Fibrocell Science, Inc. Form 10-Q May 19, 2014 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2014

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Fibrocell Science, Inc.

(Exact name of registrant as specified in its Charter.)

**Delaware** (State or other jurisdiction of incorporation)

001-31564 (Commission File Number) **87-0458888** (I.R.S. Employer Identification No.)

# Edgar Filing: Fibrocell Science, Inc. - Form 10-Q 405 Eagleview Boulevard

## Exton, Pennsylvania 19341

(Address of principal executive offices, including zip code)

#### (484) 713-6000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for any 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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer o Accelerated filer x Non-accelerated filer o Smaller reporting company "
(Do not check if a smaller reporting company)

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes x No o

As of May 12, 2014, issuer had 40,856,815 shares issued and outstanding of common stock, par value \$0.001.

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## **Explanatory Note**

In this Quarterly Report on Form 10-Q for the three months ended March 31, 2014 ( Quarterly Report ), we are restating our previously issued consolidated financial statements and the related disclosures as of December 31, 2013 and the previously issued consolidated financial statements for the quarterly period ended March 31, 2013 (collectively, the Restated Periods ). As discussed in further detail below and in Note 3 to the accompanying consolidated financial statements, the restatement is the result of a misapplication in the guidance on accounting for Warrants (as defined below). We assessed the impact of this misapplication on our prior interim and annual financial statements and concluded that the combined impact was material to these financial statements. Consequently, we have restated the prior period financial statements identified above. All amounts in this Quarterly Report affected by the restatement adjustments reflect such amounts as restated including the Consolidated Balance Sheet as of December 31, 2013 and the unaudited interim financial information for the quarter ended March 31, 2013. In addition, the following items of this Quarterly Report include restated financial data: (i) Part I, Item 1: Financial Statements; and (ii) Part I, Item 2: Management s Discussion and Analysis of Financial Condition and Results of Operations.

For a more detailed explanation of these matters and resulting restatements, please see Part I, Item 1: Financial Statements — Note 3 and Note 6 to the Consolidated Financial Statements and Part I, Item 2: Management s Discussion and Analysis of Financial Condition and Results of Operations — Restatement of Previously Issued Consolidated Financial Statements.

In addition, we will be amending our previously filed 2013 Annual Report on Form 10-K, to include the years ended December 31, 2013, December 31, 2012 and December 31, 2011, all quarterly periods of 2013 and 2012 and the quarterly period ending September 30, 2011, as they were affected by the restatement discussed above.

## **Background of Restatement**

On May 6, 2014, the Audit Committee of the Company s Board of Directors (the Audit Committee), in connection with an internal review initiated by Company management, concluded that, because of a misapplication of the accounting guidance related to certain of the Company s warrants, the Company s previously issued consolidated financial statements for all periods beginning with the quarterly period ended September 30, 2011 through December 31, 2013 (collectively, the Affected Periods) should no longer be relied upon. As such, the Company anticipates it will restate its financial statements for the following periods: (i) the years ended December 31, 2013, December 31, 2012 and December 31, 2011, (ii) all quarterly periods of 2013 and 2012 and (iii) the quarterly period ending September 30, 2011. However, these restatements result in non-cash, non-operating financial statement corrections and will have no impact on the Company s current or previously reported cash position, operating expenses or total operating, investing or financing cash flows, and net operating loss carryforward.

The warrants at issue (collectively, the Warrants ) consist of the following as of March 31, 2014:

1. warrants to purchase an aggregate of 15,080 shares of common stock, issued on October 13, 2009 at an exercise price of \$6.25 per share issued to placement agents;

- 2. Series A, class A warrants to purchase 115,440 shares of common stock, issued on October 13, 2009 at an exercise price of \$6.25 per share;
- 3. Series A, class B warrants to purchase 130,004 shares of common stock, issued on October 13, 2009 at an exercise price of \$6.25 per share;
- 4. warrants to purchase an aggregate of 393,416 shares of common stock, issued on March 4, 2010 at an exercise price of \$6.25 per share;
- 5. warrants to purchase 6,113 shares of common stock, issued on June 16, 2011 at an exercise price of \$22.50 per share issued to placement agents;
- 6. warrants to purchase 50,123 shares of common stock, issued on August 22, 2011 at an exercise price of \$13.635 per share issued to placement agents;
- 7. warrants to purchase 565,759 shares of common stock, issued on August 22, 2011 at an exercise price of \$18.75 per share;
- 8. warrants to purchase an aggregate of 1,125,578 shares of common stock, issued on June 1, 2012 at an exercise price of \$2.50 per share;
- 9. warrants to purchase an aggregate of 1,217,816 shares of common stock, issued on various dates in 2010 and 2011 at an exercise price of \$6.25 per share;
- 10. warrants to purchase an aggregate of 1,568,823 shares of common stock, issued on various dates in 2012 at an exercise price of \$7.50; and
- 11. warrants to purchase an aggregate of 768,778 shares of common stock, issued on various dates in 2010 at an exercise price of \$6.25.

The above warrant shares and exercise prices have been retroactively adjusted to reflect the April 30, 2013 reverse stock split.

