

*Three Months Ended March 31, 2007 and 2006 (table amounts in thousands)*

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>	<b>\$ Change</b>	<b>% Change</b>
Processing revenues	\$ 11,225	\$ 9,610	\$ 1,615	17%
Storage revenues	3,137	2,327	810	35
Total processing and storage revenues	14,362	11,937	2,425	20
Grant revenues	95	144	(49)	(34)
Total revenues	\$ 14,457	\$ 12,081	\$ 2,376	20%

The increase in processing revenues of \$1.6 million, or 17%, from the three months ended March 31, 2006 to the three months ended March 31, 2007 was due primarily to an increase in the total number of umbilical cords processed and an increase in the average selling price for processing. The increase in storage revenues of \$0.8 million, or 35%, from the three months ended March 31, 2006 to the three months ended March 31, 2007 was due primarily to an increase in the number of umbilical cords stored and a slight increase in the average selling price for storage.



**Table of Contents**

	<b>Three Months Ended March 31,  2007</b>	<b>Three Months Ended March 31,  2006</b>	<b>\$ Change</b>	<b>% Change</b>
Cost of processing and storage revenues	\$ 2,639	\$ 2,328	\$ 311	13%

The increase in cost of processing and storage revenues of \$0.3 million, or 13%, from the three months ended March 31, 2006 to the three months ended March 31, 2007 was due primarily to increases in variable expenses related to the increased number of umbilical cords processed and stored. These increases in variable expenses were related to higher costs for the transportation and collection of the umbilical cord blood, offset by a slight decrease in costs for testing of the umbilical cord blood.

	<b>Three Months Ended March 31,  2007</b>	<b>Three Months Ended March 31,  2006</b>	<b>\$ Change</b>	<b>% Change</b>
Research and development	\$ 3,278	\$ 3,466	\$ (188)	(5)%

During the three months ended March 31, 2007 and 2006, our research and development expenses primarily related to our ViaCyte, 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, 2006 to the three months ended March 31, 2007 was primarily due to a decrease in outside services, the reduction in clinical expenses associated with CB001, as well as a reduction in other expenses associated with our decision not to advance development of CB001 and to reduce our hematopoietic program-related costs. These decreases were partially offset by costs associated with the manufacturing of ViaCyte media and initiation of our ViaCyte clinical trial during the three months ended March 31, 2007.

	<b>Three Months Ended March 31,  2007</b>	<b>Three Months Ended March 31,  2006</b>	<b>\$ Change</b>	<b>% Change</b>
Sales and marketing	\$ 11,121	\$ 7,922	\$ 3,199	40%

The increase in sales and marketing expenses of \$3.2 million, or 40%, from the three months ended March 31, 2006 to the three months ended March 31, 2007 was primarily related to increased staffing within both the internal and external sales organization and increased external marketing expenses to strengthen our market presence. As of January 1, 2007, we also initiated payments to Mothers Work under our data license and marketing services agreement with Mothers Work. Under the terms of the agreement, we are required to pay Mothers Work \$5.0 million per year over the three year term of the agreement.

	<b>Three Months Ended March 31,  2007</b>	<b>Three Months Ended March 31,  2006</b>	<b>\$ Change</b>	<b>% Change</b>
General and administrative	\$ 4,800	\$ 4,638	\$ 162	3%

The increase in general and administrative expenses of \$0.2 million, or 3%, from the three months ended March 31, 2006 to the three months ended March 31, 2007 was primarily due to increased

20

---

**Table of Contents**

employee-related expenses of \$0.3 million, partially offset by a decrease of \$0.1 million in stock-based compensation expense.

	<b>Three Months Ended March 31,</b>	<b>Three Months Ended March 31,</b>	<b>\$</b>	<b>%</b>
	<b>2007</b>	<b>2006</b>	<b>Change</b>	<b>Change</b>
Restructuring	\$	\$ (181)	\$ (181)	(100)%

The income related to restructuring of \$0.2 million for the three months ended March 31, 2006 was related to changes in estimates of the grant refunds due to the German grant authorities. In 2006, we settled with the German grant authorities to satisfy all potential claim reimbursements. There were no outstanding payments or accruals related to restructuring as of March 31, 2007. In addition, we plan to cease operations in Singapore in the quarter ended June 30, 2007. As a result, we expect to record a restructuring charge in the range of \$0.2 million to \$0.3 million related to employee severance and facility-related costs in the quarter ended June 30, 2007.

	<b>Three Months Ended March 31,</b>	<b>Three Months Ended March 31,</b>	<b>\$</b>	<b>%</b>
	<b>2007</b>	<b>2006</b>	<b>Change</b>	<b>Change</b>
Interest income	\$ 698	\$ 724	\$ (26)	(4)%
Interest expense	(1)	(26)	25	96
Total interest income, net	\$ 697	\$ 698	\$ (1)	

Interest income is earned primarily from the investment of our cash in short-term securities and money market funds. The decrease in interest income from the three months ended March 31, 2006 to the three months ended March 31, 2007 primarily related to decreased average investment balances resulting from a lower cash balance available for investment. The decrease in interest expense from the three months ended March 31, 2006 to the three months ended March 31, 2007 related primarily to lower outstanding debt obligations.

