

VIACELL INC  
Form 10-Q  
November 14, 2006

**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 September 30, 2006**

**OR**

**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 November 7, 2006, 38,433,168 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 September 30, 2006**

**NOTE ABOUT REFERENCES TO VIACELL**

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

**NOTE ABOUT TRADEMARKS**

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

**NOTE ABOUT FORWARD-LOOKING STATEMENTS**

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

**TABLE OF CONTENTS**

	<b>Page</b>
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets September 30, 2006 and December 31, 2005</u>	4
<u>Condensed Consolidated Statements of Operations Three and nine months ended September 30, 2006 and September 30, 2005</u>	5
<u>Condensed Consolidated Statements of Comprehensive Loss Three and nine months ended September 30, 2006 and September 30, 2005</u>	6
<u>Condensed Consolidated Statements of Cash Flows Nine months ended September 30, 2006 and September 30, 2005</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	26
<u>Item 4. Controls and Procedures</u>	26
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	27
<u>Item 1A. Risk Factors</u>	27
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	42
<u>Item 3. Defaults upon Senior Securities</u>	42
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	42
<u>Item 5. Other Information</u>	42
<u>Item 6. Exhibits</u>	42
<u>Signatures</u>	43
<u>EX-31.1 Certification of CEO Section 302</u>	
<u>EX-31.2 Certification of CFO Section 302</u>	
<u>EX-32.1 Certification of CEO Section 906</u>	
<u>EX-32.2 Certification of CFO Section 906</u>	

**Table of Contents**

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

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,977	\$ 33,138
Short-term investments	29,139	27,406
Accounts receivable, less allowances of \$1,522 and \$1,111 at September 30, 2006 and December 31, 2005, respectively	12,631	13,736
Prepaid expenses and other current assets	2,699	2,679
Restricted cash		162
Total current assets	67,446	77,121
Property and equipment, net	8,507	8,702
Goodwill	3,621	3,621
Intangible assets, net	2,672	2,823
Restricted cash	1,946	1,932
Other assets	31	31
Total assets	\$ 84,223	\$ 94,230
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Current portion of long-term debt obligations	\$ 209	\$ 1,543
Accounts payable	716	1,141
Accrued expenses	9,429	7,706
Deferred revenue	7,234	5,785
Total current liabilities	17,588	16,175
Deferred revenue	13,504	9,930
Deferred rent	3,338	3,876
Contingent purchase price	8,155	8,155
Long-term debt obligations, net of current portion	40	84
Total liabilities	42,625	38,220
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 5,000,000 shares at September 30, 2006 and December 31, 2005	384	381

Edgar Filing: VIACELL INC - Form 10-Q

Common stock, \$0.01 par value; authorized 100,000,000 shares at September 30, 2006 and December 31, 2005; issued and outstanding 38,379,919 and 38,117,725 shares at September 30, 2006 and December 31, 2005, respectively

Additional paid in capital	230,922	229,955
Deferred compensation		(1,087)
Accumulated deficit	(189,895)	(173,443)
Accumulated other comprehensive income	187	204
Total stockholders' equity	41,598	56,010
Total liabilities and stockholders' equity	\$ 84,223	\$ 94,230

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

**Table of Contents**

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Processing and storage revenues	\$ 14,466	\$ 11,555	\$ 39,765	\$ 32,718
Grant revenues	201	135	521	495
<b>Total revenues</b>	<b>14,667</b>	<b>11,690</b>	<b>40,286</b>	<b>33,213</b>
Operating expenses:				
Cost of processing and storage revenues	2,893	2,169	7,757	6,151
Research and development	3,570	3,312	10,696	10,073
Sales and marketing	9,901	6,304	27,818	17,949
General and administrative	4,474	3,787	14,124	10,422
Restructuring	(890)	94	(1,070)	305
<b>Total operating expenses</b>	<b>19,948</b>	<b>15,666</b>	<b>59,325</b>	<b>44,900</b>
Loss from operations	(5,281)	(3,976)	(19,039)	(11,687)
Interest income (expense):				
Interest income	827	531	2,354	1,305
Interest expense	(8)	(113)	(50)	(306)
<b>Total interest income, net</b>	<b>819</b>	<b>418</b>	<b>2,304</b>	<b>999</b>
Loss from operations before cumulative effect of change in accounting principle	(4,462)	(3,558)	(16,735)	(10,688)
Cumulative effect of change in accounting principle			283	
<b>Net loss</b>	<b>(4,462)</b>	<b>(3,558)</b>	<b>(16,452)</b>	<b>(10,688)</b>
Accretion on redeemable convertible preferred stock				(987)
<b>Net loss attributable to common stockholders</b>	<b>\$ (4,462)</b>	<b>\$ (3,558)</b>	<b>\$ (16,452)</b>	<b>\$ (11,675)</b>
Net loss per share:				
Basic and diluted net loss per share before cumulative effect of change in accounting principle	\$ (0.12)	\$ (0.09)	\$ (0.44)	\$ (0.33)
Basic and diluted net loss per common share	\$ (0.12)	\$ (0.09)	\$ (0.43)	\$ (0.33)
Weighted average shares used in basic and diluted net loss per share computation	38,377	37,772	38,345	34,877

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

**Table of Contents**

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net loss	\$ (4,462)	\$ (3,558)	\$ (16,452)	\$ (10,688)
Foreign currency translation adjustment	(28)	(46)	(17)	(101)
Comprehensive loss	\$ (4,490)	\$ (3,604)	\$ (16,469)	\$ (10,789)

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



**Table of Contents**

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:		
Net loss	\$ (16,452)	\$ (10,688)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,687	1,508
Cumulative effect of change in accounting principle	(283)	
Stock-based compensation	2,285	1,818
Reserve for bad debt	1,090	372
Non-cash interest expense on related party notes		87
Loss on disposal of property and equipment	45	17
Tenant improvement allowance	60	
Changes in assets and liabilities:		
Accounts receivable	18	(4,525)
Prepaid expenses and other current assets	(424)	2,504
Accounts payable	(449)	(642)
Accrued expenses	1,887	352
Deferred revenue	5,024	4,812
Deferred rent	(854)	3,394
Net cash used in operating activities	(6,366)	(991)
Cash flows from investing activities:		
Purchases of property and equipment	(1,405)	(3,608)
Proceeds from the sale of equipment	25	
Proceeds from maturities of investments	37,482	29,036
Purchase of investments	(39,214)	(29,160)
Decrease in restricted cash	158	
Net cash used in investing activities	(2,954)	(3,732)
Cash flows from financing activities:		
Proceeds from exercise of stock options	57	1,093
Net proceeds from sale of common stock in initial public offering, net of offering costs		53,249
Proceeds from refund of security deposit	443	203
Repayments on credit facilities	(1,333)	(1,244)
Repayment of notes payable to related party, including accrued interest		(15,510)
Payments on capital lease principal	(50)	(64)
Net cash (used in) provided by financing activities	(883)	37,727

Edgar Filing: VIACELL INC - Form 10-Q

Effect of change in exchange rates on cash	42	(227)
Net increase (decrease) in cash and cash equivalents	(10,161)	32,777
Cash and cash equivalents, beginning of period	33,138	6,746
Cash and cash equivalents, end of period	\$ 22,977	\$ 39,523

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

7

---

**Table of Contents**

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

**1. Organization and Nature of Business**

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. The Company has a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. The Company's lead umbilical cord blood-derived stem cell therapy product candidate, CB001, is being developed as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In addition to the Company's therapeutic research and development programs, it has a reproductive health business that generates revenues from sales of ViaCord, a service offering through which expectant families can preserve their babies' umbilical cord blood for possible future medical use. The Company is working to leverage its commercial infrastructure and product development capabilities by developing ViaCyte, its product candidate being studied for its potential to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs, and by pursuing potential in-licensing or acquisition opportunities.

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

On September 30, 2003, ViaCell acquired the outstanding shares of Kourion Therapeutics AG ( "Kourion" ) in a purchase business combination. Under the terms of the agreement, shareholders of Kourion exchanged all of their outstanding shares for a \$14 million note and 549,854 shares of ViaCell's Series I convertible preferred stock, which shares converted into 549,854 shares of the Company's common stock upon the Company's initial public offering. As potential additional consideration, the Company issued 241,481 additional shares of Series I convertible preferred stock to an escrow account ( "escrow shares" ) and reserved 289,256 shares of Series I convertible preferred stock ( "reserved shares" ) for possible issuance in the future. The Company has made a determination that the underlying conditions for issuance of the escrow shares and the reserved shares are no longer capable of being met. As a result, as of September 30, 2006, the escrow shares were deemed cancelled and the reserved shares will not be issued.

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

**2. Summary of Significant Accounting Policies*****Basis of Presentation***

The accompanying condensed consolidated financial statements as of September 30, 2006 and for the three and nine months ended September 30, 2006 and 2005, and related notes, are unaudited but in management's opinion include all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary 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. The Company's accounting policies are described in the Notes to the Consolidated Financial Statements in its 2005 Annual Report on Form 10-K and updated, as necessary, in this Form 10-Q. Results for the three and nine months ended September 30, 2006 are not necessarily indicative of results for the entire fiscal year or future periods. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

**Table of Contents***Use of Estimates*

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

*Stock-Based Compensation*

The ViaCell, Inc. Amended and Restated 1998 Equity Incentive Plan (the Plan) provides for the grant of incentive and nonqualified stock options and other equity-based compensation to employees, consultants and directors of the Company. The number of shares of common stock authorized for issuance under the Plan as of September 30, 2006 was 7,200,000. Incentive stock options may only be granted to employees of the Company. The exercise price of each stock option is determined by the Company's Board of Directors. The exercise price of each incentive stock option, however, may not be less than the fair market value of the Company's common stock on the date of grant. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R Share-Based Payment (SFAS 123R) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provision of SFAS 123R, stock-based compensation expense related to stock options awarded by the Company is measured using the Black-Scholes option pricing model at the grant date based on the value of the award and is recognized as expense on a straight-line basis over the requisite service period. Previously, the Company had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretation, which resulted in the accounting for employee stock options at their intrinsic value in the consolidated financial statements.