Of the Warrants, approximately 5,335,000 were originally and correctly classified as liabilities on the Company s balance sheets. In connection with the Company s October 2012 financing and a contemporaneous modification of those Warrants to remove down-round anti-dilution protection, such Warrants were erroneously reclassified as a component of equity as opposed to liabilities on the consolidated balance sheets. The corresponding consolidated statements of operations did not include the subsequent non-cash

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changes in the estimated fair value of such Warrants. Those Warrants, however, continued to contain a cash settlement feature regarding fundamental transactions that allowed those Warrant holders to have a different settlement option than the Company s stockholders upon certain fundamental transactions, including a change of control of the Company, thereby precluding equity treatment for the Warrants. In the course of management s investigation, the Company also reviewed the Warrant agreements for approximately 622,000 Warrants that were originally classified as equity instruments upon their issuance. Those Warrants contained a similar fundamental transaction settlement provision that precluded equity treatment for such Warrants.

Based on Accounting Standards Codification 815, *Derivatives and Hedging* (ASC 815), warrant instruments that could potentially require net cash settlement in the absence of express language precluding such settlement and those which include down-round provisions should be initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. In periods subsequent to issuance, changes in the estimated fair value of the derivative instruments should be reported in the statement of operations. The Audit Committee, together with management, determined that the financial statements in the Affected Periods should be restated to reflect the Warrants as liabilities, with subsequent changes in their estimated fair value recorded as non-cash income or expense in each Affected Period.

The cumulative effect of these adjustments on our financial statements is a 15.2% decrease in the accumulated deficit in the amount of approximately \$15.6 million as of December 31, 2013. The restatement had no impact on net cash flows from operating, investing or financing activities as the adjustments resulting from the non-cash change in the fair value of the warrant liability for each period and the statements of operations only impacted net loss from continuing operations. In addition to the restatement noted above, the consolidated statements of operations and the consolidated balance sheets have also been retroactively adjusted to give effect to the Company s April 2013 reverse stock split. An explanation of the impact on our financial statements is contained in Note 3 to the consolidated financial statements contained in Part I, Item 1: Financial Statements.

#### **Restatement of Other Financial Statements**

The Company intends to include (i) restated financial information for the years ended December 31, 2013, December 31, 2012 and December 31, 2011 (ii) restated financial information for the quarterly periods in 2013 and 2012 and (iii) the quarterly period ending September 30, 2011 in the Company s Amendment No. 2 on Form 10-K/A for the year ended December 31, 2013 (the Amended 2013 10-K/A). As all material restatement information will be included in the Amended 10-K/A, the Company does not intend to amend any of its other previously filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q. The Company is presently anticipating filing the Amended 2013 10-K/A within the next two weeks, and in any event, on or before May 31, 2014.

#### **Internal Control Considerations**

Management has assessed the effect of the restatement on the Company s internal control over financial reporting and believes that this restatement represents a material weakness in its internal controls over financial reporting for all periods under restatement. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company s annual or interim consolidated financial statements will not be prevented or detected on a timely basis. For a discussion of management s consideration of the material weakness identified, see Part I, Item 4: Controls and Procedures included in this Quarterly Report.

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## PART I. FINANCIAL INFORMATION

## ITEM 1. Financial Statements.

## Fibrocell Science, Inc.

## **Consolidated Balance Sheets**

## (unaudited)

(\$ in thousands, except share and per share data)

	March 31, 2014	ī	(Restated) December 31, 2013
Assets			
Current assets:			
Cash and cash equivalents	\$ 54,001	\$	60,033
Accounts receivable, net of allowance for doubtful accounts of \$10 and \$5, respectively	58		28
Inventory	506		597
Prepaid expenses and other current assets	885		1,202
Total current assets	55,450		61,860
Property and equipment, net of accumulated depreciation of \$819 and \$735, respectively	1,696		1,701
Intangible assets, net of accumulated amortization of \$1,240 and \$1,102, respectively	5,100		5,238
Other assets	143		215
Total assets	\$ 62,389	\$	69,014
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	\$ 903	\$	2,958
Accrued expenses	1,371		487
Deferred revenue	149		148
Total current liabilities	2,423		3,593
Warrant liability	18,266		15,216
Other long term liabilities	586		539
Total liabilities	21,275		19,348
Stockholders equity:			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares outstanding			
Common stock, \$0.001 par value; 100,000,000 shares authorized; 40,856,815 and 39,832,225			
shares issued and outstanding, respectively	41		40
Additional paid-in capital	142,150		136,694
Accumulated deficit	(101,077)		(87,068)
Total stockholders equity	41,114		49,666
Total liabilities and stockholders equity	\$ 62,389	\$	69,014

## Fibrocell Science, Inc.

## **Consolidated Statements of Operations**

## (unaudited)

(\$ in thousands, except share and per share data)

	months ended rch 31, 2014	(Restated) Three months ended March 31, 2013
Revenue from product sales	\$ 46	\$ 26
Cost of sales	793	2,213
Gross loss	(747)	(2,187)
Selling, general and administrative expense	2,815	2,210
Research and development expense	7,438	1,507
Operating loss	(11,000)	(5,904)
Other income (expense):		
Warrant revaluation and other finance income (expense)	(3,050)	1,338
Other income	40	
Interest income	1	
Loss from continuing operations before income taxes	(14,009)	(4,566)
Deferred tax benefit		
Loss from continuing operations, net of tax	(14,009)	(4,566)
Loss from discontinued operations, net of tax		(4)
Net loss	\$ (14,009)	\$ (4,570)
Per share information:		
Loss from continuing operations, net of tax		
Basic	\$ (0.35)	\$ (0.17)
Diluted	\$ (0.35)	\$ (0.18)
Net loss		
Basic	\$ (0.35)	\$ (0.17)
Diluted	\$ (0.35)	\$ (0.18)
Weighted average number of basic common shares outstanding	40,583,591	26,229,909
Weighted average number of diluted common shares outstanding	40,583,591	26,631,980