**Liquidity and Capital Resources**

From inception through March 31, 2007, we have raised \$192.7 million in common and preferred stock issuances, which includes \$53.3 million in net proceeds from our initial public offering ( IPO ) in January 2005. We used approximately \$15.5 million of our net IPO proceeds to repay in full related party notes of \$14.0 million, and accrued interest thereon of \$1.5 million. As of March 31, 2007, we had approximately \$47.4 million in cash, cash equivalents and investments.

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

	<b>Three Months Ended March 31,</b>	<b>Three Months Ended March 31</b>	<b>\$</b>
	<b>2007</b>	<b>2006</b>	<b>Change</b>
Net cash used in operating activities	\$ (3.7)	\$ (1.7)	\$ (2.0)

Edgar Filing: VIACELL INC - Form 10-Q

Net cash provided by investing activities	0.1	0.4	(0.3)
Net cash provided by (used in) financing activities	0.1	(0.4)	0.5
Cash and cash equivalents, end of period	\$ 14.6	\$ 31.4	\$ (16.8)

21

---

**Table of Contents**

Net cash used in operating activities was \$3.7 million for the three months ended March 31, 2007, an increase of \$2.0 million from the \$1.7 million net cash used in operating activities for the three months ended March 31, 2006. For the three months ended March 31, 2007, the \$3.7 million net cash used in operating activities was primarily due to our net loss of \$6.7 million, reduced by non-cash expenses of \$1.5 million, net increases in deferred revenue of \$1.9 million, partially offset by a net increase in working capital (accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses) of \$0.3 million, and an increase in deferred rent of \$0.1 million. The increase in deferred revenue of \$1.9 million related to sales of long-term pre-paid storage contracts. For the three months ended March 31, 2006, the \$1.7 million net cash used in operating activities 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 of \$1.0 million, partially 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.

Net cash provided by investing activities for the three months ended March 31, 2007 was \$0.1 million as compared to \$0.4 million for the three months ended March 31, 2006. For the three months ended March 31, 2007, \$17.1 million of U.S. Government and high-rated corporate securities matured and \$16.7 million was invested in similar securities. We also invested approximately \$0.3 million in property and equipment for the three months ended March 31, 2007. 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 was invested in similar securities. We also invested approximately \$0.4 million in property and equipment for the three months ended March 31, 2006.

Net cash provided by financing activities for the three months ended March 31, 2007 was \$0.1 million as compared to net cash used in financing activities of \$0.4 million for the three months ended March 31, 2006. For the three months ended March 31, 2007, the net cash provided by financing activities was principally related to proceeds of \$0.1 million relating to stock options exercised. For the three months ended March 31, 2006, the net cash used in financing activities was principally related to payments of \$0.4 million on our credit facilities.

We anticipate that our current cash, cash equivalents and investments will be sufficient to fund our operations and meet our anticipated liquidity needs 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 and meet our anticipated liquidity needs 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.

Other than outstanding warrants exercisable for up to 1,193,333 shares of our common stock at March 31, 2007, we have no off balance sheet arrangements, as defined by Item 303(a)(4) of the SEC's Regulation S-K.

**Other Arrangements***Mothers Work Data and Marketing Services*

In August 2006, we entered into a data license and marketing services agreement with Mothers Work, Inc., the world's largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as Motherhood Maternity<sup>®</sup>, A Pea in the Pod<sup>®</sup>, Mimi Maternity<sup>®</sup> and Destination Maternity<sup>™</sup>. Under the terms of our agreement, Mothers Work has granted us an

**Table of Contents**

exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. Under the terms of our agreement, we will pay Mothers Work \$5.0 million per year over the three-year term of the agreement which began on January 1, 2007 and, unless earlier terminated, ends on December 31, 2009. Under certain circumstances, we will also be obligated, at the beginning of 2009, to issue Mothers Work a warrant to purchase 100,000 shares of our common stock (see note 5 to our condensed consolidated financial statements). A third party is claiming that it has rights under an agreement with Mothers Work that supersede Mothers Work's commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. The arbitrator has denied a challenge to his ruling by the third party. While there is no assurance that the third party will not again challenge the ruling, we believe that reversal of this ruling is unlikely and that the termination rights under our agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us.

We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the low likelihood that we might have to pay damages or legal fees given the arbitrator's ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of March 31, 2007.

*Miltenyi*

In January 2005, we entered into a supply agreement with Miltenyi Biotec GmbH (Miltenyi). The supply agreement with Miltenyi provides for the exclusive supply by Miltenyi to us of cell separation kits consisting of various antibodies conjugated with magnetic particles to be used in Selective Amplification, our proprietary technology for the expansion of stem cell populations for the development and commercialization of certain of our cellular therapy product candidates. The initial term of the supply agreement is seven years. In 2006, we purchased approximately \$1.3 million of cell separation kits to be used in our research. We purchased \$0.1 million of cell separation kits in the first quarter of 2007, and have a firm order to purchase an additional \$0.2 million of kits in 2007. Since we have decided not to advance CB001 into further clinical trials, we intend to use these cell separation kits in our other research and development activities.