The Company recognized the full impact under SFAS 123R of the Company's equity-based plan as stock-based compensation expense for continuing operations in its unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2006 as follows (in thousands):

	<b>Three Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2006</b>
Cost of processing and storage revenues	\$ 17	\$ 49
Research and development	85	325
Sales and marketing	73	200
General and administrative	579	1,711
Total stock-based compensation expense	\$ 754	\$ 2,285

Upon adoption of SFAS 123R, using the modified prospective method, the Company recognized a one-time benefit of \$0.3 million for the three months ended March 31, 2006 as a cumulative effect of a change in accounting principle resulting from the adjustment to estimate forfeitures of the Company's stock option grants at the date of grant instead of recognizing them as incurred. The estimated forfeiture rate was applied to the previously recorded stock-based compensation expense of the Company's unvested stock options in determining the cumulative effect of a change in accounting principle. The impact to the Company of adopting SFAS 123R for the three and nine months ended September 30, 2006 was an increase to loss from operations of \$0.8 million and \$2.3 million, respectively, an increase to net loss of \$0.8 million and \$2.0 million, respectively, and an increase in net loss per basic and diluted share of \$0.02 and \$0.06, respectively.

The Company had previously adopted the provisions of SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, through disclosure only. The following table illustrates the effect on net loss and net loss per share for the three and nine month periods ended September 30, 2005 as if the Company had applied the fair value recognition provisions of

SFAS No. 123 to stock-based employee awards.

**Table of Contents**

	<b>Three Months Ended September 30, 2005</b>	<b>Nine Months Ended September 30, 2005</b>
<b>In thousands except per share data</b>		
Net loss attributable to common stockholders as reported	\$ (3,558)	\$ (11,675)
Add: employee stock-based compensation expense included in reported net loss	1,024	1,818
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards	(1,298)	(3,520)
Pro forma net loss attributable to common stockholders	\$ (3,832)	\$ (13,377)
Basic and diluted net loss per share as reported	\$ (0.09)	\$ (0.33)
Pro forma basic and diluted net loss per share	\$ (0.10)	\$ (0.38)

The Company's expected stock-price volatility assumption in its Black-Scholes option-pricing model is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. For stock option grants issued during the three and nine month periods ended September 30, 2006, the Company used a weighted-average expected stock-price volatility of 68% and 65%, respectively.

The Company determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three and nine month periods ended September 30, 2006, the Company used a weighted average expected option life assumption of 4.57 years. The risk-free interest rate used for each grant is equal to the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

The fair market value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	<b>Three Months ended September 30, 2006</b>	<b>Nine Months ended September 30, 2006</b>	<b>Three Months ended September 30, 2005</b>	<b>Nine Months ended September 30, 2005</b>
Option life	4.57 years	4.57 years	5 years	5 Years
Risk-free interest rate	5.00%	4.66%	4.18%	3.90%
Stock volatility	68%	65%	100%	100%
Dividend rate	0%	0%	0%	0%

As of September 30, 2006, there remained approximately \$5.4 million of compensation costs related to non-vested stock options to be recognized as expense over a weighted-average period of approximately 1.7 years.

Presented below is the Company's stock option activity for the nine months ended September 30, 2006 and 2005:

	<b>Nine Months Ended September 30, 2006</b>		<b>Nine Months Ended September 30, 2005</b>	
	<b>Number of Options Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Number of Options Outstanding</b>	<b>Weighted Average Exercise Price</b>
Outstanding, December 31	3,930,694	\$ 2.77	4,455,538	\$ 2.28

Edgar Filing: VIACELL INC - Form 10-Q

Granted	589,875	4.96	402,200	7.37
Exercised	(53,901)	1.06	(611,233)	1.80
Canceled	(165,956)	5.18	(235,384)	4.52
Outstanding, September 30	4,300,712	\$ 3.00	4,011,121	\$ 2.74
Exercisable, September 30	2,374,204		1,925,841	
Weighted average fair value of options granted		\$ 2.81		\$ 4.96

**Table of Contents**

<b>Options Outstanding at September 30, 2006</b>			<b>Options Exercisable at September 30, 2006</b>		
<b>Exercise Price</b>	<b>Number of Shares</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Exercise Price</b>	<b>Number of Shares</b>	<b>Weighted Average</b>
\$0.30	1,380,043	3.63	\$ 0.30	1,080,043	\$ 0.30
0.75	32,200	4.36	0.75	32,200	0.75
0.95	116,986	4.59	0.95	116,986	0.95
2.00	726,075	5.22	2.00	200,075	2.00
4.00	55,775	6.73	4.00	40,775	4.00
4.04	67,250	9.80	4.04	1,014	4.04
5.00	1,118,316	7.11	5.00	683,933	5.00
5.03	264,187	9.64	5.03	53,949	5.03
5.21	217,255	9.42	5.21	29,677	5.21
5.31	137,233	8.98	5.31	34,479	5.31
5.62	9,750	9.19	5.62	2,044	5.62
7.25	25,000	8.57	7.25	9,375	7.25
8.17	94,392	8.26	8.17	65,437	8.17
9.00	7,000	8.36	9.00	1,750	9.00
10.89	40,000	8.78	10.89	20,000	10.89
11.10	9,250	8.78	11.10	2,467	11.10
	4,300,712	6.02	\$ 3.00	2,374,204	\$ 2.50

The aggregate intrinsic value of outstanding and exercisable options as of September 30, 2006 was \$7.5 million and \$5.2 million, respectively. The intrinsic value of options exercised during the three months ended September 30, 2006 and 2005 was \$0.02 million and \$1.7 million, respectively. The intrinsic value of options exercised during the nine months ended September 30, 2006 and 2005 was \$0.2 million and \$4.1 million, respectively.

**Net Loss Per Common Share**

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

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Basic and diluted net loss per share	\$ (4,462)	\$ (3,558)	\$ (16,452)	\$ (11,675)



Net loss attributable to common stockholders				
Weighted average number of common shares outstanding	38,377	37,772	38,345	34,877
Basic and diluted net loss per share	\$ (0.12)	\$ (0.09)	\$ (0.43)	\$ (0.33)

**Table of Contents**

The following potentially dilutive securities were excluded because their effect was antidilutive due to the Company's net loss for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Options	4,270	3,895	4,049	3,778
Warrants	1,443	3,409	1,597	3,549

**3. Accrued Expenses**

At September 30, 2006 and December 31, 2005, accrued expenses consisted of the following (in thousands):

	September 30, 2006	December 31, 2005
Payroll and payroll related	\$ 1,637	\$ 1,541
Management incentive	831	881
Professional fees	2,345	1,206
Accrued marketing	2,073	1,260
Accrued restructuring (Note 5)	65	632
Deferred rent, current	408	619
Accrued taxes	366	537
Other	1,704	1,030
Accrued expenses	\$ 9,429	\$ 7,706

**4. Commitments and Contingencies****Agreements**

In August 2006, the Company entered into a data license and marketing services agreement and related amendment with Mothers Work, Inc. (Mothers Work). Under the agreement, Mothers Work has granted the Company an exclusive (within a specifically defined field) license to use information and data related to certain Mothers Work customers for direct marketing purposes (where such customers have affirmatively opted-in to permit such disclosure of information and data) and to receive certain marketing services from Mothers Work for its ViaCord service offering. Under the terms of the agreement, ViaCell will pay Mothers Work \$5,000,000 per year over the three-year term of the agreement which begins on January 1, 2007 and ends on December 31, 2009. The agreement can be terminated early by either party if the other party commits a material breach of the agreement and can be terminated by the Company in the event that Mothers Work is acquired by a competitor of the Company. In addition, either party can terminate the agreement under certain circumstances arising from claims by a third party alleging that the third party has rights that supersede Mothers Work's commitment to ViaCell. Such a claim has been commenced against Mothers Work in an arbitration proceeding. The Company anticipates a decision in the dispute between Mothers Work and such third party in the fourth quarter of 2006. There is, however, no assurance that the dispute between Mothers Work and the third party will be resolved in a timely fashion. There is also no assurance that Mothers Work will be successful in its dispute with the third party, or that the termination rights under the agreement between the Company and Mothers Work will not be triggered, or that the agreement will not be terminated. In certain circumstances, the Company will, on January 1, 2009, issue to Mothers Work a warrant to purchase 100,000 shares of the Company's common stock with an exercise price at 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 1 year period beginning on January 1, 2010.

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 will focus on dosing, delivery and targeting of ViaCell s expanded proprietary cord blood stem cells using Cordis NOGA 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

**Table of Contents**

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 September 30, 2006, SCIV has reimbursed the Company approximately \$15,000 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 development and supply agreements with Miltenyi Biotec GmbH. The development agreement provides for the development by Miltenyi of a cGMP cell separation kit for ViaCell consisting of various antibodies conjugated with magnetic particles to be used in ViaCell's proprietary Selective Amplification process for the development and commercialization of certain of ViaCell's proprietary cellular therapy product candidates. Under the development agreement, Miltenyi is obligated to perform various tasks set forth in the agreement in connection with the development of the cell separation kit, including making various filings with the FDA. The Company is obligated to pay up to \$950,000 to Miltenyi under the agreement. For the year ended December 31, 2005, the Company had recognized \$950,000 of expense related to this development agreement. As of September 30, 2006, the Company had paid \$950,000 relating to the development of the product, and has recognized the expense as the work was performed over the development period.

The supply agreement with Miltenyi provides for the exclusive supply of the cell separation kits by Miltenyi to ViaCell. The initial term of the supply agreement is seven years. The Company has purchased \$937,500 of cell separation kits in the first nine months of 2006, and has committed to purchase an additional \$312,500 of cell separation kits during the remainder of 2006. The Company also has certain minimum annual purchase requirements starting in fiscal 2007.