## Fibrocell Science, Inc.

## 

## (unaudited)

(\$ in thousands, except share and per share data)

	Comm Shares	non Stoc	k Amount	Additional aid-in capital	A	Accumulated deficit	,	Fotal Equity (Deficit)
Balance, December 31, 2013 (Restated)	39,832,225	\$	40	\$ 136,694	\$	(87,068)	\$	49,666
Stock-based compensation expense				303				303
Issuance of common stock	1,024,590		1	5,153				5,154
Net loss						(14,009)		(14,009)
Balance, March 31, 2014	40,856,815	\$	41	\$ 142,150	\$	(101,077)	\$	41,114

## Fibrocell Science, Inc.

## **Consolidated Statements of Cash Flows**

## (unaudited)

## (\$ in thousands, except share and per share data)

	Three months	(Restated) Three months
	ended March 31, 2014	ended March 31, 2013
Cash flows from operating activities:		
Net loss \$	(14,009)	\$ (4,570)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	303	173
Stock issued for supplemental stock issuance agreement	5,154	
Warrant revaluation and other finance expense (income)	3,050	(1,338)
Depreciation and amortization	222	226
Provision for doubtful accounts	5	(9)
Change in operating assets and liabilities:		
Accounts receivable	(35)	45
Inventory	91	
Prepaid expenses and other current assets	317	166
Other assets	72	
Accounts payable	(2,055)	324
Accrued expenses and other liabilities	931	(82)
Deferred revenue	1	6
Net cash used in operating activities	(5,953)	(5,059)
Cash flows from investing activities:		
Purchase of property and equipment	(79)	(100)
Net cash used in by investing activities	(79)	(100)
Cash flows from financing activities:		
Proceeds from financing activity		
Net cash provided by financing activities		
Effect of exchange rate changes on cash balances		(1)
Net decrease in cash and cash equivalents	(6,032)	(5,160)
Cash and cash equivalents, beginning of period	60,033	31,346
Cash and cash equivalents, end of period	54,001	\$ 26,186

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#### Fibrocell Science, Inc.

#### **Notes to Consolidated Financial Statements**

(unaudited)

#### Note 1. Business and Organization

Fibrocell Science, Inc. (Fibrocell or the Company) is the parent company of Fibrocell Technologies (Fibrocell Tech) and Fibrocell Science Hong Kong Limited (Fibrocell Hong Kong), a company organized under the laws of Hong Kong. Fibrocell Tech is the parent company of Isolagen Europe Limited, a company organized under the laws of the United Kingdom (Isolagen Europe), Isolagen Australia Pty Limited, a company organized under the laws of Australia (Isolagen Australia), and Isolagen International, S.A., a company organized under the laws of Switzerland (Isolagen Switzerland). The Company is international activities are currently immaterial.

Fibrocell is an autologous cell therapy company primarily focused on developing first-in-class treatments for skin diseases and conditions with high unmet medical needs. Based on its proprietary autologous fibroblast technology, the Company is pursuing medical applications of azficel-T for restrictive burn scarring and vocal cord scarring. The Company s collaboration with Intrexon Corporation (NYSE:XON) ( Intrexon ), a leader in synthetic biology, includes using genetically-modified fibroblasts for treating orphan skin diseases for which there are no currently approved products and exploring the localized treatment of the most common autoimmune skin disease, moderate-to-severe psoriasis. The Company s collaboration with UCLA, focusing on skin-derived stem cells and more efficient ways to convert skin cells to other cell types, holds potential for future discovery and development of autologous cell therapeutics.

#### Note 2. Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by GAAP for complete consolidated financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments and the impact of restatements on prior periods) considered necessary for a fair presentation have been included. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2013 as amended and to be filed with the Securities and Exchange Commission (SEC) within the next two weeks, and in any event, on or before May 31, 2014. The results of the Company s operations for any interim period are not necessarily indicative of the results of operations for any other interim period or full year.

On April 30, 2013, the Company completed a reverse stock split on the basis of one share of common stock for each currently outstanding 25 shares of pre-split common stock. All common share and per share data included in these financial statements reflect this reverse stock split.

#### Note 3. Restatement of Consolidated Financial Statements

On May 6, 2014, the Audit Committee of the Company s Board of Directors (the Audit Committee), in connection with an internal review initiated by Company management, concluded that, because of a misapplication of the accounting guidance related to certain of the Company s warrants, the Company s previously issued consolidated financial statements for all periods beginning with the quarterly period ended September 30, 2011 through December 31, 2013 (collectively, the Affected Periods) should no longer be relied upon. As such, the Company anticipates it will restate its financial statements for the following periods: (i) the fiscal years ended December 31, 2013, December 31, 2012 and December 31, 2011, (ii) all quarterly periods of 2013 and 2012 and (iii) the quarterly period ending September 30, 2011. However, these restatements result in non-cash, non-operating expense corrections and will have no impact on the Company s current or previously reported cash position, operating expenses or total operating, investing or financing cash flows, and net operating loss carryforward.