We are a party to various agreements in addition to those previously discussed, including license, research collaboration, consulting and employment agreements, and expect to enter into additional agreements in the future. We may require additional funds for conducting clinical trials and for preclinical research and development activities relating to our product candidates, as well as for the expansion of our cord blood preservation facility, construction of a cellular therapy manufacturing facility, acquisitions of technologies or businesses, the establishment of partnerships and collaborations complementary to our business and the expansion of our sales and marketing activities.

**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 US Patents No. 5,004,681 (681) and No. 5,192,553 (553), relating to certain aspects of the collection, cryopreservation and storage of

**Table of Contents**

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., a subsidiary of Cord Blood America 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 prove infringement, consequently we have not recorded a liability as of March 31, 2007. 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 at the U.S. Court of Appeals for the Federal Circuit, on April 4, 2006 and a final ruling has not been issued.

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.

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. Patent and Trademark Office ( U.S. PTO ) on the patent re-examinations described below.

In late 2006, the U.S. PTO issued final decisions in the existing 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. The U.S. PTO had ordered a second re-examination of the '427 patent in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO issued notice of its intent to allow the remaining claims of all of the patents.

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have significant damages awarded against us. If we are 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, 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

**Table of Contents**

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.

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

**Critical Accounting Estimates**

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

Our critical accounting policies include:

revenue recognition;

accounting for stock-based compensation;

accounting for accounts receivable;

accounting for research and development expenses; and

accounting for the Mothers Work indemnification agreement.

*Revenue Recognition.* Our revenues are currently generated principally through our umbilical cord blood preservation and storage activities. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements, (SAB 101) as amended by SAB 104, *Revenue Recognition, corrected copy*, and Emerging Issues Task Force (EITF) Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) for all revenue transactions entered into in fiscal periods beginning after June 30, 2003. We receive fees for collecting, testing, freezing and storing of umbilical cord blood units and recognize revenue upon the successful completion of these processes. Storage revenue is deferred and recognized over the storage period. We analyze our multiple element arrangements entered into after June 30, 2003 to determine whether the elements can be separated and accounted for individually as separate units of accounting in accordance with EITF No. 00-21. We recognize fees received from collecting, testing and freezing processes (collectively known as processing) as revenue if it has stand alone value to the customer and the fair value of the undelivered storage services can be determined. We have concluded that the collection, testing and freezing service has stand alone value to the customer. The fair value of our processing service cannot be determined but we have objective evidence of the fair value of the undelivered storage. The fair value of the storage is equal to the annual storage fee charged to customers on a stand-alone basis. We charge an initial fee which covers collection, testing, freezing, and, typically, one year of storage. We defer the fair value of the revenue related to the future storage of the unit and recognize the remainder of the revenue for processing under the residual method.

*Accounting for Stock-Based Compensation.* We have one stock-based employee compensation plan. We have followed Statement of Financial Accounting Standards No. 123(R) *Share-Based Payment* (SFAS 123R) since our January 1, 2006 adoption using the modified prospective method, which results



**Table of Contents**

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 at the grant date based on the value of the award and is recognized as expense over the requisite service period.

We utilize the Black Scholes option pricing model to calculate the fair value of stock options granted under SFAS 123(R). We are required to make significant estimates to note all required inputs to the Black Scholes model including expected volatility and expected term. Changes in the subjective input assumptions can materially affect the fair value estimate of stock-based compensation expense. 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. Higher estimated volatility increases the fair value of a stock option, and therefore increases the expense to be recognized for each stock option. 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. Longer expected term assumptions increase the fair value of the stock option, and therefore increase the expense to be recognized for each stock option.

*Accounting for accounts receivable.* Accounts receivable consists of amounts primarily due from customers that have used the ViaCord service offering. Accounts receivable are stated at amounts due from customers, net of an allowance for doubtful accounts. We determine the allowance by considering receivables that are past due, our previous loss history, and the customers' current ability to pay its obligations. We write off accounts receivable when they become uncollectible and payments subsequently received on such accounts receivable are credited to the allowance for doubtful accounts.

*Accounting for research and development expenses.* Our research and development expenses consist primarily of costs associated with development of our stem cell product candidates, including the recently completed Phase 1 clinical trial of our expanded umbilical cord blood product candidate, CB001, and development of ViaCyte, our oocyte cryopreservation product candidate. These expenses represent both preclinical and clinical development costs, and the costs associated with non-clinical support activities such as toxicological testing, manufacturing, process development and regulatory consulting services. Clinical development costs represent internal costs for personnel, external costs incurred at clinical sites and contracted payments to third party clinical research organizations to perform certain clinical trials. Our product candidates do not currently have regulatory approval; accordingly, we expense license fees and milestone payments when we incur the liability. We accrue research and development expenses for activities occurring during the fiscal period prior to receiving invoices from clinical sites and third party clinical research organizations. We accrue external costs for clinical studies based on the progress of the clinical trials, including patient enrollment, progress by the enrolled patients through the trial, and contracted costs with clinical sites. We record internal costs primarily related to personnel in clinical development and external costs related to non-clinical studies and basic research when incurred. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. We expect that our research and development expenses will increase for the foreseeable future as we add personnel, expand our clinical trial activities and increase our discovery research capabilities. The amount of these potential increases is difficult to predict due to the uncertainty inherent in the timing of clinical trials, progress in our discovery research program, the rate of patient enrollment and the detailed design of future trials. In addition, the results from our trials, as well as the results of trials of similar drugs under development by others, will influence the number, size and duration of both planned and unplanned trials.