The Company has entered into an agreement with the Economic Development Board (EDB) of the Government of Singapore under which the Government of Singapore has agreed to give the Company a grant of up to \$5,900,000 to fund stem cell research and development programs conducted in Singapore. Under this agreement, the Government of Singapore reimburses the Company for a portion of research and development expenses incurred for work done in Singapore. The Company funded approximately \$298,000 and \$337,000 of research and development in Singapore during the three months ended September 30, 2006 and 2005, respectively, and recorded grant revenue of approximately \$201,000 and \$196,000 during the three months ended September 30, 2006 and 2005, respectively. The Company funded approximately \$825,000 and \$974,000 of research and development in Singapore during the nine months ended September 30, 2006 and 2005, respectively, and recorded grant revenue of approximately \$521,000 and \$559,000 during the nine months ended September 30, 2006 and 2005, respectively.

The Company enters into indemnification provisions under its agreements with other companies and individuals performing services for the Company in the ordinary course of business, typically with business partners, licensors and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the party's activities. Certain indemnification provisions survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date, the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. The Company has approximately \$51,000 recorded for these agreements as of September 30, 2006 and December 31, 2005.

**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., which was recently acquired by Cord Blood of 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,  
13

---

**Table of Contents**

based on 6.125% royalties on the Company's revenue from the processing and storage of umbilical cord blood stem cells since April 2000. In 2004, the District Court judge in the case overturned the jury's verdict stating that PharmaStem had failed to prove infringement, consequently the Company has not recorded a liability as of September 30, 2006. PharmaStem has appealed the judge's decision. The Company has appealed the jury's finding as to validity of the patents. A hearing on the appeal took place on April 4, 2006 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. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That motion is currently stayed. The Company believes the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, the Company filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, the Company's request was granted. The cases have been consolidated in Delaware.

The U.S. Patent and Trademark Office ( ' U.S. PTO ) ordered the re-examination of both the '553 method patent and the '681 composition patent at issue in the first case and the '645 and '427 patents at issue in the second case based on prior art. The U.S. PTO ordered a second re-examination of the '427 patent in order to determine whether certain claims of the '427 patent should expire in 2008, rather than in 2010. In the second quarter of 2006, the U.S. PTO issued separate office actions rejecting all of the claims of the '645, '681, '553 and '427 patents. The U.S. PTO ruled that PharmaStem's patent claims are unpatentable over prior art. The office actions issued by the U.S. PTO are not final determinations. PharmaStem has responded to the office actions and is challenging the U.S. PTO's decision. PharmaStem will also have recourse through the Board of Appeals on the office actions.

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

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

**5. Restructuring**

In December 2004, the Company restructured its German operations and sublet its laboratory facility in Germany to a third party effective January 1, 2005. As a result, the Company recorded an additional restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility-related costs of \$1.1 million and a contract termination



**Table of Contents**

fee of \$0.1 million. The majority of the facility-related costs consisted of the write off of the leasehold improvements and fixed assets in the Company's German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future sublease payments received from the sublessee. At December 31, 2004, restructuring costs of \$1.2 million had been paid, the net book value of fixed assets was written down by \$0.9 million and the accrued liability relating to the restructurings was \$0.9 million. In November 2005, the sub-lessee verbally gave notice of their intent not to extend the sublease past December 31, 2006. The sub-lessee had prepaid rent through December 2006. In March 2006, the Company executed an agreement with the sub-lessee under which the sub-lessee made a one-time payment to the Company of approximately \$0.2 million for giving notice of termination prior to the termination of the first period of the sublease agreement. In August 2006, the Company amended its German facility office lease to change the termination date from May 31, 2008 to December 31, 2006. In addition, the Company sold fixed assets at the facility that had been written off in the December 2004 restructuring for approximately \$0.6 million. The sale of fixed assets, combined with the amendment of the lease, is reflected as a change in the Company's December 2004 restructuring estimates of approximately \$0.9 million for the quarter ended September 30, 2006. As a result of the lease amendment, the Company has paid substantially all of the remaining fiscal 2004 restructuring liabilities except for \$0.1 million representing the remaining three months of lease obligations and miscellaneous entity close down costs.

In 2005, the Company was notified by German grant authorities that approximately \$0.5 million in proceeds related to fixed asset and operating expenditures in Germany from a grant made by the German government to our German affiliate were not reimbursable under the grant and would have to be repaid. In August 2006, the Company settled with the German grant authorities, and remitted approximately \$0.4 million to satisfy all potential claim reimbursements relating to the grants. Payments applied to the restructuring accrual during the three months ended September 30, 2006 consist of repayment to the German grant authorities of approximately \$0.4 million, \$0.1 million in professional fees incurred in connection with the negotiations with the German grant authorities and fees associated with the August 2006 lease amendment and sale of fixed assets.

As of September 30, 2006, the Company had received approximately \$3.6 million in cumulative grant proceeds from the German grant authorities and remitted back approximately \$0.4 million as noted above.

Following is the Company's activity in the restructuring accrual for the nine months ended September 30, 2006 (in thousands):

Balance, December 31, 2005	\$ 632
Payments	(567)
Balance, September 30, 2006	\$ 65

**6. Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements ( SFAS No. 157 ) which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (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. Earlier adoption is encouraged. The Company does not expect the adoption of SFAS No. 157 to have a significant immediate effect on its financial position or results of operations.

In September 2006, the SEC issued Staff Accounting Bulletin 108 ( SAB 108 ), which was issued to address diversity in practice in quantifying financial statement misstatements and the potential under current practice for the build up of improper amounts on the balance sheet. The Company is evaluating the potential impact, if any, of SAB 108 on future periods.



**Table of Contents**

In June 2006, FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109 ( FIN 48 ), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 will be effective for fiscal years beginning after December 15, 2006. The Company has not yet completed its evaluation of the impact of adoption of FIN 48 on its financial position or results of operations

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

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

**Overview**

ViaCell is a biotechnology company dedicated to researching, developing and commercializing cellular therapies. We have a pipeline of proprietary umbilical cord blood-derived and adult-derived stem cell product candidates being studied as possible treatments for cancer, cardiac disease and diabetes. CB001, our lead umbilical cord blood-derived stem cell therapy product candidate, is being developed as a possible treatment for hematopoietic stem cell reconstitution in patients affected by a variety of cancers. In July 2006, we announced that we had completed enrollment and treated the last patient in the Phase 1 trial of CB001. We expect to complete analysis of the results of the trial in the first quarter of 2007. In addition to our therapeutic research and development programs, we have a reproductive health business unit 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. We are 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. In June 2006, the FDA gave conditional approval of an Investigational Device Exemption to allow ViaCyte to be used in a clinical trial. We are currently planning to conduct a single, pivotal clinical trial to study the safety and efficacy of ViaCyte. We expect to initiate the trial in the first quarter of 2007. The goal of the clinical trial is to generate data to submit to the FDA for 510(k) clearance for ViaCyte. We also continue to explore leveraging our commercial infrastructure and development capabilities through potential in-licensing or acquisition opportunities.

Our management currently uses consolidated financial information in determining how to allocate resources and assess performance. We have determined that we conduct operations in one business segment. The majority of our revenues since inception have been generated in the U.S., and the majority of our long-lived assets are located in the U.S.

**Revenues**

Our current revenues are derived primarily from fees charged to families for the preservation and storage of a child's umbilical cord blood 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 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

**Table of Contents**

allow for this exposure and consider the amount of this reserve to be adequate as of September 30, 2006.

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 in such suit. 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 the appeal, or the additional ongoing litigation with PharmaStem, it could have a material adverse effect on our net sales, revenues or income from continuing operations, including, possibly, resulting in an injunction preventing us from operating our cord blood preservation business.

In addition to the revenues generated by our ViaCord service offering, we recorded revenues in the periods presented from a grant agreement with the Economic Development Board (EDB) of the Government of Singapore. Government grants are routinely subject to review. We maintain a research facility in Singapore. We are in discussions with the EDB regarding the expectations of potential future activity upon conclusion of the current grant, which expires in May 2007. In discussing whether or not we would agree to extend the grant, the EDB has suggested that a prior period increase in the EDB's cost reimbursement percentage constituted an advance on future grant funding. We, however, believe that the increase constituted a mutually agreed upon increase in the reimbursement percentage for the period, after which the reimbursement rate was to revert to the rate prior to such increase. The amount received by us under the increased reimbursement percentage was approximately \$0.9 million. The EDB has proposed that the issue be resolved through an extension of the grant term during which the EDB would continue the grant but at a lower cost reimbursement rate. If we choose not to extend the grant, we believe that the EDB may also assert that we have not fulfilled a commitment to employ a specified number of people in Singapore that was an original condition of the grant. Under the terms of the grant, a breach of a condition of the grant could result in the EDB pursuing repayment of some or all of the amounts disbursed to us. We believe that the EDB has waived this commitment and that, as a result, we have satisfied all requirements under the grant. While there is also no assurance that, if we do not agree to extend the grant term, EDB will not seek to recover grant funds previously paid and/or withhold payment of existing or future grant claims that are as yet unpaid, we believe we have met our performance obligations and would be successful in our defense of any such claims. As of September 30, 2006, we had received grant payments from EDB totaling approximately \$1.9 million and had recognized cumulative grant revenues of approximately \$1.9 million.

***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 also 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 revenue. Such costs are included in research and development expense.

In 2003, we recorded a royalty expense of \$3.3 million following an unfavorable jury verdict in the PharmaStem litigation. In 2004, the District Court overturned the jury verdict. Based on the court's ruling, we reversed the entire royalty accrual in 2004 and have not recorded any royalties since such date. PharmaStem has appealed the District Court's ruling. 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 these litigations could result in damages payable for infringement of PharmaStem's patents, at a higher or lower amount than previously awarded by the jury in Delaware. Should this occur, our financial position and results of operations could be materially affected. We may enter into settlement negotiations with PharmaStem regarding the litigation. If a settlement agreement were entered into, we do not know whether it would provide for a payment by us of an ongoing royalty or payment of other amounts by us to PharmaStem, or what those amounts might be.



