# SECURITIES AND EXCHANGE COMMISSION

# FORM 8-K

Current report filing

Filing Date: **2006-08-03** | Period of Report: **2006-08-03** | SEC Accession No. 0000950135-06-004708

(HTML Version on secdatabase.com)

# **FILER**

**VIACELL INC** 

CIK:1114529| IRS No.: 043244816

Type: 8-K | Act: 34 | File No.: 000-51110 | Film No.: 061000055

SIC: 8731 Commercial physical & biological research

Mailing Address 245 FIRST STREET CAMBRIDGE MA 02142 Business Address 245 FIRST STREET CAMBRIDGE MA 02142 617-914-3400

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM 8-K

# CURRENT REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): August 3, 2006

# VIACELL, INC.

(Exact name of registrant as specified in its charter)

Delaware		000-51110	04-3244816	
(State or other jurisdiction of		(Commission	(I.R.S. Employer	
	of incorporation or organization)	File Number)	Identification No.)	
	(Add	First Street, Cambridge, Massachusetts 0214 ress of Principal Executive Offices) (Zip Coctelephone number, including area code: (617	de)	
	k the appropriate box below if the Form 8-K is blowing provisions (see General Instruction A		ne filing obligation of the registrant under any of	
	Written communications pursuant to Rule 42	25 under the Securities Act (17 CFR 230.425	)	
	Soliciting material pursuant to Rule 14a-12 u	under the Exchange Act (17 CFR 240.14a-12		
	Pre-commencement communications pursuan	nt to Rule 14d-2(b) under the Exchange Act	(17 CFR 240.14d-2(b))	
	Pre-commencement communications pursual	nt to Rule 13e-4(c) under the Exchange Act (	(17 CFR 240.13e-4(c))	
<u> </u>	Pre-commencement communications pursuan	nt to Rule 13e-4(c) under the Exchange Act (	(17 CFR 240.13e-4(c))	

# **TABLE OF CONTENTS**

<u>Item 2.02. Results of Operations and Financial Condition</u> <u>Item 9.01 Financial Statements and Exhibits</u> <u>SIGNATURE</u>

**EXHIBIT LIST** 

Ex-99.1 Press release dated August 3, 2006

#### **Table of Contents**

#### Item 2.02. Results of Operations and Financial Condition

On August 3, 2006, ViaCell, Inc. issued a press release relating to its results of operations and financial condition for the second quarter of 2006. The press release attached as Exhibit 99.1 includes information with respect to ViaCell's proforma basic and diluted net loss per common share in the first six months of 2005. These are non-GAAP financial measures. Management believes that these non-GAAP financial measures are useful because they exclude those non-operational activities or transactions that are not necessarily relevant to understanding the trends of the Company or the prospects of future performance. Management uses these non-GAAP financial measures to establish operational goals and believes that they may assist investors in analyzing the underlying trends in the Company's business over time. The presentation of this information is not meant to be considered in isolation or as a substitute for GAAP financial measures.

The information furnished herewith pursuant to Item 2.02 of this Current Report shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 - Press release issued by ViaCell, Inc. dated August 3, 2006.

# **Table of Contents**

## **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIACELL, INC.

Date: August 3, 2006 By: /s/ Stephen Dance

Name: Stephen Dance

Title: Senior Vice President, Finance and

Chief Financial Officer

# **Table of Contents**

# **EXHIBIT LIST**

99.1 Press release issued by ViaCell, Inc. dated August 3, 2006

#### For More Information Contact:

Justine E. Koenigsberg Senior Director, Corporate Communications (617) 914-3494

#### FOR IMMEDIATE RELEASE

### ViaCell Reports Second Quarter 2006 Financial Results

Cambridge, MA (August 3, 2006) – ViaCell, Inc. (Nasdaq: VIAC) today announced its consolidated financial results for the second quarter ended June 30, 2006.

Total revenues were \$13.5 million for the second quarter of 2006 compared to \$11.4 million for the same period in 2005. Sales of ViaCord®, ViaCell's product for the preservation of umbilical cord blood, generated revenues of \$13.4 million in the second quarter of 2006, representing a 19 percent increase over the \$11.2 million of revenues in the same period in 2005.