The warrants at issue (collectively, the Warrants ) consist of the following:

- 1. warrants to purchase an aggregate of 15,080 shares of common stock, issued on October 13, 2009 at an exercise price of \$6.25 per share issued to placement agents;
- 2. Series A, class A warrants to purchase 115,440 shares of common stock, issued on October 13, 2009 at an exercise price of \$6.25 per share;
- 3. Series A, class B warrants to purchase 130,004 shares of common stock, issued on October 13, 2009 at an exercise price of \$6.25 per share;
- 4. warrants to purchase an aggregate of 393,416 shares of common stock, issued on March 4, 2010 at an exercise price of \$6.25 per share;
- 5. warrants to purchase 6,113 shares of common stock, issued on June 16, 2011 at an exercise price of \$22.50 per share issued to placement agents;

#### Fibrocell Science, Inc.

#### **Notes to Consolidated Financial Statements**

#### (unaudited)

#### Note 3. Restatement of Consolidated Financial Statements (continued)

- 6. warrants to purchase 50,123 shares of common stock, issued on August 22, 2011 at an exercise price of \$13.635 per share issued to placement agents;
- 7. warrants to purchase 565,759 shares of common stock, issued on August 22, 2011 at an exercise price of \$18.75 per share;
- 8. warrants to purchase an aggregate of 1,125,578 shares of common stock, issued on June 1, 2012 at an exercise price of \$2.50 per share;
- 9. warrants to purchase an aggregate of 1,217,816 shares of common stock, issued on various dates in 2010 and 2011 at an exercise price of \$6.25 per share;
- 10. warrants to purchase an aggregate of 1,568,823 shares of common stock, issued on various dates in 2012 at an exercise price of \$7.50; and
- 11. warrants to purchase an aggregate of 768,778 shares of common stock, issued on various dates in 2010 at an exercise price of \$6.25.

The above warrant shares and exercise prices have been retroactively adjusted to reflect the April 30, 2013 reverse stock split.

Of the Warrants, approximately 5,335,000 were originally and correctly classified as liabilities on the Company s balance sheets. In connection with the Company s October 2012 financing and a contemporaneous modification of those Warrants to remove down-round anti-dilution protection, such Warrants were erroneously reclassified as a component of equity as opposed to liabilities on the balance sheets. The corresponding statements of operations did not include the subsequent non-cash changes in the estimated fair value of such Warrants. Those Warrants, however, continued to contain a cash settlement feature regarding fundamental transactions that allowed those Warrant holders to have a different settlement option than the Company s stockholders upon certain fundamental transactions, including a change of control of the Company, thereby precluding equity treatment for the Warrants. In the course of management s investigation, the Company also reviewed the Warrant agreements for approximately 622,000 Warrants that were originally classified as equity instruments upon their issuance. Those Warrants contained a similar fundamental transaction settlement provision that precluded equity treatment for such Warrants.

Under the guidance of Accounting Standards Codification, *Derivatives and Hedging*, (ASC 815), warrant instruments that could potentially require net cash settlement in the absence of express language precluding such settlement and those which include down-round provisions should be initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. In periods subsequent to issuance, changes in the estimated fair value of the derivative instruments should be reported in the statement of operations. The Audit Committee, together with management, determined that the financial statements in the Affected Periods should be restated to reflect the Warrants as liabilities, with subsequent changes in their estimated fair value recorded as non-cash income or

expense in each Affected Period.

The impact of the restatement on the unaudited condensed consolidated balance sheet, statement of operations and statement of cash flows as of and for the three-month period ended March 31, 2013 is presented below. The restatement had no impact on net cash flows from operating, investing or financing activities as the adjustments resulting from the non-cash change in the fair value of the warrant liability for each period and the statements of operations only impacted net income (loss) from continuing operations. In addition to the restatement noted above, the consolidated statements of operations and the consolidated balance sheets have also been retroactively adjusted to give effect to the Company s April 2013 reverse stock split.

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## Fibrocell Science, Inc.

## **Notes to Consolidated Financial Statements**

(unaudited)

## Note 3. Restatement of Consolidated Financial Statements (continued)

## **Impact of the Restatement**

(\$ in thousands)

Thron	Months	Ended	Manah	21	2012
i nree	VIONINS	ranaea	viarcn	ЭI.	. 2013

11110	C MIOHUH	3 Eliucu Mai cii 31,	2013	
•	1	Adjustment		As Restated
\$ 58	\$	1,280	\$	1,338
(5,846)		1,280		(4,566)
(5,846)		1,280		(4,566)
\$ (5,850)	\$	1,280	\$	(4,570)
\$ (0.22)	\$	.05	\$	(.17)
\$ (0.22)	\$	.04	\$	(.18)
\$ (0.22)	\$	.05	\$	(.17)
\$ (0.22)	\$	.04	\$	(.18)
	\$ 58 (5,846) (5,850) \$ (0.22) \$ (0.22)	As Previously Reported  \$ 58 \$ (5,846) (5,846) \$ (5,850) \$ \$ (0.22) \$ \$ (0.22) \$ \$ (0.22) \$	As Previously Reported Adjustment  \$ 58 \$ 1,280 \$ 1,280 \$ (5,846) \$ 1,280 \$ (5,846) \$ 1,280 \$ \$ (5,850) \$ 1,280 \$ (0.22) \$ 0.05 \$ (0.22) \$ 0.04 \$ (0.22) \$ 0.05	Reported       Adjustment         \$ 58       1,280         (5,846)       1,280         (5,846)       1,280         \$ (5,850)       1,280         \$ (0.22)       0.5         \$ (0.22)       0.4         \$ (0.22)       0.5         \$ (0.22)       0.5

As of December 31, 2013

	As F	Previously			
	R	eported	A	Adjustment	As Restated
Consolidated Balance Sheet Data:					
Warrant liability	\$	210	\$	15,006	\$ 15,216
Total liabilities		4,342		15,006	19,348
Additional paid-in capital		167,342		(30,648)	136,694
Accumulated deficit		(102,710)		15,642	(87,068)
Total stockholders equity		64,672		(15,006)	49,666

Three Months Ended March 31, 2013

	A	as Previously		
		Reported	Adjustment	As Restated
Consolidated Cash Flows Data (unaudited):				
Net loss	\$	(5,850)	\$ 1,280	\$ (4,570)
Decrease in fair value of warrants		(58)	(1,280)	(1,338)

## Note 4. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and notes. In addition, management s assessment of the Company s ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Actual results may differ materially from those estimates.