**Table of Contents**

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

We expect that research and development expenses will increase in the foreseeable future as we potentially add personnel, expand our clinical trial activities, including activities related to the pivotal clinical trial of ViaCyte, and increase our development and clinical and regulatory capabilities. The amount of these increases is difficult to predict given that we have not yet analyzed the data generated in the CB001 Phase 1 trial to determine if the results support further development, and given the uncertainty inherent in our research, development and manufacturing programs and activities, the timing and scope of our clinical trials, the rate of patient enrollment in our clinical trials, and the detailed design of future clinical trials. In addition, the results from our clinical trials, as well as the results of trials of similar therapeutics under development by others, will influence the number, size and duration of planned and unplanned trials. On an ongoing basis, we evaluate the results of our product candidate programs, all of which are currently in early stages. Based on these assessments, 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. The majority of these costs relate to our sales force and support personnel, marketing expenses and telecommunications expense related to our call center. We also incur external costs associated with advertising, direct mail, promotional and other marketing services. We expect that sales and marketing expenses will remain steady in the fourth quarter of 2006. However, we may, from time to time, implement additional promotions and other marketing programs that may increase sales and marketing expenses.

Our general and administrative expenses include our costs related to the finance, legal, human resources, business development, investor relations and corporate governance areas. These costs consist primarily of expenses related to our staff, as well as external fees paid to our legal and financial advisors, business consultants, and others. We expect that these costs will increase in future years as we expand our business activities.

In December 2004, we restructured our German operations and sub-leased our German facility to a third party. As a result we recorded a restructuring charge of \$1.2 million in the fourth quarter of 2004, including facility costs of \$1.1 million and \$0.1 million related to a contract termination fee. The majority of the facility-related costs consists of the write off of the leasehold improvements and fixed assets in our German facility, as well as the future minimum lease payments related to the facility. The amount of this write off was partially reduced by the minimum future lease payments receivable from the sub-lessee, as described in *Results of Operations Restructuring*. In August 2006, we amended our German facility office lease to change the termination date from May 31, 2008 to December 31, 2006. In addition, we sold fixed assets at the facility that had been written off in the December 2004 restructuring for approximately \$0.6 million. The sale of fixed assets, combined with the amendment of the lease, is reflected as a change in our December 2004 restructuring estimates of approximately \$0.9 million for the quarter ended September 30, 2006. As a result of the lease amendment, we have paid substantially all of the remaining fiscal 2004 restructuring liabilities except for \$0.1 million representing the remaining three months of lease obligations and miscellaneous entity close down costs.

In August 2006, we finalized discussions with German grant authorities regarding repayment of part of certain grants made to our German subsidiary in 2003 and 2004. In 2005, we were notified that approximately \$500,000 in grant proceeds related to fixed asset and operating expenditures in Germany were not reimbursable under the grant and would have to be repaid. In conjunction with these final discussions, we settled with the German grant authorities,

and remitted approximately \$400,000 to satisfy all potential claim reimbursements.

**Table of Contents**

Payments applied to the restructuring accrual during the three months ended September 30, 2006 consist of repayment to the German grant authorities of approximately \$0.4 million, \$0.1 million in professional fees incurred in connection with the negotiations with the German grant authorities and fees associated with the August 2006 lease amendment and sale of fixed assets.

As of September 30, 2006, we had received approximately \$3.6 million in cumulative grant proceeds from the German grant authorities and remitted back approximately \$0.4 million as noted above.

**Results of Operations****Three and Nine Months Ended September 30, 2006 and 2005 (table amounts in thousands)**

	Three Months Ended			Nine Months Ended		
	September 30,		Change	September 30,		Change
	2006	2005		2006	2005	
Processing revenues	\$ 11,714	\$ 9,549	23%	\$ 32,146	\$ 27,217	18%
Storage revenues	2,752	2,006	37%	7,619	5,501	39%
Total processing and storage revenues	14,466	11,555	25%	39,765	32,718	22%
Grant revenues	201	135	49%	521	495	5%
Total revenues	\$ 14,667	\$ 11,690	25%	\$ 40,286	\$ 33,213	21%

The increase in processing revenues of \$2.2 million, or 23%, from the three months ended September 30, 2005 to the three months ended September 30, 2006, and the increase in processing revenues of \$4.9 million, or 18%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 were due primarily to an increase in the total number of umbilical cords processed, and to a lesser extent due to an increase in the average selling price for processing.

The increase in storage revenues of \$0.7 million, or 37%, from the three months ended September 30, 2005 to the three months ended September 30, 2006, and the increase in storage revenues of \$2.1 million, or 39%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 were due primarily to increases in the number of umbilical cords stored, and to a lesser extent due to a slight increase in the average selling price for storage.

The slight increase in grant revenues of \$0.1 million, or 49%, from the three months ended September 30, 2005 to the three months ended September 30, 2006 and the slight increase in grant revenues of \$0.03 million, or 5%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006, were primarily due to the reversal of grant revenues in the three and nine months ended September 30, 2005 related to certain fixed asset and operating expenditures in Germany which were deemed not reimbursable under the grant.

	Three Months Ended			Nine Months Ended		
	September 30,		Change	September 30,		Change
	2006	2005		2006	2005	
Cost of processing and storage revenues	\$ 2,893	\$ 2,169	33%	\$ 7,757	\$ 6,151	26%

The increase in cost of processing and storage revenues of \$0.7 million, or 33%, from the three months ended September 30, 2005 to the three months ended September 30, 2006 and the increase in cost of processing and storage revenues of \$1.6 million, or 26%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 were due primarily to increases in variable expenses related to the increased number of umbilical cords processed and an increase in the number of umbilical cords stored.

**Table of Contents**

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Research and development	\$ 3,570	\$ 3,312	8%	\$ 10,696	\$ 10,073	6%

During the three and nine months ended September 30, 2006 and 2005, our research and development expenses primarily related to our CB001, cardiac and diabetes programs, as well as our basic research programs. The increase in costs associated with research and development of \$0.3 million, or 8%, from the three months ended September 30, 2005 to the three months ended September 30, 2006 and \$0.6 million, or 6%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006, was primarily due to an increase in outside services related to ongoing clinical and preclinical testing of our therapeutic product candidates for cancer, cardiac disease, and diabetes, as well as an increase in headcount-related expenses.

	Three Months Ended September 30,			Nine Months Ended Sept 30,		
	2006	2005	Change	2006	2005	Change
Sales and marketing	\$ 9,901	\$ 6,304	57%	\$27,818	\$17,949	55%

The increase in sales and marketing expenses of \$3.6 million, or 57%, from the three months ended September 30, 2005 to the three months ended September 30, 2006, and the increase in sales and marketing expenses of \$9.9 million, or 55%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 were primarily related to increased staffing within both the internal and external sales organization and increased external marketing expenses to strengthen our market presence.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
General and administrative	\$ 4,474	\$ 3,787	18%	\$ 14,124	\$ 10,422	36%

The increase in general and administrative expenses of \$0.7 million, or 18%, from the three months ended September 30, 2005 to the three months ended September 30, 2006 was primarily due to increased accounting fees and outside service fees associated with compliance with the Sarbanes-Oxley Act of 2002, increased employee related expenses, increased bad debt expense reflecting higher processing and storage revenues, offset by a decrease in stock-based compensation expense. During the three months ended September 30, 2005, we recorded additional stock-based compensation expense of approximately \$0.7 million related to the modification of stock option grants to the Board of Directors outstanding as of September 30, 2005.

The increase in general and administrative expenses of \$3.7 million, or 36%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 was primarily due to increased accounting fees and outside service fees associated with compliance with the Sarbanes-Oxley Act of 2002, increased employee related expenses, increased bad debt expense reflecting higher processing and storage revenues, as well as increased stock-based compensation expense associated with the adoption of Statement of Financial Accounting Standards No. 123R Share-Based Payment ( SFAS 123R ).

**Table of Contents**

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Restructuring	\$ (890)	\$ 94	(1,047)%	\$ (1,070)	\$ 305	(451)%

The decreases in restructuring expense for the three and nine months ended September 30, 2006 reflect changes to the original estimate of our restructuring accrual. The decrease in restructuring expense for the three months ended September 30, 2006 reflects changes to the original estimate of our restructuring accrual related to the August 2006 sale of fixed assets and the lease amendment described above of approximately \$1.0 million, offset by a repayment of \$0.2 million paid by our sub-lessee in connection with the August 2006 lease amendment.

During the nine months ended September 30, 2006, we recorded a reduction to restructuring expense of approximately \$0.6 million related to our agreement to sell certain property, plant and equipment previously written off in the December 2004 restructuring. We also accelerated the recognition of \$0.4 million of prepaid rent received from our German sub-lessee for the period of January 2007 through May 2008 as a result of the August 2006 amendment of our German facility office lease which changed the termination date from May 31, 2008 to December 31, 2006.

Restructuring expense for the three and nine months ended September 30, 2005 is related to changes in estimates of the amounts due to the German grant authorities during preliminary discussions with them at that time. In August 2006, we settled with the German grant authorities and remitted approximately \$400,000 to satisfy all potential claim reimbursements.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Interest income	\$ 827	\$ 531	56%	\$ 2,354	\$ 1,305	80%
Interest expense	(8)	(113)	(93)%	(50)	(306)	(84)%
Total interest income, net	\$ 819	\$ 418	96%	\$ 2,304	\$ 999	131%

Interest income is earned primarily from the investment of our cash in short-term securities and money market funds. The increase in interest income of \$0.3 million, or 56%, from the three months ended September 30, 2005 to the three months ended September 30, 2006 primarily relates to an increase in interest rates. The increase in interest income of \$1.0 million, or 80%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 primarily relates to an increase in interest rates, as well as \$0.4 million of interest income from customers recognized in the nine months ended September 30, 2006.

The decrease in interest expense of \$0.1 million, or 93%, from the three months ended September 30, 2005 to the three months ended September 30, 2006 was primarily related to the repayment of debt obligations. The decrease in interest expense of \$0.3 million, or 84%, from the nine months ended September 30, 2005 to the nine months ended September 30, 2006 relates primarily to the repayment of debt obligations, as well as the reduction of interest on the related party notes payable, which were paid in full following the closing of our initial public offering ( IPO ) in January 2005.

**Liquidity and Capital Resources**

From inception through September 30, 2006, we have raised \$192.0 million from common and preferred stock issuances, which includes \$53.3 million in net proceeds from our IPO in January 2005. We used approximately \$15.5 million of the net proceeds from the IPO to repay in full related party notes of \$14.0 million, and accrued interest on the notes of \$1.5 million. As of September 30, 2006, we had approximately \$52.1 million in cash, cash equivalents and investments.