"This quarter we completed our planned commercial expansion and, coupled with other initiatives, we expect that this will support a further acceleration of ViaCord sales growth," said Marc D. Beer, President and Chief Executive Officer. "We have built a highly leverageable commercial organization focused on obstetricians and gynecologists that we hope will support an expanded product line in the future including ViaCyte(SM), our investigational product for oocyte cryopreservation, if we are successful in our development efforts. We have satisfied all the FDA requirements to begin the ViaCyte pivotal trial and expect enrollment to begin in late 2006."

Total operating expenses in the second quarter of 2006 were \$21.2 million compared to \$14.9 million for the same period in 2005.

Research and development expenses for the second quarter of 2006 were \$3.7 million compared to research and development expenses of \$3.1 million for the second quarter of 2005, reflecting ongoing clinical and preclinical testing of ViaCell's programs for cancer, cardiac disease, and diabetes.

Sales and marketing expenses for the second quarter of 2006 were \$10.0 million compared to sales and marketing expenses of \$6.1 million in the second quarter of 2005. The higher sales and marketing expenses were a result of increased spending on ViaCord sales and marketing, including an expansion of the ViaCord sales force, which was completed in the first half of 2006.

General and administrative expenses for the second quarter of 2006 were \$5.0 million compared to \$3.6 million in the second quarter of 2005. The increase in general and administrative expenses was primarily a result of costs associated with being a publicly traded company.

The net loss attributable to common stockholders for the second quarter of 2006 was \$6.9 million, or \$0.18 per share, compared to a net loss attributable to common stockholders of \$3.1 million, or \$0.08 per share, for the corresponding period in 2005.

As of June 30, 2006, ViaCell had \$56.7 million in cash, cash equivalents, and investments as compared to \$58.0 million at March 31, 2006 and \$60.5 million as of December 31, 2005.

- more -

ViaCell Reports Second Quarter 2006 Results, Page 2

As previously communicated, the Company expects ViaCord sales growth of greater than 20 percent in 2006 compared to 2005, with higher growth in the second half of the year than in this first half, compared to corresponding prior periods. In addition, the Company increased its sales and marketing expenses in the first half of the year to drive sales growth and believes the sales and marketing expenses in the second quarter of 2006 provide a reasonable approximation for sales and marketing expenses in the third and fourth quarters of 2006. Consequently, the Company expects net loss per share in 2006 to be in the range of \$0.56 to \$0.59 per share before charges for stock-based compensation expense. The Company estimates that charges for stock-based compensation will be \$0.08 to \$0.09 per share for the year, resulting in an expected GAAP-based net loss per share in 2006 of \$0.64 to \$0.68 per share.

#### Highlights

ViaCell achieved several milestones related to its ViaCord business and the advancement of its pipeline. The following is a summary of selected highlights.

*ViaCord sales force expansion.* ViaCell completed its commercial expansion in the second quarter of 2006. The expanded sales force, coupled with other sales and marketing initiatives, is intended to support an acceleration of ViaCord sales growth in the second half of 2006. In addition, ViaCell expanded its management team in the second quarter with the appointment of Jim Corbett to the position of President, ViaCell Reproductive Health. The Company also achieved a significant milestone in passing the 100,000 customer mark during the second quarter.

*Launch of first FDA-approved collection bag*. As part of its initiative to differentiate its ViaCord product offering, ViaCell launched the first FDA-approved sterile field collection bag, Cell Sentinel™, as part of the ViaCord collection kit during the second quarter of 2006. Pall Corporation and ViaCell collaborated on the development and design of the new collection bag.

Agreement with CHORI to expand cord blood program. In May 2006, ViaCell signed an agreement with Children's Hospital Oakland Research Institute (CHORI) to combine the companies' directed transplant programs for sibling donor cord blood. ViaCell believes the combined programs establish it as a leading provider of related cord blood stem cells for directed transplantation. In addition, the Company reported patient outcomes for transplants from 19 cord blood units at a scientific conference in May. The data compare favorably with reports of unrelated cord blood transplantation.

*Enrollment in ViaCyte pivotal trial expected to begin in late 2006.* In June 2006, ViaCell received conditional approval from the FDA to begin enrolling patients in the pivotal clinical trial for ViaCyte. ViaCell has responded to the FDA and satisfied all requests required to begin the ViaCyte pivotal trial. The Company expects to begin enrollment in the trial in late 2006.