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#### Fibrocell Science, Inc.

#### **Notes to Consolidated Financial Statements**

(unaudited)

Note 4. Summary of Significant Accounting Policies (continued)	Note 4	4.	Summary	of Sigr	nificant	Accounting	Po	licies	(continued	)
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Reclassifications

The prior year financial statements contain certain reclassifications to the results of operations for the three months ended March 31, 2013 to conform to the presentation for the three months ended March 31, 2014 on this Form 10-Q. These reclassifications were made in conjunction with the Company s shift in focus away from its commercial product LAVIV® and to further research and development of the underlying azficel-T process. See Note 4 for additional details on intangible amortization expense and Food and Drug Administration (FDA) license fees.

Cost of Sales

Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. Beginning in 2014, cost of sales is accounted for using a standard cost system which allocates the direct costs associated with our manufacturing, facility, quality control, and quality assurance operations as well as overhead costs. The principal reason for the relatively small level of revenue as compared to the cost of sales is that we changed corporate strategy in 2013 to de-emphasize sales of azficel-T into the aesthetic markets, and strategically transition to focus on high-value therapeutic applications for treatment of unmet medical conditions of the skin and connective tissue.

Research and Development Expenses

Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices, and a portion of facilities cost. Research and development costs also include costs to develop manufacturing, cell collection and logistical process improvements.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third party contractors. Invoicing from third party contractors for services performed can lag several months. The Company accrues the costs of services rendered in connection with third party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs.

#### Property and Equipment

Property and equipment is carried at acquisition cost less accumulated depreciation. Depreciation is computed on a straight-line basis over the estimated useful life of the asset. The cost of repairs and maintenance is charged to expense as incurred. As of December 31, 2013, the useful life for all property and equipment was three years, except for leasehold improvements which were depreciated over the remaining lease term or the life of the asset, whichever is shorter. In the first quarter of 2014, the Company adjusted its useful lives to reflect the expected consumption of the economic benefit of these assets as noted in the following table:

Property and equipment category	Useful life
Laboratory equipment	6 years
Computer equipment and software	3 years
Furniture and fixtures	10 years
Leasehold improvements	Lesser of remaining lease term or life of asset

In accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) ASC 250 Accounting Changes and Error Corrections, the Company accounted for this change in useful lives as a change in estimate, with prospective application only. The impact of this change in estimate on depreciation expense for the three months ended March 31, 2014 was immaterial to the results on the Consolidated Statement of Operations.

Intangible Assets

Intangible assets are research and development assets related to the Company s primary study on azficel-T that was recognized upon emergence from bankruptcy. Azficel-T has three current indications: the Company s commercial product, LAVIV®, a clinical development program for restrictive burn scarring and a clinical development program for vocal cord scarring.

Effective January 1, 2012, the Company launched LAVIV® and as a result, the research and development intangible assets related to the Company's primary study were considered to be finite-lived intangible assets and are being amortized over 12 years. For the three months ended March 31, 2014, amortization expense of approximately \$0.1 million was included in research and development expense on the Consolidated Statement of Operations. For the three months ended March 31, 2013, amortization expense of approximately \$0.1 million was reclassed from cost of sales to research and development expense on the Consolidated Statement of Operations to conform to the current presentation.

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis. In accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 360-10-35 Impairment or Disposal of Long-Lived Assets, the Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There was no impairment expense recognized for the three months ended March 31, 2014 or 2013.

FDA License Fees

For the three months ended March 31, 2014, FDA license fees related to the Company s Biologics License Application (BLA) of approximately \$0.2 million were included in research and development expense on the Consolidated Statement of Operations. For the

## Fibrocell Science, Inc.

## **Notes to Consolidated Financial Statements**

(unaudited)

#### Note 4. Summary of Significant Accounting Policies (continued)

three months ended March 31, 2013, FDA license fees of approximately \$0.2 million were reclassified from selling, general and administrative expense to research and development expense on the Consolidated Statement of Operations to conform to the current presentation.

Loss Per Share Data

Basic loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during a period. The diluted loss per share calculation gives effect to dilutive options, warrants, convertible notes, convertible preferred stock, and other potential dilutive common stock including selected restricted shares of common stock outstanding during the period. Diluted loss per share is based on the treasury stock method and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options, assuming the exercise of all in-the-money stock options. Common share equivalents have been excluded where their inclusion would be anti-dilutive.

	For the three months ended  March 31,				
(\$ in thousands except share & per share data)	2014	,	2013 (Restated)		
Loss per share - basic:			, ,		
Numerator for basic loss per share	\$ (14,009)	\$	(4,570)		
Denominator for basic loss per share	40,583,591		26,229,909		
Basic loss per common share	\$ (0.35)	\$	(0.17)		
Loss per share - diluted:					
Numerator for diluted loss per share	\$ (14,009)	\$	(4,570)		
Add back: Fair value of in the money warrants outstanding			305		
Net loss attributable to common share	\$ (14,009)	\$	(4,875)		
Denominator for basic loss per share	40,583,591		26,229,909		
Plus: Incremental shares underlying in the money warrants					
outstanding			402,071		
Denominator for diluted loss per share	40,583,591		26,631,980		
Diluted net loss per common share	\$ (0.35)	\$	(0.18)		

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding, as their effect would be anti-dilutive:

## Three months ended March 31,

	2014	2013 (Restated)
Shares underlying out of the money options outstanding	2,273,720	592,340
Shares underlying out of the money warrants outstanding	4,831,352	4,845,352
Shares underlying in the money warrants outstanding	1,201,698	41,120

Subsequent Events

The Company evaluates all subsequent events, through the date the consolidated financial statements are issued, to determine if there are any events that require disclosure. No such events have been identified through the date of this filing.