**Table of Contents**

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

	<b>Nine Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2005</b>	<b>\$ Change</b>
Net cash used in operating activities	\$ (6.4)	\$ (1.0)	\$ (5.4)
Net cash used in investing activities	(3.0)	(3.7)	0.7
Net cash provided by (used in) financing activities	(0.9)	37.7	(38.6)
Cash and cash equivalents, end of period	\$ 23.0	\$ 39.5	\$(16.5)

Net cash used in operating activities was \$6.4 million for the nine months ended September 30, 2006, an increase of \$5.4 million from the \$1.0 million used in operating activities in the nine months ended September 30, 2005. For the nine months ended September 30, 2006, the \$6.4 million cash used by operations was primarily due to our net loss of \$16.5 million, reduced by non-cash expenses of \$5.0 million, net increases in deferred revenue of \$5.0 million, and a net decrease in working capital (accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses) of \$1.0 million, offset by a decrease in deferred rent of \$0.9 million. The increase in deferred revenue of \$5.0 million related to sales of long-term pre-paid storage contracts. For the nine months ended September 30, 2005, the \$1.0 million used in operating activities was due to our net loss, net of adjustments for non-cash expenses, of \$6.9 million and a net increase in working capital (account receivable, prepaid expense and other current assets, accounts payable, and accrued expenses) of \$2.3 million. These net uses of cash in operating activities for the nine months ended September 30, 2005 were partially offset by net increases in deferred rent of \$3.4 million and deferred revenue of \$4.8 million. The increase in deferred rent was due to payments from our landlord related to the build-out of our laboratory facility in Cambridge and prepaid rent received by us from a sublease tenant in Germany. The increase in deferred revenue of \$4.8 million related to sales of long-term prepaid storage contracts, as well as advances received in connection with our grant from the Government of Singapore.

Net cash used in investing activities for the nine months ended September 30, 2006 was \$3.0 million as compared to net cash used of \$3.7 million for the nine months ended September 30, 2005. For the nine months ended September 30, 2006, \$37.4 million of U.S. Government and high-rated corporate securities matured and \$39.2 million was invested in similar securities. We also invested approximately \$1.4 million in property and equipment for the nine months ended September 30, 2006. For the nine months ended September 30, 2005, \$29.0 million of U.S. Government and high-rated corporate securities matured and \$29.1 million was invested in similar securities. We also invested \$3.6 million in property and equipment for the nine months ended September 30, 2005. Approximately \$2.5 million of the total amount that we spent on property and equipment during the nine months ended September 30, 2005 related to the build-out of our manufacturing facility and laboratory in Cambridge, which was completed in August 2005. We expect that this facility will give us the capacity to complete Phase 2 and Phase 3 clinical trials of CB001, if data supports further development, and to proceed to initial commercialization of CB001, if successfully developed. We expect that we will need to build or acquire another manufacturing facility in order to fully commercialize CB001 and our other product candidates, if successfully developed. The timing and cost of such a facility is not known at this time, however the cost is likely to be substantial.

Net cash used in financing activities for the nine months ended September 30, 2006 was \$0.9 million as compared to net cash provided of \$37.7 million for the nine months ended September 30, 2005. For the nine months ended September 30, 2006, the net cash used in financing activities was principally related to repayments of \$1.4 million on our long-term debt obligations, offset by proceeds received from the refund of a security deposit from a lender of \$0.4 million and proceeds from stock option exercises of \$0.1 million. For the nine months ended September 30, 2005, the net cash provided by financing activities included net proceeds from our IPO of \$53.3 million and proceeds of \$1.1 million relating to stock options exercised. These proceeds were partially reduced by cash used to repay a related party note related to the acquisition of Kourion Therapeutics of \$15.5 million and repayment of \$1.2 million on our long-term debt obligation, net of proceeds received from the return of a security deposit which secured our long-term debt obligations.



**Table of Contents**

We anticipate that our current cash, cash equivalents and investments will be sufficient to fund our operations for the next three years. However, our forecast for the period of time during which our financial resources will be adequate to support our operations is subject to a number of 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 1,430,833 shares of our common stock at September 30, 2006, we have no off balance sheet arrangements, as defined by Item 303(a)(4) of the SEC's Regulation S-K. Please see note 8 of our Form 10-K for the year ended December 31, 2005 for a description of the warrants.

**Commitments and Contingencies****Agreements**

In August 2006, we entered into a data license and marketing services agreement and related amendment with Mothers Work, Inc. (Mothers Work). Under the agreement, Mothers Work granted us an exclusive (within a specifically defined field) license to use information and data related to certain Mothers Work customers for direct marketing purposes (where such customers have affirmatively opted-in to permit such disclosure of information and data) and to receive certain marketing services from Mothers Work for our ViaCord service offering. Under the terms of the agreement, we will pay Mothers Work \$5,000,000 per year over the three-year term of the agreement which begins on January 1, 2007 and ends on December 31, 2009. The agreement can be terminated early by either party if the other party commits a material breach of the agreement and can be terminated by us in the event that Mothers Work is acquired by a competitor of ours. In addition, either party can terminate the agreement 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. Such a claim has been commenced against Mothers Work in an arbitration proceeding. We anticipate a decision in the dispute between Mothers Work and such third party in the fourth quarter of 2006. There is, however, no assurance that the dispute between Mothers Work and the third party will be resolved in a timely fashion. There is also no assurance that Mothers Work will be successful in its dispute with the third party, or that the termination rights under the agreement between us and Mothers Work will not be triggered, or that the agreement will not be terminated. In certain circumstances, we will, on January 1, 2009, issue to Mothers Work a warrant to purchase 100,000 shares of our common stock with an exercise price at a 30% premium to the average closing price of our common stock over the ten trading days immediately preceding January 1, 2007. The warrant would be exercisable for a 1-year period beginning on January 1, 2010.

In June 2006, we entered into a research collaboration agreement with the Stem Cell Internal Venture (SCIV) of Centocor Research and Development, Inc. to evaluate our 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 will focus on dosing, delivery and targeting of our expanded proprietary cord blood stem cells using Cordis's NOGA delivery system. Under the terms of the agreement, we received an initial up-front payment of \$350,000 which we recorded as a liability and are 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 we incur under the collaboration, consistent with the agreed upon budget. In addition, the agreement provides SCIV with the first right to negotiate a collaboration with us on the clinical development and commercialization of a cardiac product offering based on our proprietary cord blood stem cells.

**Legal Proceedings**

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

In 2003, a jury ruled against us and the other defendants, Cbr Systems Inc, CorCell, Inc., which was recently acquired by 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



**Table of Contents**

on our revenue from the processing and storage of umbilical cord blood since April 2000. In 2004, the District Court judge in the case overturned the jury's verdict stating that PharmaStem had failed to prove infringement, consequently we have not recorded a liability as of September 30, 2006. 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 took place 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. On January 7, 2005, PharmaStem filed a Motion for Preliminary Injunction in the Massachusetts litigation. That motion is currently stayed. We believe the issues presented in this case are substantially the same as the issues presented in the original Delaware litigation. Accordingly, we filed a motion to consolidate the Massachusetts case with six other actions against other defendants in a single proceeding in the District of Delaware. On February 16, 2005, our request was granted. The cases have been consolidated in Delaware.

The U.S. Patent and Trademark Office ( U.S. PTO ) ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and 427 patents at issue in the second case based on prior art. The U.S. PTO ordered a second re-examination of the 427 patent in order to determine whether certain claims of the 427 patent should expire in 2008, rather than in 2010. In the second quarter of 2006, the U.S. PTO issued separate office actions rejecting all of the claims of the 645, 681, 553 and 427 patents. The U.S. PTO ruled that PharmaStem's patent claims are unpatentable over prior art. The office actions issued by the U.S. PTO are not final determinations. PharmaStem has responded to the office actions and is challenging the U.S. PTO's decision. PharmaStem will also have recourse through the Board of Appeals on the office actions.

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

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against it. 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 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 its 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. 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



**Table of Contents**

conditions. Our critical accounting policies include:

*Accounting for Stock-Based Compensation.* We have one stock-based employee compensation plan. On January 1, 2006, we adopted SFAS 123R using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the condensed consolidated financial statements 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. Stock-based employee compensation expense was \$0.8 million and \$2.3 million for the three and nine months ended September 30, 2006. Previously, we had followed Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, which resulted in the accounting for employee stock options at their intrinsic value in the condensed consolidated financial statements.

We are required to make significant estimates under SFAS 123R. 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. For stock options granted during the three and nine month periods ended September 30, 2006, we used a weighted-average expected stock-price volatility of 68% and 65%, respectively. Higher estimated volatility increases the fair value of a stock option, and therefore increases the expense to be recognized per 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. For stock option grants made during the three and nine month periods ended September 30, 2006, we used a weighted-average expected option life assumption of 4.57 years. Longer expected term assumptions increase the fair value of the stock option, and therefore increase the expense to be recognized per stock option.

We recognized the full impact of our stock-based employee compensation plan in the condensed consolidated statement of income for the three and nine month periods ended September 30, 2006 under SFAS 123R and did not capitalize any such costs on the condensed consolidated balance sheets. Upon adoption of SFAS 123R, using the modified prospective method, we recognized a benefit of \$0.3 million during the nine months ended September 30, 2006 as a cumulative effect of a change in accounting principle resulting from the requirement to estimate forfeitures of our stock option grants at the date of grant instead of recognizing them as incurred. The estimated forfeiture rate was applied to the previously recorded stock based compensation expense of our unvested stock options in determining the cumulative effect of a change in accounting principle.

**Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ( SFAS No. 157 ) which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (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. Earlier adoption is encouraged. We do not expect the adoption of SFAS No. 157 to have a significant immediate effect on its financial position or results of operations.

In September 2006, the SEC issued Staff Accounting Bulletin SAB 108 ( SAB 108 ), which was issued to address diversity in practice in quantifying financial statement misstatements and the potential under current practice for the build up of improper amounts on the balance sheet. We are evaluating the potential impact, if any, of SAB 108 on future periods.