**Table of Contents**

*Accounting for the Mothers Work indemnification agreement.* In August 2006, we entered into a data license and marketing services agreement with Mothers Work, Inc., the world's largest designer and retailer of maternity apparel. Mothers Work operates several large maternity store retail chains such as Motherhood Maternity<sup>®</sup>, A Pea in the Pod<sup>®</sup>, Mimi Maternity<sup>®</sup>, and Destination Maternity<sup>™</sup>. Under the terms of our agreement, Mothers Work has granted us an exclusive license within the field of preserving stem cells from cord blood and other sources to market directly to those Mothers Work customers who have affirmatively agreed to permit disclosure of their data and information. Mothers Work has also agreed to provide certain in-store marketing services related to the ViaCord service offering. The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work's commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. The arbitrator has denied a challenge to his ruling by the third party. While there is no assurance that the third party will not again challenge the ruling, we believe that reversal of the ruling is unlikely and that the termination rights under our agreement with Mothers Work are unlikely to be triggered. As a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us. We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45), requires us to record a liability based on the estimated fair value of the indemnification provided. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the amount of damages and legal fees that could be payable, and the low likelihood that they might have to be paid given the arbitrator's ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of March 31, 2007. Our assumptions involve judgments by management and are subject to change based on on-going developments or binding results of the arbitration proceedings that could result in materially different results than our current estimate.

**Recent Accounting Pronouncements**

In February 2007, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 ( SFAS 159 )*, which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 will be effective for the first fiscal year that begins after November 15, 2007. We have not yet completed our evaluation of the impact of adoption of SFAS 159 on our financial condition or results of operations.

In September 2006, FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements ( SFAS No. 157 )* which defines fair value under GAAP, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. Where applicable, SFAS No. 157 simplifies and codifies related guidance within GAAP and does not require any new fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We do not expect the adoption of SFAS No. 157 to have a significant effect on our financial condition or results of operations.

**Table of Contents****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 U.S. 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 the expenses of these subsidiaries are denominated in Euros and Singapore dollars, the fluctuations of exchange rates may adversely affect our results of operations, financial condition 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, 2007 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, 2007 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Table of Contents**

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

**ITEM 1A. RISK FACTORS**

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to events and potential results related to our research and development programs, and our views as to the possible outcome of pending litigation related to our intellectual property portfolio and other disputes. 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 "Risk Factors" section. 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 may not achieve our goal of becoming cash flow positive, and may never become profitable.***

We have generated operating losses since our inception. As of March 31, 2007, we had cumulative net losses of approximately \$201.2 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately \$118.9 million since our inception. We expect that our research and development expenses will continue to increase over the next several years as a result of increased costs and expenses associated with our ViaCytel clinical trial and possible future clinical trials of other product candidates, including our preclinical product candidate being studied as a potential treatment for cardiac disease, if preclinical data supports moving forward. Future research and development expenses may also include costs associated with product candidates that we might license or acquire, and, if our programs are successful, costs and expenses associated with submissions for regulatory approvals and the expansion of clinical and commercial scale manufacturing facilities. However, the amount of these increases is difficult to predict, and will depend on a number of factors, such as results of our clinical and preclinical programs, the design of future clinical trials, the results of our efforts to acquire or license new technologies, and decisions made with respect to advancement of our clinical and preclinical programs. Furthermore, we may make additional sales and marketing investments in our Reproductive Health business, if deemed advisable to expand the market for our ViaCord service offering or to market new products or service offerings that we may license or acquire. Our ability to become cash flow positive and to achieve profitability, and the timing of such events, will depend on many factors, including some or all of the following:

- our ability to increase sales of our ViaCord service offering particularly in the face of significant competition;

- continued acceptance in the marketplace for private cord blood banking;

**Table of Contents**

the impact of any unexpected issues or failures related to the collection, processing, or storage of umbilical cord blood by us or others in the industry;

the impact of any potential adverse outcome in the patent infringement lawsuits brought against us by PharmaStem, including legal expenses, and the material impact on our business if PharmaStem were able to obtain an injunction;

the level of our expenses, including as a result of difficulties or delays related to our research and development programs, and any unexpected expenses; and

the overall net impact on revenues and expenses of new licensing deals, collaborations or other strategic efforts.

We cannot assure you that we will ever become cash flow positive or profitable. Other factors that may affect our ability to become cash flow positive and 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 were \$14.4 million in the first quarter of 2007 and have grown significantly over the past several years, from \$7.1 million in 2001, to \$20.1 million, \$30.9 million, \$36.8 million, \$43.8 million and \$54.1 million in 2002, 2003, 2004, 2005 and 2006, respectively. 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 preservation. We may not be able to sustain this growth rate or the current level of ViaCord's revenues in the future. The principal factors that may adversely affect our revenues include competition from other private cord blood banks, any decline in the market or market acceptance for cord blood banking, the impact of recommendations as to public banking over private banking from physician groups, such as the policy statement issued by the American Academy of Pediatricians, the risks associated with litigation, in particular, the pending PharmaStem litigation, the risk of operational issues, the risks of not being able to maintain relationships with key third party marketing partners, 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 research and 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 service 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 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., a subsidiary of Cord Blood America 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 revenues from the processing and storage of umbilical cord blood since

**Table of Contents**

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 prove infringement. Consequently, we have not recorded a liability as of March 31, 2007. 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 at the U.S. Court of Appeals for the Federal Circuit on April 4, 2006. A final ruling has not been issued in the appeal.