#### Fibrocell Science, Inc.

#### **Notes to Consolidated Financial Statements**

(unaudited)

## Note 5. Inventory

Inventories consisted of the following as of:

(\$ in thousands)	March 3 2014	31,	December 31, 2013
Raw materials	\$	449	\$ 511
Work in process		57	86
Inventory	\$	506	\$ 597

#### Note 6. Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with Accounting Standards Codification 815, *Derivatives and Hedging* (ASC 815) if the stock warrants contain down-round protection or other terms that could potentially require net cash settlement and therefore, do not meet the scope exception for treatment as a derivative. Since down-round protection is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company s own stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require net cash settlement in the absence of express language precluding such settlement and those which include down-round provisions are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to classify the fair value of the warrants that contain down-round protection and net cash settlement as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability.

The following table summarizes outstanding warrants to purchase common stock as of:

		December 31,	Exercise	
	March 31, 2014	2013	Price	Expiration Dates
Liability-classified warrants				
Issued in March 2010 and Preferred Stock				
offerings	2,640,534	2,640,534	\$ 6.25	Oct 2015-Dec 2016

Issued in Preferred Stock offerings	76,120	76,120	\$ 2.50	Nov 2015-Sept 2017
Issued in June 2011 financing	6,113	6,113	\$ 22.50	June 2016
Issued in August 2011 financing	565,759	565,759	\$ 18.75	Aug 2016
Issued to placement agents in August 2011				
financing	50,123	50,123	\$ 13.64	Aug 2016
Issued with Convertible Notes	1,125,578	1,125,578	\$ 2.50	June 2018
Issued in Series E Preferred Stock offering	1,568,823	1,568,823	\$ 7.50	Sept 2018
Total	6,033,050	6,033,050		

There were no warrants exercised or cancelled during the three months ended March 31, 2014.

Liability-classified Warrants

The foregoing warrants are recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in other income (expense) in the Company s statement of operations in each subsequent period. The change in the estimated fair value of our warrant liability for the quarters ended March 31, 2014 and March 31, 2013 resulted in non-cash expense of approximately \$3.1 million and non-cash income of approximately \$1.3 million, respectively. The Company utilizes the Monte Carlo simulation valuation method to value the liability classified warrants.

The estimated fair value of these warrants is determined using Level 3 inputs. Inherent in the Monte Carlo valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The estimated fair value of these warrants also require Level 3 inputs which are based on the Company s estimates of the probability and timing of potential future financings, and qualifying fundamental transactions. The range for other assumptions used by the Company are summarized in the following table:

	March 31, 2014	December 31, 2013
Weighted average remaining expected life (years)	3.3 years	3.5 years
Interest rate	0.9%	1.2%
Dividend yield		
Volatility	70%	70%

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#### **Notes to Consolidated Financial Statements**

(unaudited)

Note 7. Equity

Preferred stock

The Company is authorized to issue 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of the Company s preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of the Company or other corporate action. There were no preferred shares issued or outstanding as of March 31, 2014 or March 31, 2013.

Common stock

In connection with the execution of the Second Amendment to the Exclusive Channel Collaboration Agreement (the Second Amendmenton) January 10, 2014 between the Company and Intrexon, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon. The Company agreed to issue to Intrexon Corporation (Intrexon), who is an affiliate of NRM VII Holdings I, LLC, the Company's largest shareholder, a number of shares of Company common stock based on a per share value of the closing price of the Company's common stock on the NYSE MKT on the day prior to execution of the Supplemental Stock Issuance Agreement (the Supplemental Access Fee Shares). The Supplemental Access Fee Shares were issued upon the satisfaction of customary closing conditions, including the approval for the listing of the Supplemental Access Fee Shares on the NYSE MKT. The closing took place on January 24, 2014. The Company recorded a research and development expense in the first quarter of 2014 for the shares issued to Intrexon as a technology access fee. 1,024,590 shares were issued based on a per share value of \$5.03 based on the closing price of the Company's common stock on the closing date, totaling approximately \$5.2 million. For additional discussion on Intrexon, see Note 10.

**Note 8. Fair Value Measurements** 

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company adopted the accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following fair value hierarchy table presents information about each major category of the Company s financial assets and liability measured at fair value on a recurring basis as of March 31, 2014 and December 31, 2013:

	Fair value measurement using						
			Significant other	-	gnificant bservable		
	Quo	ted prices in	observable	İ	inputs		
(\$ in thousands)	active m	arkets (Level 1)	inputs (Level 2)	(1	Level 3)		Total
Balance at March 31, 2014							
Assets:							
Cash and cash equivalents	\$	54,001	\$	\$		\$	54,001
Liabilities:							
Warrant liability	\$		\$	\$	18,266	\$	18,266

#### Fibrocell Science, Inc.

#### **Notes to Consolidated Financial Statements**

#### (unaudited)

		Fair value measurement using					
			Significant other	•	gnificant bbservable		
	Quo	ted prices in	observable		inputs		
(\$ in thousands)	active m	arkets (Level 1)	inputs (Level 2)	(1	Level 3)		Total
Balance at December 31, 2013							
Assets:							
Cash and cash equivalents	\$	60,033	\$	\$		\$	60,033
Liabilities:							
Warrant liability (restated)	\$		\$	\$	15,216	\$	15,216

The reconciliation of warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	W	'arrant
(\$ in thousands)	L	iability
Balance at December 31, 2013 (restated)	\$	15,216
Exercise of warrants		
Change in fair value of warrant liability		3,050
Balance at March 31, 2014	\$	18,266

The fair value of the warrant liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 6 for further discussion of the warrant liability.