**CB001 Phase I study completed.** In July 2006, ViaCell completed enrollment and treatment in the ten person CB001 Phase 1 study. CB001 is being studied for hematopoietic stem cell transplantation for the treatment of a variety of cancers. Following the 100-day post transplant follow up, ViaCell expects to complete the analysis of the study data and report top-line data by the end of 2006.

Cardiac agreement with Centocor. In June 2006, ViaCell entered into a research collaboration with Centocor Research and Development to evaluate, in preclinical studies, ViaCell's cord blood-derived multi-potent stem cells delivered using Cordis Corporation's NOGA XP delivery system as a potential treatment for cardiac disease. If the preclinical data support further development, ViaCell expects to file an Investigational New Drug Application in 2007.



ViaCell Reports Second Quarter 2006 Results, Page 3

#### **Conference Call and Webcast**

ViaCell will host a conference call and live audio webcast with investment analysts today, August 3, 2006, at 10:00 a.m. Eastern Time to discuss its second quarter financial results. To participate by telephone, dial (913) 981-5550. A live audio webcast can be accessed on the ViaCell web site at <a href="http://www.viacellinc.com">http://www.viacellinc.com</a> within the Investor Information section.

A replay of this conference call will be available for two weeks, beginning August 3, 2006 at 1:00 p.m. Eastern Time by dialing (719) 457-0820 and using the access code 7231484. In addition, a replay of the webcast will be archived on the ViaCell website in the Investor Information section.

### About ViaCell, Inc.

ViaCell is a biotechnology company focused on enabling the widespread use of human cells as medicine. The Company is developing a pipeline of proprietary stem cell product candidates intended to address cancer, cardiac disease, and diabetes. CB001, its lead cord blood derived stem cell therapy product candidate, is being developed for hematopoietic stem cell transplantation in patients affected by a variety of cancers. In addition to its therapeutic development programs, ViaCell's reproductive health business commercializes ViaCord®, a product that offers expecting families the option of preserving their baby's umbilical cord blood. The Company is working to leverage its commercial infrastructure and product development capabilities by developing ViaCyteSM, its investigational product offering intended to broaden reproductive choices for women through the cryopreservation of human unfertilized eggs. ViaCell is headquartered in Cambridge, Massachusetts with a processing and storage facility in Kentucky and additional research and development operations in Singapore. Additional information about ViaCell is available online at http://www.viacellinc.com.

This press release contains forward-looking statements regarding the Company's financial outlook, including the potential for growth in the ViaCord business, the level of sales and marketing expenses and estimated net loss per share, the potential for new products and plans for its development programs. These statements are based on management's current expectations, and are subject to a number of risks and uncertainties that could cause actual results to differ materially from the Company's current expectations. For example, the Company's financial performance and its ability to achieve its expectations for growth and stated financial goals may be negatively affected by the impact of competition in the umbilical cord preservation industry, the impact of any potential adverse outcome in pending patent infringement litigation related to the cord blood preservation business, any unexpected material issues, delays or failures in the collection, processing or storage of umbilical cord blood by the Company or others in the industry, and by the fluctuations in the level and timing of expenses as a result of difficulties or delays in the development of the Company's product candidates or in connection with licensing deals or collaborations, and any other unexpected expenses or costs. The development of product candidates and product offerings like those being developed by ViaCell involve a high degree of risk. The success of the Company's development programs and the potential for new products could be negatively impacted by a number of factors, including new data regarding the safety or efficacy of the Company's product candidates or offerings, unexpected delays, technical or intellectual property hurdles, or unexpected concerns or requirements raised by regulatory authorities. The Company's long-term financial performance and growth is dependent on the Company's ability to bring new products to the marketplace. Currently, the Company's product candidates are at an early stage of development. There can be no assurance that the Company will be successful in its efforts to develop these or other products. For more detailed information on the risks and uncertainties associated with these forward looking statements and the Company's other activities, see the periodic reports filed by the Company with the Securities and Exchange Commission. The Company does not undertake any obligation to publicly update any forwardlooking statements, whether as a result of new information, future events, or otherwise.