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 that we do not infringe them. 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.

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. Patent and Trademark Office ( U.S. PTO ) on the patent re-examinations described below.

In late 2006, the U.S. PTO issued final decisions in the existing 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. The U.S. PTO had ordered a second re-examination of the '427 patent in order to determine whether certain claims of the patent should expire in 2008, rather than in 2010. The U.S. PTO issued notice of its intent to allow the remaining claims of all of the patents.

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 at anytime 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 service offering, which is currently our only commercialized product, and would have a significant adverse impact on our business, financial condition, 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.

**Table of Contents*****A third party may again seek to challenge the arbitrator's decision related to our agreement with Mothers Work.***

We have an agreement with Mothers Work related to the marketing of our ViaCord service offering. The agreement can be terminated early by either company if the other company commits a material breach of the agreement or under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work's commitment to us. A third party has claimed that it has rights under an agreement with Mothers Work that supersede Mothers Work's commitment to us. The dispute between Mothers Work and the third party was the subject of an arbitration proceeding. In February 2007, the arbitrator ruled in favor of Mothers Work. The arbitrator has denied a challenge to his ruling by the third party. While there is no assurance that the third party will not again challenge the ruling, we believe that reversal of the ruling is unlikely. If the third party were to be successful in efforts to overturn the arbitrator's decision, the termination rights under our agreement with Mothers Work could be triggered. In addition, as a condition to commencing the agreement on January 1, 2007, we agreed to indemnify Mothers Work for any damages that Mothers Work may be assessed in the event that Mothers Work is found to be in breach of its agreement with the third party as a result of having entered into an agreement with us. We also agreed to reimburse Mothers Work for certain legal fees if the fees exceed a specified threshold. Our potential obligation to Mothers Work under the indemnification agreement is unlimited. However, based on our assessment of the low likelihood that we might have to pay damages or legal fees given the arbitrator's ruling, we concluded the fair value of our indemnification obligation is not material and have not recorded a liability as of March 31, 2007.

***If we are not able to successfully develop and commercialize new products, our future prospects may be limited.***

Drug development in general involves a high degree of risk. 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. For example, in February 2007, we made the decision not to advance CB001, one of our product candidates in the area of hematopoietic stem cell therapy, in future clinical trials. We may also change the indication being pursued for a particular product candidate or otherwise revise the development plan for that candidate. Moreover, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical testing.

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 financial condition, results of 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.

Our cellular therapy product candidates are in the early stages of development. Very few companies have been successful in their 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 their approval or commercial use.

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

**Table of Contents**

candidates may be more complex and lengthy than the pathway for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the 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.

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 currently planning to conduct a single, pivotal clinical trial to study the safety and efficacy of ViaCyte. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. In June 2006, the FDA gave us conditional approval of our Investigational Device Exemption, or IDE, to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. We subsequently satisfied all of the conditions imposed upon us by the FDA and, in March 2007, we initiated the ViaCyte clinical trial. However, in April 2007, the FDA disapproved a supplement to the IDE which is necessary to change our contract manufacturer for the ViaCyte media to Invitrogen. The FDA has asked us to respond to questions related to the specifications and sourcing of certain raw materials used in the manufacturing of the ViaCyte media. We are currently working to address the questions raised by the FDA. We believe we will ultimately be able to satisfy the FDA and obtain approval of the IDE supplement. However, there is no assurance that we will be able to obtain approval on a timely basis or at all. Failure to obtain approval on a timely basis could delay enrollment in the trial and may cause completion of the trial to be significantly delayed. If we are unable to address the issues raised by the FDA, we may need to change our manufacturing process. There is no assurance that we would be able to make acceptable changes on a timely basis or at all. Changes in the manufacturing process could result in significant delays in the trial or involve significant additional expense, and may not be practical. Since we no longer use our original manufacturer, failure to obtain approval of the IDE supplement would likely cause us to have to discontinue the trial. Even if we are successful in our efforts to obtain approval of the IDE supplement, there is no assurance that we will be able to show that our ViaCyte cryopreservation product candidate is safe and effective for its intended use. While methods for preserving sperm and embryos are well-established and have been utilized for *in vitro* fertilization procedures, methods for cryopreserving oocytes have not been widely employed due to difficulties encountered in freezing this cell. We may not be able to generate the number of live births needed to show that ViaCyte is effective. We may also encounter unexpected safety, regulatory or manufacturing issues. Even if the results of the trial are favorable, 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 ViaCyte, the FDA could ask for post-approval safety monitoring which would entail additional expense. The FDA could also restrict the label for ViaCyte to limited patient populations which could limit its commercial potential.