In June 2006, FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* An Interpretation of FASB Statement No. 109 ( FIN 48 ), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 will be effective for fiscal years beginning after December 15, 2006. We have not yet completed our evaluation of the impact of adoption of FIN 48 on our financial position 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 US dollars are included as a separate component of stockholders' equity. We hold Euro-based and Singapore dollar-based currency accounts to mitigate foreign currency transaction risk. Since both the revenues and expenses of the Singapore subsidiary are denominated in Singapore dollars and the expenses of the German subsidiary are denominated in Euros, the fluctuations of exchange rates may adversely affect our results of operations, financial position and cash flows.

***Interest Rate Risk***

We invest our cash in a variety of financial instruments, principally securities issued by the 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 September 30, 2006 and, based on their evaluation, our principal executive officer and principal financial officer have concluded that these controls and procedures are effective. Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

There were no changes in our internal controls over financial reporting during the three months ended September 30, 2006 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****NOTE ABOUT FORWARD-LOOKING STATEMENTS**

This report contains forward-looking statements, including statements about our current projections as to future financial performance, our expectations as to the potential and anticipated results of our development programs, and our views as to the possible outcome of pending litigation and other disputes and actions related to our intellectual property portfolio. We have based these forward-looking statements on our current expectations about such future events. While we believe these expectations are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those discussed in this report under this

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

We have generated operating losses since our inception. As of September 30, 2006, we had cumulative net losses of approximately \$189.9 million. These losses have resulted principally from the costs of our research and development activities, which have totaled approximately \$112.4 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 research, clinical trials, and, if our programs are successful, 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 programs, including the CB001 Phase 1 clinical trial, the design of future clinical trials and decisions made with respect to advancement of our clinical programs. Furthermore, we may make additional sales and marketing investments in our ViaCell Reproductive Health business, if deemed advisable to expand the market for our ViaCord service offering. Our ability to become profitable 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, the level of our expenses including those related to research and development, our ability to establish the safety and efficacy of our product candidates, obtain necessary regulatory approvals for such product candidates and successfully commercialize the resulting products, and our ability to acquire additional product candidates or marketed products through licensing or acquisition activities. We cannot assure you that we will ever become profitable. Factors that may affect our ability to become profitable are described in more detail elsewhere in this "Risk Factors" section.

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

Revenues from sales of ViaCord have grown significantly over the past several years, from \$7.1 million in fiscal year 2001, to \$20.1 million, \$30.9 million, \$36.8 million, and \$43.8 million in fiscal years 2002, 2003, 2004, and 2005, respectively. In the first nine months of 2006, we had revenues from sales of ViaCord of \$39.8 million, an increase of 22% over the first nine months of 2005. We believe that this revenue growth is a result of our increased marketing efforts and from increased awareness by the public generally of the concept of umbilical cord blood preservation. We may not be able in the future, however, to sustain this growth rate or the current level of ViaCord's revenues. The principal factors that may adversely affect our revenues include competition from other private cord blood banks, any decline in the market for cord blood banking, 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

**Table of Contents**

our future revenues are described in more detail elsewhere in this Risk Factors section. If we are unable to sustain our revenues, we may need to reduce our product development activities or raise additional funds earlier than anticipated or on unfavorable terms, and our stock price may be adversely affected.

***If we do not prevail in the PharmaStem litigation, we may be prevented from selling our ViaCord 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 US Patents No. 5,004,681 ( 681) and No. 5,192,553 ( 553), relating to certain aspects of the collection, cryopreservation and storage of hematopoietic stem cells and progenitor cells from umbilical cord blood. We believe that we do not infringe these patents and that the patents are invalid.

In 2003, a jury ruled against us and the other defendants, Cbr Systems Inc, CorCell, Inc., which was recently acquired by 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 September 30, 2006. PharmaStem has appealed the judge's decision. We have appealed the jury's finding as to validity of the patents. A hearing on the appeal was held on April 4, 2006 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.

The U.S. PTO has ordered the re-examination of both the 553 method patent and the 681 composition patent at issue in the first case and the 645 and the 427 patents at issue in the second case based on prior art. The U.S. PTO 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. In the second quarter of 2006, the U.S. PTO issued separate office actions rejecting all of the claims of the 645, 681, 553 and 427 patents. The U.S. PTO ruled that PharmaStem's patent claims are unpatentable over prior art. The office actions issued by the U.S. PTO are not final determinations. PharmaStem has responded to the office action and is challenging the U.S. PTO's decision. PharmaStem will also have recourse through the Board of Appeals on the office actions.

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

In either of the pending cases, if we are ultimately found to infringe valid claims of the PharmaStem patents, we could have a significant damages award entered against us. If we are found to infringe or at any other time during the course of either case, including if the court of appeals were to overturn the district court's non-infringement ruling, we could also face an injunction which could prohibit us from further engaging in the umbilical cord stem cell business absent a license from PharmaStem. PharmaStem would be under no legal obligation to grant us a license or to do so on economically reasonable terms, and previously informed us that it would not do so after October 15, 2004. While we do not believe this outcome is likely, in the event of an injunction, if we are not able to obtain a license under the disputed patents on economically reasonable terms or at all and we cannot operate under an equitable doctrine known as intervening rights, we could be required to stop preserving and storing cord blood

**Table of Contents**

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, results of operations and stock price. Even if we ultimately prevail, we are likely to incur significant legal expenses during the course of the cases.

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

No company has yet been successful in its efforts to develop and commercialize a stem cell product. Stem cell products in general may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval or commercial use.

Our cellular therapy product candidates are in the early stages of development. Only one of our therapeutic product candidates, CB001, has been tested in human clinical trials. CB001 consists of a highly enriched population of hematopoietic stem cells which are expanded from umbilical cord blood using our Selective Amplification technology. While stem cell populations expanded using our Selective Amplification technology have shown promising results in preclinical research, those results have not been obtained in humans and may not be indicative of results we may encounter in clinical trials. We may discover that manipulation of stem cells using Selective Amplification or any of our other expansion technologies changes the biological characteristics of the stem cells. For this or other reasons, therapeutic products developed with our stem cell expansion technology may fail to work as intended, even in areas where stem cell therapy is already in use. This may result from the failure of our product candidates to:

properly engraft into the recipient's body in the desired manner;

provide the intended therapeutic benefits; or

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

In July 2006, we announced that we had completed enrollment and treated the last patient in the Phase 1 clinical trial of CB001. We expect to complete analysis of the results of the trial in the first quarter of 2007. If the final results of the trial are positive, we intend to advance the product into a Phase 2 trial. There is no assurance that the results of the Phase 1 trial will warrant further clinical development or that CB001 will ultimately prove to be safe and effective. If we were to continue development of CB001, we can give no assurance about the timing or path of such clinical development. We may encounter hurdles related to the clinical path for CB001. For example, in improving our Selective Amplification process, the resulting product candidate may be viewed by the FDA as different from the product candidate being used in our current Phase 1 clinical trial. If so, the FDA may require that we conduct new Phase 1 clinical trials using the product candidate manufactured using the improved process to generate appropriate safety data to support later stage clinical trials. In addition, there is evidence that clinicians are increasingly using a new procedure for stem cell transplant patients involving less toxic doses of chemotherapy and radiation than used in conventional transplants. This so called mini-transplant procedure was not used in our Phase 1 trial. If we need to redesign trials for CB001 that incorporate mini-transplants, it could require repeating earlier trials. Repeating clinical trials for any reason would significantly delay our development efforts related to CB001.

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. 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.



**Table of Contents**

We cannot market any product candidate until regulatory agencies grant marketing approval or licensure. The industry and the FDA have relatively little experience with therapeutics based on cellular medicine generally. As a result, the pathway to regulatory approval for our stem cell-based product candidates, including CB001, may be more complex and lengthy than the pathway for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the U.S., we will need to submit clinical data concerning our products and receive regulatory approval from the appropriate governmental agencies. Standards for approval outside the U.S. may differ from those required by the FDA. We may encounter delays or rejections if changes occur in regulatory agency policies during the period in which we develop a product candidate or during the period required for review of any application for regulatory agency approval.

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

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

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

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 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 response to the original 510(k) application filed by our media supplier, the FDA indicated that the media supplier had not demonstrated substantial equivalence of the media to a predicate device and, as a result, the FDA could not clear the media for commercial use. The FDA indicated that the 510(k) application could be re-submitted when additional data supporting substantial equivalence of the media to a predicate device were available. We are currently working to submit additional information related to the clinical trial to a central Institutional Review Board, or IRB, that represents several of our possible clinical trial sites after an initial disapproval by this IRB of our submission. We addressed similar issues with the FDA prior to our IDE approval. If we are able to gain IRB approval, which we believe we will, we expect the clinical trial will commence in the first quarter of 2007. There is no assurance that we will be able to gain the approval of IRBs for the clinical trial. If we are unable to gain the approval of the requisite IRBs, we would likely have to discontinue clinical development of ViaCyte. If the trial is approved by the requisite IRBs, 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 for the past three decades, methods for cryopreserving oocytes have not been widely employed due to difficulties encountered in freezing this cell. There is no assurance that we will be able to generate the number of live births needed to show that our product candidate is effective. We may also encounter unexpected safety issues. Even if 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 the ViaCyte oocyte cryopreservation product candidate, the FDA could ask for post-approval safety monitoring which would entail additional expense. The FDA could also restrict the label for the product to limited patient populations which could limit its commercial potential.