- Financial Tables to Follow -

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Processing and storage revenues	\$13,362	\$11,188	\$25,299	\$21,163
Grant revenues	177	195	320	360
Total revenues	13,539	11,383	25,619	21,523
Operating expenses:				
Cost of processing and storage revenues	2,536	2,028	4,864	3,981
Research and development	3,660	3,116	7,126	6,762
Sales and marketing	9,995	6,076	17,916	11,645
General and administrative	5,013	3,588	9,650	6,635
Restructuring	0	90	(180 )	211
Total operating expenses (Note 1)	21,204	14,898	39,376	29,234
Loss from operations	(7,665)	(3,515)	(13,757)	(7,711)
Interest income (expense):				
Interest income	803	458	1,527	773
Interest expense	<u>(17</u> )	(38 )	(43 )	(193)
Total interest income, net	786	420	1,484	580
Loss from operations before cumulative effect of change in accounting principle	(6,879)	(3,095)	(12,273)	(7,131)
Cumulative effect of change in accounting principle (Note 2)	_	_	283	_
Net loss	(6,879)	(3,095)	(11,990)	(7,131)
Accretion on redeemable convertible preferred stock				987
Net loss attributable to common stockholders	\$(6,879)	\$(3,095)	\$(11,990)	\$(8,118)
Net loss per share:				
Net loss per common share, basic and diluted	\$(0.18)	\$(0.08)	\$(0.31)	\$(0.24)
Weighted average shares used in basic and diluted net loss per share computation	38,367	37,526	38,329	33,261
Pro forma net loss per common share, basic and diluted (Note 3)	\$(0.18)	\$(0.08)	\$(0.31)	\$(0.20)
Weighted average shares used in pro forma basic and diluted net loss per share computation	38,367	37,526	38,329	36,398

Note 1: The following table presents share-based compensation expense for continuing operations included in the Company's unaudited consolidated statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Cost of processing and storage revenues	\$17	\$5	\$32	\$10
Research and development	136	90	240	160
Sales and marketing	70	42	127	120
General and administrative	597	221	1,132	504
Total stock-based compensation expense	\$820	\$358	\$1,531	\$794

Note 2: The requirement of Statement of Financial Accounting Standards No. 123R (FAS 123R) to estimate future forfeitures resulted in a cumulative benefit of \$283,000 in the three months ended March 31, 2006 from the adoption of FAS 123R related to estimating forfeitures rather than recording the benefit of the forfeitures as they occur.

### ViaCell Reports Second Quarter 2006 Results, Page 5

Note 3: The non-GAAP financial measure of pro forma basic and diluted net loss per common share presented below for the six months ended June 30, 2005 is utilized by ViaCell's management to gain an understanding of the comparative financial performance of the Company. Management believes that this non-GAAP financial measure is useful because it includes all outstanding shares of the Company, whether common or preferred, in the calculation of basic and diluted earnings per share. The presentation of this information is not meant to be considered in isolation or as a substitute for GAAP financial measures. Pro forma disclosure assumes all convertible preferred shares were considered as outstanding common stock and no related accretion was recorded during both periods reported.

Reconciliation of GAAP Basic and Diluted Net Loss Per Common Share to Pro Forma Basic and Diluted Net Loss Per Common Share (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net loss attributable to common stockholders	\$(6,879)	\$(3,095)	\$(11,990)	\$(8,118)
Accretion on redeemable convertible preferred stock				987
Pro forma net loss attributable to common stockholders	\$(6,879)	\$(3,095)	\$(11,990)	\$(7,131)
Weighted average shares used in basic and diluted net loss per share calculation	38,367	37,526	38,329	33,261
Increase in weighted average common shares outstanding assuming conversion of preferred stock at January 1		_	_	3,137
Weighted average shares used in pro forma basic and diluted net loss per share calculation	38,367	37,526	38,329	36,398

## Condensed Consolidated Balance Sheet Data (in thousands) (unaudited)

	June 30, 2006	December 31, 2005
Cash, cash equivalents and investments	\$56,688	\$ 60,544
Accounts receivable, net	11,876	13,736
Other current assets	3,377	2,841
Property & equipment, net	8,877	8,702
Intangible assets	6,343	6,444
Other assets	1,975	1,963
Total assets	\$89,136	\$ 94,230
Current liabilities	19,793	16,175
Deferred revenue & rent	15,808	13,806
Contingent purchase price	8,155	8,155
Long-term debt	53	84
Stockholders' equity	45,327	56,010
Total liabilities and stockholders' equity	\$89,136	\$ 94,230

ViaCell® and ViaCord® are federally registered trademarks, Cell Sentinel™ is a trademark and ViaCyteSM is a service mark of ViaCell, Inc.