**Table of Contents**

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

As of March 31, 2007, we had approximately \$47.4 million in cash, cash equivalents and short-term investments. In order to develop and bring 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 service offering;

the costs of increasing or expanding our ViaCord sales and marketing efforts;

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 and other disputes;

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

the costs of research and development work focused on developing clinical and commercial scale processes for manufacturing cellular products and, if we advance our products, the costs of building and operating our manufacturing facilities, both to support our clinical activities and also in anticipation of growing our commercialization activities;

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

the costs of maintaining, expanding and protecting our intellectual property portfolio, including litigation costs and liabilities; and

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

We may seek additional funding through collaborative arrangements and public or private financings. Additional funding may not be available to us on acceptable terms, or at all. If we obtain additional capital through collaborative arrangements, these arrangements may require us to relinquish greater rights to our technologies or product candidates than we might otherwise have done. If we raise additional capital through the sale of equity, or securities convertible into equity, further dilution to our then existing stockholders will result. If we raise additional capital through the incurrence of debt, our business may be affected by the amount of leverage we incur. For instance, such borrowings could subject us to covenants restricting our business activities, servicing interest would divert funds that would otherwise be available to support research and development, clinical or commercialization activities, and

**Table of Contents**

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 research and development 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 U.S. patents and international patents. We also own or have exclusive licenses to pending applications in the U.S. and 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 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 technologies. For example, our patent applications covering Unrestricted Somatic Stem Cells, or USSC, claim these cells and/or their use in the treatment of many diseases. It is possible, however, 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 our 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 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. 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

**Table of Contents**

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. 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.

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 specific 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, 2007, we have incurred total legal expenses of approximately \$7.4 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.

Any successful infringement action brought against us may also adversely affect our ability to market 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

**Table of Contents**

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.

***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 or commercialize or market competitive products 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, potential products or existing products may be substantially delayed or adversely impacted.

***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 regulations, or GTPs, that establish a comprehensive regulatory program for human cellular and tissue-based products. Our ViaCord service offering is subject to GTPs. We have registered with the FDA as an umbilical cord blood preservation service and we are subject to FDA inspection. We believe that we comply with GTPs, 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. Unlike our business of private cord blood banking for related use, the collection, processing and storage of umbilical cord blood stem cells intended to be used in a recipient unrelated to the donor is regulated as biological products. In January 2007, the FDA published draft guidance document for comment that would require public cord blood banks to file Biologics License Applications. While the draft guidance does not currently apply to us, the FDA could decide to impose these requirements or others on our business. Moreover, the cost of compliance with government regulations may adversely affect our revenues and profitability. If the FDA were to require companies that bank umbilical cord blood for related use to comply with the recommendations set forth in the guidance, we would need to change certain of our processes. The costs of such changes or the cost of compliance with any other new requirements that may be imposed in the future could adversely affect our revenues and profitability. Regulation of our cord blood preservation services in foreign jurisdictions is still evolving.

We provide cord blood banking services in all 50 states. Several states require that cord blood services be licensed, permitted or registered. We believe that we are currently licensed, permitted or registered to operate in all states requiring us to be licensed, permitted or registered. If other states adopt

**Table of Contents**

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 approval of the technology used in oocyte cryopreservation. We are currently planning to conduct a single, pivotal clinical trial to study the safety and efficacy of ViaCyte. In June 2006, the FDA gave us conditional approval of an IDE to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. We subsequently satisfied all of the conditions imposed upon us by the FDA and, in March 2007, we initiated the ViaCyte clinical trial. However, in April 2007, the FDA disapproved a supplement to the IDE which is necessary to change our contract manufacturer for the ViaCyte media to Invitrogen. The FDA has asked us to respond to questions related to the specifications and sourcing of certain raw materials used in the manufacturing of the ViaCyte media. We are currently working to address the questions raised by the FDA. We believe we will ultimately be able to satisfy the FDA and obtain approval of the IDE supplement. However, there is no assurance that we will be able to obtain approval on a timely basis or at all. Failure to obtain approval on a timely basis could delay enrollment in the trial and may cause completion of the trial to be significantly delayed. If we are unable to address the issues raised by the FDA, we may need to change our manufacturing process. There is no assurance that we would be able to make acceptable changes on a timely basis or at all. Changes in the manufacturing process could result in significant delays in the trial or involve significant additional expense, and may not be practical. Since we no longer use our original manufacturer, failure to obtain approval of the IDE supplement would likely cause us to have to discontinue the trial. The goal of the clinical trial is to generate data to submit to the FDA for a 510(k) application. There is no assurance that we will be able to complete the clinical trial or that we will be able to show that our ViaCyte cryopreservation product candidate is safe and effective for its intended use. We may also encounter unexpected safety, regulatory or manufacturing issues, any of which could delay or cause us to stop the trial. If we submit a new 510(k) and the FDA does not find the information adequate to support 510(k) clearance, the FDA could require us to obtain PMA to market ViaCyte. This requirement could substantially lengthen our planned developmental timeline and increase the costs of developing and commercializing ViaCyte. We may not receive either 510(k) clearance or PMA for ViaCyte. 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. We may not be able to generate sufficient data to receive approval to market ViaCyte in the U.S. or any other jurisdictions.