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

As of September 30, 2006, we had approximately \$52.1 million in cash, cash equivalents and short-term investments. In order to develop and bring our new products to market, we must commit substantial resources to costly and time-consuming research and development, preclinical testing and clinical trials. While we anticipate that

**Table of Contents**

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 scope and results of our research and development programs;

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

the results of litigation;

the timing of and the costs involved in obtaining regulatory approvals for our product candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug given the FDA's relatively little experience with cellular-based therapeutics;

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

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

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

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

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

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

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

***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



**Table of Contents**

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 recently been the subject of much litigation. Neither the U.S. PTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents. The claims of our existing U.S. patents and those that may issue in the future, or those licensed to us, may not offer significant protection of our Selective Amplification and other technologies. Our patents on Selective Amplification, in particular, are quite broad. While Selective Amplification is covered by issued patents and we are not aware of any challenges to the validity of these patents, patents with broad claims tend to be more vulnerable to challenge by other parties than patents with more narrowly written claims. Our patent applications covering Unrestricted Somatic Stem Cells, or USSCs, claim these cells and/or their use in the treatment of many diseases. It is possible that these cells could be covered by other patents or patent applications which identify, isolate or use the same cells by other markers, although we are not aware of any. Third parties may challenge, narrow, invalidate or circumvent any patents we obtain based on these applications. Interference proceedings brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management.

Competitors may infringe our patents or the patents of our collaborators or licensors. Although we have not needed to take such action to date, we may be required to file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us in a manner that does not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. For instance, our issued patents on Selective Amplification will expire in 2015. To the extent our product candidates based on that technology are not commercialized significantly ahead of this date, or to the extent we have no other patent protection on such products, those products would not be protected by patents beyond 2015. Without patent protection, those products might have to compete with identical products by competitors.

In an effort to protect our unpatented proprietary technology, processes and know-how as trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. 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.



**Table of Contents*****Third parties may own or control patents or patent applications that are infringed by our technologies or product candidates.***

Our success depends in part on our not infringing other parties' patents and proprietary rights as well as not breaching any licenses relating to our technologies and product candidates. In the U.S., patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, there may be patent applications of which we are unaware that will result in issued patents in our field, and avoiding patent infringement may be difficult. We may inadvertently infringe third party patents or patent applications. These third parties could bring claims against us, our collaborators or our licensors that, even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. For example, some aspects of our Selective Amplification technology involve the use of antibodies, growth factors and other reagents that are, in certain cases, the subject of third party rights. We believe we have the rights to third party patents for use of all growth factors employed in manufacturing our current product candidates for preclinical and clinical testing, including licenses from Amgen for ex vivo use for SCF, G-CSF and Flt3-L and GlaxoSmithKline for TPO mimetic. The media in which we amplify the cells is available from several commercial sources. Before we commercialize any product utilizing this technology, including CB001, we may need to obtain additional license rights to use reagents from third parties not covered by these patents or licenses. If we are not able to obtain these rights on reasonable terms or redesign our Selective Amplification process to use other reagents, we may not be able to commercialize any products, including CB001. If we must redesign our Selective Amplification process to use other reagents, we may need to demonstrate comparability in subsequent clinical trials or be required to repeat earlier clinical trials, which would be costly and time consuming.

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 September 30, 2006, we have incurred total legal expenses of approximately \$7.3 million related to these cases. Depending upon the results of PharmaStem's appeal of the District Court's decision to overturn the jury verdict against us in this case, and the extent to which we are required to litigate the second lawsuit brought by PharmaStem and any related appeals, we estimate that we could incur at least an additional \$1.0 million to \$5.0 million in litigation expenses.

In addition to the two PharmaStem patent infringement lawsuits we are contesting, we are aware that PharmaStem owns an additional patent, U.S. Patent No. 6,605,275, in the umbilical cord blood preservation field, which is the field in which we currently do business with our ViaCord service offering and potentially might relate to our CB001 product candidate, if approved and commercialized. This patent expires in 2010. We are also aware of two patents relating to compositions of purified hematopoietic stem cells and their use in hematopoietic stem cell transplantation, which could impact our stem cell therapeutics business. We believe, based on advice of our patent counsel, that we do not infringe any valid claims of this additional PharmaStem patent or of these two other patents. We cannot state with assurance, however, that if we are sued on any of these patents we would prevail. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed

by issued patents. If we are found to infringe these patents and are not able to obtain a license, we may not be able to operate our business.

**Table of Contents**

Any successful infringement action brought against us may also adversely affect marketing of the infringing product in other markets not covered by the infringement action, as well as our marketing of other products by us based on similar technology and may also delay the regulatory approval process for future product candidates. Furthermore, we may suffer adverse consequences from a successful infringement action against us even if the action is subsequently reversed on appeal, nullified through another action or resolved by settlement with the patent holder. The damages or other remedies awarded, if any, may be significant. As a result, any infringement action against us may harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

***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. For example, our agreement with Mothers Work, Inc. related to the marketing of our ViaCord service offering is subject to termination by either party under various specified circumstances. In addition, either party can terminate the agreement 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. Such a claim has been commenced against Mothers Work in an arbitration proceeding. We anticipate a decision in the dispute between Mothers Work and such third party in the fourth quarter of 2006. There is, however, no assurance that the dispute between Mothers Work and the third party will be resolved in a timely fashion. There is also no assurance that Mothers Work will be successful in its dispute with the third party, or that the termination rights under the agreement between us and Mothers Work will not be triggered, or that the agreement will not be terminated.

***The Government of Singapore may seek to recover grant funds received by the Company if we do not agree to extend the term of the current grant.***

We record revenues from a grant agreement with the Economic Development Board (EDB) of the Government of Singapore related to our research facility in Singapore. Government grants are routinely subject to review. We are in discussions with the EDB regarding expectations of potential future activity upon conclusion of the current grant, which expires in May 2007. In discussing whether or not we would agree to extend the grant, the EDB has suggested that a prior period increase in the EDB's cost reimbursement percentage constituted an advance on future grant funding. We, however, believe that the increase constituted a mutually agreed upon increase in the reimbursement percentage for the period, after which the reimbursement rate was to revert to the rate prior to such increase. The amount received by us under the increased reimbursement percentage was approximately \$0.9 million. The EDB has proposed that the issue be resolved through an extension of the grant term during which the EDB would continue the grant but at a lower cost reimbursement rate. If we choose not to extend the grant, we believe that the EDB may also assert that we have not fulfilled a commitment to employ a specified number of people in Singapore that was an original condition of the grant. Under the terms of the grant, a breach by us of a condition of the grant could result in the EDB pursuing repayment of some or all of the amounts disbursed to us. We believe that the EDB has waived this commitment, and that, as a result, we have satisfied all requirements under the grant. While there is no assurance that, if we do not agree to extend the grant term, EDB will not seek to recover grant funds previously paid and/or withhold payment of existing or future grant claims that are as yet unpaid, we believe we have met our performance obligations

and would be successful in our defense of any such claims. As of September 30, 2006, we had received grant payments from EDB totaling approximately \$1.9 million and had recognized cumulative grant revenues of approximately \$1.9 million.

**Table of Contents**

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

*Cord blood preservation.* The FDA has adopted good tissue practice, or GTP, regulations that establish a comprehensive regulatory program for human cellular and tissue-based products. Our ViaCord service offering is subject to GTP regulations. We have registered with the FDA as an umbilical cord blood preservation service, listed our products with the FDA, and we are subject to FDA inspection. We believe that we comply with the new GTP regulations as adopted, though we have not yet been inspected by the FDA. However, we may not be able to maintain this compliance or comply with future regulatory requirements that may be imposed on us, including product standards that may be developed. Moreover, the cost of compliance with government regulations may adversely affect our revenue and profitability. Regulation of our cord blood preservation services in foreign jurisdictions is still evolving.

Consistent with industry practice, the ViaCord collection kits have not been cleared as a medical device. The FDA could at any time require us to obtain PMA or 510(k) clearance for the collection kits, or new drug application (NDA) approval for a drug component of the kits or to file an Investigational New Drug Application (IND) or Biologics License Application (BLA), and seek approval for the cell product. Securing any necessary medical device 510(k) clearance or PMA for the cord blood collection kits, or NDA approval for a drug component of the kits or BLA, would likely involve the submission of a substantial amount of data and may require a lengthy substantive review. The FDA also could require that we cease distributing the collection kits and require us to obtain medical device 510(k) clearance or PMA for the kits or NDA approval of a drug component of the kits or BLA approval prior to further distribution of the kits.

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

*Oocyte cryopreservation.* There are no established precedents for U.S. and international regulation of oocyte cryopreservation. The FDA has informed us that it will require a clinical study to support approval of the technology used in oocyte cryopreservation. In June 2006, the FDA gave us conditional approval of an IDE to allow our ViaCyte cryopreservation product offering to be used in a clinical trial. 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. We are currently working to submit additional information related to the clinical trial to a central IRB that represents several of our possible clinical trial sites after an initial disapproval by this IRB of our submission. We addressed similar issues with the FDA prior to our IDE approval. If we are able to gain IRB approval, which we believe we will, we expect the trial will commence in the first quarter of 2007. There is no assurance that we will be able to gain the approval of IRBs for the clinical trial or that, if the trial is approved by the requisite IRBs and ultimately completed, we will be able to show that our ViaCyte cryopreservation product candidate is safe and effective for its intended use. 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 this product candidate. We cannot assure you that this product candidate will receive either 510(k) clearance or PMA. We believe that the time to conduct a clinical study, prepare a new 510(k), and receive FDA clearance for our oocyte cryopreservation product candidate will take several years. We have not investigated the regulations for the cryopreservation of oocytes in foreign jurisdictions. There is no assurance that we will ever be able to generate sufficient data to receive approval to market technology for the cryopreservation of oocytes.

***We have only limited experience manufacturing cell therapy product candidates, and we may not be able to manufacture our product candidates in quantities sufficient for clinical studies or for commercial scale.***

We currently produce limited quantities of stem cells using our Selective Amplification and USSC technologies. We have not built commercial scale manufacturing facilities, and have no experience in manufacturing cellular products in the volumes that will be required for later stage clinical studies or commercialization. If we



**Table of Contents**

successfully obtain marketing approval for any products, we may not be able to produce sufficient quantities of our products at an acceptable cost. Commercial-scale production of therapies made from live human cells involves production in small batches and management of complex logistics. Cellular therapies are inherently more difficult to manufacture at commercial-scale than chemical pharmaceuticals, which are manufactured using standardized production technologies and operational methods. We may encounter difficulties in production due to, among other things, quality control, quality assurance and component supply. These difficulties could reduce sales of our products, increase our cost or cause production delays, all of which could damage our reputation and hurt our profitability.