***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 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 obtain marketing approval for any cell therapy 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.

**Table of Contents*****We are dependent upon third parties to supply us with certain components of our cell therapy product candidates, the loss of which may delay development of our product candidates***

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. 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 preclinical 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, we may not be able to advance the development of our preclinical stem cell product candidates.

***The loss of our contract manufacturer for ViaCyte or our failure to respond to questions raised by the FDA related to the specifications and sourcing of certain raw materials used in the manufacturing of ViaCyte may delay or cause us to discontinue development of our ViaCyte product candidate.***

We are utilizing Invitrogen to manufacture, supply and package our ViaCyte product candidate for our clinical trial. We are dependent on Invitrogen and our relationships with component and testing service providers to satisfy all regulatory requirements and produce sufficient amounts of cGMP-quality product on commercially reasonable terms for the trial. Manufacturing our ViaCyte product candidate is highly complex. Due to its complexity, Invitrogen may be unable to consistently manufacture ViaCyte to specifications. Invitrogen has the ability to terminate its obligation to manufacture clinical supplies of ViaCyte under certain conditions including if it is unable for reasons outside of its control to consistently meet specifications or if there is a change in specifications it cannot meet or an uncured material breach by us. In June 2006, the FDA gave us conditional approval of an IDE to allow our ViaCyte cryopreservation product candidate to be used in a clinical trial. We subsequently satisfied all of the conditions imposed upon us by the FDA and, in March 2007, we initiated the ViaCyte clinical trial. However, in April 2007, the FDA disapproved a supplement to the IDE which is necessary to change our contract manufacturer for the ViaCyte media to Invitrogen. The FDA has asked us to respond to questions related to the specifications and sourcing of certain raw materials used in the manufacturing of the ViaCyte media. We are currently working to address the questions raised by the FDA. We believe we will ultimately be able to satisfy the FDA and obtain approval of the IDE supplement. However, there is no assurance that we will be able to obtain approval on a timely basis or at all. Failure to obtain approval on a timely basis could delay enrollment in the trial and may cause completion of the trial to be significantly delayed. If we are unable to address the issues raised by the FDA, we may need to change our manufacturing process. There is no assurance that we would be able to make acceptable changes on a timely basis or at all. Changes in the manufacturing process could result in significant delays in the trial or involve significant additional expense, and may not be practical. Since we no longer use our original manufacturer, failure to obtain approval of the IDE supplement would likely cause us to have to discontinue the trial. If ViaCyte is successfully developed, we will need

**Table of Contents**

to establish similar relationships with third party contract manufacturers for our commercial supply. In the event that we are unable to maintain a suitable contract manufacturer that is willing to produce such products on commercially reasonable terms or the contract manufacturer terminates or breaches its relationship with us or our contract manufacturers or we encounter unexpected technical or manufacturing hurdles or delays, we may not be able to complete our clinical trial or, if successfully developed, to commercialize our ViaCord product candidate.

***We are dependent on our existing suppliers to successfully commercialize our ViaCord service offering. The loss of such suppliers may inhibit our ability to commercialize ViaCord.***

We source a substantial portion of the components of our ViaCord collection kits and processing and testing services from a concentrated group of third party contractors. The production of the collection kits and the processing and testing of cord blood units require successful coordination among ourselves and multiple third party providers. Our inability to coordinate these efforts or any other problems with the operations of our third party contractors could increase our costs, cause us to lose revenue or market share, and damage our reputation. Some of the components of our ViaCord collection kits, including our Cell Sentinel™ bag, are produced by single source providers. For other components, we make every effort to qualify new vendors and to develop contingency plans so that our ViaCord business is not impacted by short-term issues associated with single source providers. Our business could be materially impacted by long-term or chronic issues associated with single source providers or other vendors.

***If our cord blood processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, 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. In addition, from time to time, we transport large quantities of cord blood units from other storage facilities to our facility in Hebron, Kentucky. If we encounter problems during transportation, some or all of the transported units could be damaged. Depending on the extent of these losses, such an event could reduce our ability to provide cord blood stem cells when requested, could expose us to significant liability from cord blood banking customers and could affect our ability to continue to provide umbilical cord blood preservation services.

We expect to manufacture all of our stem cell product candidates in our Cambridge manufacturing 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, and against damage to cord blood units being transported to our facility, 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 \$22.2 million against damage to our property and equipment, and an additional \$18.8 million to cover incremental expenses and loss of profits resulting from such damage.

**Table of Contents**

***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, Inc., Cryo-Cell International, Inc., CorCell, Inc., a subsidiary of Cord Blood America Inc., and LifeBank USA, a division of Celgene Cellular Therapeutics, a wholly-owned subsidiary of Celgene Corporation. 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 other public cord blood banks around the world. Public cord blood banks provide families with the option of donating their cord blood for public use at no cost. The Stem Cell Therapeutic and Research Act of 2005, or the Stem Cell Therapeutic Act, provides financing for a national system of public cord blood banks in the U.S. to encourage cord blood donations from an ethnically diverse population. In addition, many states are evaluating the feasibility of establishing cord blood repositories for transplantation purposes. An increase in the number and diversity of publicly-available cord blood units from public banks would increase the probability of finding suitably matched cells for a family member, which may result in a decrease in the demand for private cord blood banking. 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, Inc., Cellerant Therapeutics, Inc., Celgene Corporation, Cytori Therapeutics, Inc., Gamida-Cell Ltd., 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. In addition, public cord blood banks may, as a result of the Stem Cell Therapeutic Act, be able to better compete with our potential cell therapy products. 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.

In oocyte cryopreservation, if our ViaCyte product candidate is successfully developed and approved, we expect to compete with IVF centers and individual companies offering oocyte cryopreservation, including Extend Fertility. Current and future competitors in this field may also 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 are already performing oocyte cryopreservation on a limited basis and Extend Fertility is offering related services, which may make it more difficult ViaCyte, if successfully developed and approved, to 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



**Table of Contents**

industry is characterized by rapid technological change. 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. 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 service offering. This is due in significant part to the nature of the service we provide. For instance, as part of our ViaCord service offering, we are assuming custodial care of a child's umbilical cord blood stem cells 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. 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.

***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 clinical and 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.

***Our success is dependent upon recruiting and retaining qualified management and other personnel.***

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, has significant and unique expertise in stem cell expansion and related technologies. We maintain key man life insurance on the lives of Mr. Beer and Mr. Kraus. Additionally, we have several other employees with scientific or other skills that we consider important to the successful commercialization of our products and development of our technology. Any of our key employees could

**Table of Contents**

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.

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 Global Market, place significant 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.

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.

***Our business could be disrupted or harmed and we could be subject to liability if we are unable to operate our information systems effectively, successfully implement new technologies and protect the confidentiality of our or our customers data.***

The efficient operation of our business is dependent on our information systems, including our ability to operate them effectively and to successfully implement new technologies, systems, controls and adequate disaster recovery systems. In addition, we must protect the confidentiality of our and our customers data, including credit card information. The failure of our information systems to perform as designed or our failure to implement and operate them effectively could disrupt our business, harm our reputation and/or subject us to liability, any of which could impact our financial condition and results of operations.

***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, Inc. in 2000, Cerebrotec, Inc. in 2001 and Kourion Therapeutics

**Table of Contents**

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. 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 products may depend on patients and physicians obtaining reimbursement for products 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, potentially, outside the U.S. 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 patients and physicians 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. If our potential cell therapy products are not reimbursed by government or third party insurers, the market for those products would be limited. We cannot be sure that third party payers will reimburse sales of a product or enable us or our partners to sell the product at prices that will provide a sustainable and profitable revenue stream.

Although we are aware of a small fraction of ViaCord customers receiving reimbursement, we believe our ViaCord service offering, like other private cord blood banking, is not generally subject to reimbursement. We do not currently believe that our ViaCyte product candidate will be subject to reimbursement. In cases of preserving eggs for fertility preservation for cancer patients, it is unknown at this time if it will be covered.

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

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

Most health care providers, including research collaborators from whom we obtain patient information, are subject to privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. 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 or unethical, 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 and Kentucky 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 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.

**Table of Contents**

***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 2007, we issued 187,437 shares of common stock to a warrant holder upon the exercise of a warrant that we issued in connection with our Series D preferred stock financing. In lieu of using cash to pay the exercise price, the warrant holder utilized a cashless exercise procedure in which it forfeited 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 warrant issuance and related stock issuance were exempt from registration under the Securities Act under Regulation D and Section 4(2) thereunder because the exercise and issuance 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 under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-114209) in connection with our initial public offering was declared effective by the SEC on January 19, 2005. The offering commenced as of January 20, 2005. 8,625,000 shares of our common stock registered were sold in the offering. The offering did not terminate before any securities were sold. We completed the offering on January 26, 2005. Credit Suisse and UBS Investment Bank were the managing underwriters.

**Table of Contents**

All 8,625,000 shares of our common stock registered in the offering were sold, with an initial public offering price per share of \$7.00. The aggregate purchase price of the offering 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 nor 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 initial public offering, 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 and normal investing activities, we have not used any of the net proceeds from the initial public offering and there has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act.

**Issuer Purchase of Equity Securities**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5. OTHER INFORMATION**

(a) None.

(b) None.

**ITEM 6. EXHIBITS**

See the Exhibit Index following the Signatures page below.

47

---

**Table of Contents**

**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 10, 2007

/s/ Marc D. Beer

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

May 10, 2007

/s/ Stephen G. Dance

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

48

---

**Table of Contents**

**EXHIBIT INDEX**

<b>No.</b>	<b>Item</b>
10.1(1)	Amended and restated employment agreement dated March 12, 2007 between ViaCell and Marc D. Beer.**
10.2(1)	Amended and restated letter agreement dated March 12, 2007 between ViaCell and Anne Marie Cook.**
10.3(1)	Amended and restated letter agreement dated March 12, 2007 between ViaCell and Jim Corbett.**
10.4(1)	Amended and restated employment agreement dated March 12, 2007 between ViaCell and Morey Kraus.**
10.5(1)	Amended and restated letter agreement dated March 12, 2007 between ViaCell and Mary Thistle.**
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 the Company's current report on Form 8-K (No. 000-51110) filed with the SEC on March 13, 2007.

\*\* Indicates a management contract or compensatory plan