***We are dependent on our existing suppliers and establishing relationships with certain other suppliers to successfully commercialize our ViaCord service offering, for certain components of our product candidates and to manufacture and supply ViaCyte. The loss of such suppliers or our inability to establish such relationships may inhibit our ability to commercialize ViaCord, delay development or limit our ability to manufacture our stem cell therapy products or our ViaCyte product candidate.***

In order to produce cells for use in clinical studies and produce stem cell products for commercial sale, certain biological components used in our production process will need to be manufactured in compliance with current good manufacturing practices, or cGMP. To meet this requirement, we will need to maintain supply agreements with third parties who manufacture these components to cGMP standards. Once we engage these third parties, we may be dependent on them for supply of cGMP grade components. If we are unable to obtain cGMP grade biological components for our product candidates, we may not be able to market our stem cell product candidates.

Certain antibodies, growth factors and other reagents are critical components used in our stem cell production process. Our Selective Amplification process currently uses components sold to us by certain manufacturers, and we need to establish relationships with other suppliers to manufacture cGMP grade products for commercial sale. We are dependent on our suppliers for such components as SCF, Flt3-L, TPO mimetic and cGMP grade antibodies conjugated with magnetic particles. Some of these components are currently supplied to us by Amgen and Miltenyi Biotec, who are currently single-source suppliers. Other components, such as research grade materials that are suitable for production of stem cells used for research and in Phase 1 human clinical studies, are purchased as catalog products from vendors, such as StemCell Technologies and R&D Systems, with whom we do not have relationships. In order to continue our clinical trials and commercialize our Selective Amplification product candidates, we will need to establish relationships with some of these suppliers. In the event that our suppliers are unable or unwilling to produce such components on commercially reasonable terms, and we are unable to find substitute suppliers for such components, we may not be able to commercialize our stem cell product candidates. We depend on our suppliers to perform their obligations in a timely manner and in accordance with applicable government regulations. In the event that any of these suppliers becomes unwilling or unable to continue to supply necessary components for the manufacture of our stem cell products, we will need to repeat certain development work to identify and demonstrate the equivalence of alternative components purchased from other suppliers. If we are unable to demonstrate the equivalence of alternative components in a timely manner, or purchase these alternative components on commercially reasonable terms, development of our product candidates may be delayed and we may not be able to complete development of or market our stem cell product candidates.

We will utilize contract manufacturers to manufacture, supply and package our ViaCyte product candidate. We will be dependent on these manufacturers and relationships to satisfy all regulatory requirements and produce sufficient amounts of cGMP-quality product on commercially reasonable terms. 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 we encounter unexpected manufacturing hurdles or delays, we may not be able to develop or commercialize our ViaCyte product candidate.

We also 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 the ViaCord collection kits are produced by single source providers. We make every effort to qualify new vendors and

to develop contingency plans so that our ViaCord business is not impacted by short-term



**Table of Contents**

issues associated with single source providers. Nonetheless, our business could be materially impacted by long-term or chronic issues associated with single source providers.

***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. Depending on the extent of loss, such an event could reduce our ability to provide cord blood stem cells when requested, could expose us to significant liability from our cord blood banking customers and could affect our ability to continue to provide umbilical cord blood preservation services.

In September 2006, we completed validation of our manufacturing facility in Cambridge, Massachusetts and transferred substantially all of our manufacturing operations to the Cambridge facility from our former clinical manufacturing facility in Worcester, Massachusetts. We expect to manufacture all of our stem cell product candidates in the Cambridge facility for the next several years. If the Cambridge facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. In the event of a temporary or protracted loss of this facility or equipment, we may be able to transfer manufacturing to a third party, but the shift would likely be expensive, and the timing would depend on availability of third party resources and the speed with which we could have a new facility approved by the FDA.

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

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

The private umbilical cord banking business is highly competitive. In private umbilical cord blood banking, we compete with companies such as Cbr Systems, Cryo-Cell International, Inc., CorCell, Inc., which was recently acquired by 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 approximately 50 other cord blood banks around the world. Public cord blood banks provide families with the option of donating their cord blood for public use. There is no cost to donate and, as public banks grow in size and increase in diversity, the probability of finding suitably matched cells for a family member may increase, which may result in a decrease in demand for private cord blood banking. 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 could diminish the demand by families for private umbilical 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, Cellerant Therapeutics, Inc., Celgene Corporation, Cytori Therapeutics,

**Table of Contents**

Inc., Gamida-Cell, Genzyme Corporation, Bioheart, Inc., and Osiris Therapeutics, Inc. We also face competition in the cell therapy field from academic institutions and governmental agencies. We are also aware that some larger pharmaceutical and biopharmaceutical companies have programs in the cell therapy area. Some of these competitors, and future competitors, may have similar or better product candidates or technologies, greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities. In addition, public cord blood banks may, as a result of a recent legislative initiative, be able to better compete with our potential cell therapy products, such as CB001. An increase in the number and diversity of publicly-available cord blood units from public banks could diminish the necessity for cord blood-derived therapeutics produced with our Selective Amplification technology.

In oocyte cryopreservation, if our ViaCyte product candidate is successfully developed and approved, we expect to compete with IVF centers and individual companies offering oocyte cryopreservation, including Extend Fertility. Current and future competitors in this field, too, may have greater financial and human resources than we have, and may have similar or better product candidates or technologies, or product candidates which are brought to the market more quickly than ours. Specifically, several IVF centers are already performing oocyte cryopreservation on a limited basis and Extend Fertility is offering related services, which may make it more difficult for us to establish our product candidate or achieve a significant market share.

We anticipate this competition to increase in the future as new companies enter the stem cell therapy, cord blood preservation and oocyte cryopreservation markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our product candidates obsolete.

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

Our reputation among clients and the medical and birthing services community is extremely important to the commercial success of our ViaCord 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 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



**Table of Contents**

terms or at all. If we are unable to obtain insurance or any claims against us substantially exceed our coverage, then our business could be adversely impacted.

***If we are not able to recruit and retain qualified management and other personnel, we may fail in developing our technologies and product candidates.***

Our success is highly dependent on the retention of the principal members of our scientific, management and sales personnel. Marc D. Beer, our President and Chief Executive Officer, is critical to our ability to execute our overall business strategy. Morey Kraus, our Chief Technology Officer and co-founder, is a co-inventor of our Selective Amplification technology and has significant and unique expertise in stem cell expansion and related technologies. We maintain key man life insurance on the lives of Marc D. Beer and Morey Kraus. Additionally, we have several other employees with scientific or other skills that we consider important to the successful development of our technology. Any of our key employees could terminate his or her relationship with us at any time and, despite any non-competition agreement with us, work for one of our competitors. Furthermore, our future growth will require hiring a significant number of qualified technical, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success.

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

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

We expect to continue expanding our reproductive health business and our research and development activities. This expansion could put significant strain on our management, operational and financial resources. To manage future growth, we would need to hire, train and manage additional employees.

We completed our initial public offering in January 2005. 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 additional demands on our finance and accounting staff, on our financial, accounting and information systems and on our internal controls. We have increased the number of our accounting and finance personnel and have taken steps to proactively monitor our networks and to improve our financial, accounting and information systems and internal controls in order to fulfill our responsibilities as a public company and to support growth in our business. We cannot assure you that our current and planned personnel, systems procedures and controls will be adequate to support our anticipated growth or that management will be able to hire, train, retain, motivate and manage required personnel.

Our failure to manage growth effectively could limit our ability to achieve our research and development and commercialization goals or to satisfy our reporting and other obligations as a public company.

***If we acquire other businesses or technologies the transactions may be dilutive and we may be unable to integrate them successfully with our business, our financial performance could suffer.***

If we are presented with appropriate opportunities, we may acquire other businesses. We have had limited experience in acquiring and integrating other businesses. Since our incorporation in 1994, we have acquired three businesses: ViaCord in 2000, Cerebrotec, Inc. in 2001 and Kourion Therapeutics AG in 2003. The integration process following any future acquisitions may produce unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. 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.

**Table of Contents*****The successful commercialization of our potential cell therapy products will depend on patients and physicians obtaining reimbursement for use of these product candidates 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.

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. However, if our potential cell therapy products are not reimbursed by the government or third party insurers, the market for those products would be limited. We cannot be sure that third party payers will reimburse sales of a product or enable us or our partners to sell the product at prices that will provide a sustainable and profitable revenue stream.

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

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

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

**Table of Contents**

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

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

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

We have facilities in Massachusetts, Kentucky, and Singapore that are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. In the U.S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these regulations, we cannot assure you that accidental contamination or injury to employees and third parties from these materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

***Volatility of Our Stock Price***

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

material public announcements;

the data, positive or negative, generated from the development of our product candidates;

setbacks or delays in any of our development programs;

the outcome of material litigation;

the financial results achieved by our cord blood preservation business;

the impact of competition;

unusual or unexpectedly high expenses;

developments related to patents and other proprietary rights;

market trends affecting stock prices in our industry; and

economic or other external factors.

**Table of Contents**

**ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds**

**Sales of Unregistered Securities**

None.

**Use of Proceeds from Registered Securities**

We registered shares of our common stock in connection with our initial public offering ( IPO ) under the Securities Act of 1933. Our Registration Statement on Form S-1 (Reg. No. 333-114209) in connection with the IPO was declared effective by the SEC on January 19, 2005. The IPO commenced as of January 20, 2005. 8,625,000 shares of our common stock registered were sold in the IPO. The IPO did not terminate before any securities were sold. We completed the IPO on January 26, 2005. Credit Suisse and UBS Investment Bank were the managing underwriters.

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

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

**ITEM 3. Defaults Upon Senior Securities**

None.

**ITEM 4. Submission of Matters to a Vote of Security Holders**

None.

**ITEM 5. Other Information**

None.

**ITEM 6. Exhibits**

See the Exhibit Index following the Signatures page below.

**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.

November 14, 2006

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

November 14, 2006

/s/ Stephen G. Dance  
Stephen G. Dance  
Chief Financial Officer  
*(Principal Financial Officer)*  
43

---



**Table of Contents**

**Exhibit Index**

- 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