The Company believes that the fair values of our current assets and current liabilities approximate their reported carrying amounts. There were no transfers between Level 1, 2 and 3 during the periods presented.

## Note 9. Equity-based Compensation

The Company s board of directors (the Board ) adopted the 2009 Equity Incentive Plan (as amended to date, the Plan ) effective September 3, 2009. The Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisors by providing incentives for such persons to exert maximum efforts for the success of the Company. The Plan allows for the issuance of up to 2,600,000 shares of the Company s common stock. In addition, there were 206,000 options issued outside of the Plan to consultants.

The types of awards that may be granted under the Plan include options (both nonqualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units and other stock-based awards. The term of each award is determined by the Compensation Committee of the Board at the time each award is granted, provided that the terms of options do not exceed ten years. Vesting schedules for the stock options vary, but generally vest 25% per year, over four years. The Plan had 508,280 options available for grant as of March 31, 2014.

Total stock-based compensation expense recognized using the straight-line attribution method in the Consolidated Statement of Operations is as follows:

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## Fibrocell Science, Inc.

## **Notes to Consolidated Financial Statements**

#### (unaudited)

	Three months ended March 31,				
(\$ in thousands)		2014		2013	
Stock option compensation expense for employees and					
directors	\$	300	\$		173
Equity awards for nonemployees issued for services		3			
Total stock-based compensation expense	\$	303	\$		173

## Note 9. Equity-based Compensation (continued)

(\$ in thousands except share and per share data)	Number of shares	Weighted- average exercise price	Weighted- average remaining contractual term (in years)	Aggrega intrinsi value	c
Outstanding at December 31, 2013	2,068,720	\$ 7.93	8.4	\$	544
Granted	205,000	\$ 4.44			
Exercised					
Forfeited					
Outstanding at March 31, 2014	2,273,720	\$ 7.61	8.5	\$	1,949
Exercisable at March 31, 2014	775,437	\$ 14.31	7.3	\$	182

The total fair value of shares vested during the three months ended March 31, 2014 was approximately \$0.2 million. As of March 31, 2014, there was approximately \$3.1 million of total unrecognized compensation cost, related to time-based non-vested stock options. That cost is expected to be recognized over a weighted-average period of 4.4 years. As of March 31, 2014, there was approximately \$0.6 million of total unrecognized compensation expense related to performance-based, non-vested non-employee options.

During the three months ended March 31, 2014 and 2013, the weighted average fair market value of the options granted was \$2.88 and \$2.07, respectively. The fair market value of the options was computed using the Black-Scholes option-pricing model with the following key weighted average assumptions for the three months ended as of the dates indicated:

	March 31, 2014	March 31, 2013
Expected life (years)	6.25 years	5.0 years
Interest rate	2.0%	0.9%
Dividend yield		
Volatility	71%	69%

## Note 10. Collaboration with Related Party

Intrexon is an affiliate of our largest shareholder, NRM VII Holdings I, LLC. In addition, two of our seven directors are also affiliates of NRM VII Holdings I, LLC.

On January 10, 2014, the Company and Intrexon entered into a Second Amendment to the parties Exclusive Channel Collaboration Agreement dated October 5, 2012, as previously amended on June 28, 2013 (the Channel Agreement and such previous amendment, the First Amendment ). The Channel Agreement provides for a channel collaboration arrangement governing a strategic collaboration for the development and commercialization of genetically-modified and non-genetically-modified autologous fibroblasts and autologous dermal cells in the United States. The Channel Agreement originally granted the Company an exclusive license to use proprietary technologies and other intellectual property of Intrexon to research, develop, use, import, export, make, have made, sell, and offer for sale certain products in the Field in the United States.

In connection with the execution of the Second Amendment to the Channel Agreement on January 10, 2014 between the Company and Intrexon, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon. The Company agreed to issue to Intrexon, who is an affiliate of NRM VII Holdings I, LLC, the Company s largest shareholder, a number of shares of Company common stock based on a per share value of the closing price of the Company s common stock on the NYSE MKT on the day prior to execution of the Supplemental Stock Issuance Agreement. The Supplemental Access Fee Shares were issued upon the satisfaction of customary closing conditions, including the approval for the listing of the Supplemental Access Fee Shares on the NYSE MKT. The closing took place on January 24, 2014. The Company recorded a research and development expense in the first quarter of 2014 for the shares issued to Intrexon as a technology access fee. 1,024,590 shares were issued based on a per share value of \$5.03 based on the closing price of the Company s common stock on the closing date, totaling approximately \$5.2 million.

## Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This report contains certain forward-looking statements relating to Fibrocell that are based on management s exercise of business judgment and assumptions made by and information currently available to management. When used in this document, the words anticipate, believe, estimate, expect, intend, the facts suggest and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements. Several of these factors include, without limitation:

- whether our clinical human trials relating to the use of autologous cell therapy applications, in particular, for restrictive burn scars, vocal cord scars and genetically-modified orphan indications, and such other indications as we may identify and pursue can be conducted within the timeframe that we expect, whether such trials will yield positive results, or whether additional applications for the commercialization of autologous cell therapy can be identified by us and advanced into human clinical trials;
- our ability to meet requisite regulations or receive regulatory approvals in the United States, our ability to retain any regulatory approvals that we may obtain and the absence of adverse regulatory developments in the United States;
- our dependence on one facility in Exton, Pennsylvania for our research, development and manufacturing operations, and the potential that such facility is damaged or if we are otherwise required to discontinue production at such facility:
- new entrance of competitive products or further penetration of existing products in our markets;
- the effect on us from adverse publicity related to our products or the company itself;
- any adverse claims relating to our intellectual property; and
- our dependence on physicians to correctly follow our established protocols for the safe and optimal administration of our product.

These factors are not necessarily all of the important factors that could cause actual results of operations to differ materially from those expressed in these forward-looking statements. Other unknown or unpredictable factors also could have material adverse effects on our future

results. We cannot assure you that projected results will be achieved.

## **Restatement of Previously Issued Consolidated Financial Statements**

As discussed in the Explanatory Note and Note 3 of the consolidated financial statements, the unaudited 2013 consolidated financial statements and related disclosures presented here have been restated to give effect to correction of a misapplication in the guidance on accounting for Warrants.

The following discussion and analysis of our financial condition and results of operations incorporate the restated amounts. For this reason, the data set forth in this section will not be comparable to discussion and data in our previously filed Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.

#### General

We are an autologous cell therapy company primarily focused on developing first-in-class treatments for skin diseases and conditions with high unmet medical needs. Based on our proprietary autologous fibroblast technology, we are pursuing breakthrough medical applications of azficel-T for restrictive burn scarring and vocal cord scarring. Driving Fibrocell s innovative therapies is its Personalized Biologics platform, which embraces two product engines: the Azficel-T Autologous Fibroblast Product Engine and the Protein Expression Product Engine. These two product engines enable Fibrocell to harness the favorable characteristics of fibroblasts to develop new therapies for diseases and conditions of the skin and connective tissues where there are limited or no treatment options. The Azficel-T Autologous Fibroblast Product Engine is developing biologic solutions for the treatment of serious and debilitating scarring conditions. The Protein Expression Product Engine is creating biologic products by genetically modifying fibroblasts to express target proteins that are inactive or missing from patients with rare genetic skin and tissue disorders.

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Our collaboration with Intrexon, a leader in synthetic biology, includes using genetically-modified fibroblasts for treating orphan skin diseases for which there are no currently approved products and exploring the localized treatment of the most common autoimmune skin disease, moderate-to-severe psoriasis. This collaboration with Intrexon is discussed in more detail below. Additional collaborations with the University of California, Los Angeles ( UCLA ) and the Massachusetts Institute of Technology ( MIT ) focus on skin-derived stem cells.

#### **Critical Accounting Policies**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make significant judgments and estimates 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 expenses during the reporting period. Management bases these significant judgments and estimates on historical experience and other assumptions it believes to be reasonable based upon information presently available. Actual results could differ from those estimates under different assumptions, judgments or conditions. There were no material changes to our critical accounting policies and use of estimates previously disclosed in our 2013 Annual Report on Form 10-K, as amended, other than those discussed below.

Warrant Liability: The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with Accounting Standards Codification 815, Derivatives and Hedging (ASC 815) if the stock warrants contain down-round protection or other terms that could potentially require net cash settlement and therefore, do not meet the scope exception for treatment as a derivative. Since down-round protection is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company s own stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require net cash settlement in the absence of express language precluding such settlement and those which include down-round provisions are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to classify the fair value of the warrants that contain down-round protection and net cash settlement as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability.

Cost of Sales: Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. Beginning in 2014, cost of sales is accounted for using a standard cost system which allocates the direct costs associated with our manufacturing, facility, quality control, and quality assurance operations as well as overhead costs.

#### **Results of Operations**

Comparison of Three Months Ended March 31, 2014 and 2013

Revenue and Cost of Sales. Revenue and cost of sales were comprised of the following:

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		Three mor	nths en		Increase			
		March 31,				(Decrease)		
(\$ in thousands)	2	2014		2013	\$		%	
Total revenue	\$	46	\$	26	\$	20	76.9%	
Cost of sales		793		2,213		(1,420)	-64.2%	
Gross loss	\$	(747)	\$	(2,187)	\$	1,440	-65.8%	

Revenue was immaterial for each of the three months ended March 31, 2014 and 2013. Revenue is booked based on the shipment of cells to the patients for injection of LAVIV®.

Cost of sales was approximately \$0.8 million and \$2.2 million for the three months ended March 31, 2014 and 2013, respectively. Cost of sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. Beginning in 2014, cost of sales is accounted for using a standard cost system which allocates the costs associated with our manufacturing, facility, quality control, and quality assurance operations as well as overhead costs. The decrease of \$1.4 million is primarily due to the transition away from the aesthetic market and to a focus on research and development.

The principal reasons for the relatively small level of revenue as compared to the cost of sales are: (1) We changed corporate strategy in 2013 to de-emphasize sales of azficel-T into the aesthetic markets, and strategically transition to focus on high-value therapeutic applications for treatment of unmet medical conditions of the skin and connective tissue; (2) Manufacturing capacity our current manufacturing capacity is limited by the FDA to approximately 1,000 biopsies annually; (3) Charging for biopsies and injections we offered complimentary and reduced price biopsies and injections throughout 2012 and 2013; and (4) Manufacturing complexity and quality control and assurance criteria. We currently have adequate manufacturing capacity to meet clinical demand and the limited commercial demand we expect for 2014. We believe that cost of sales will remain at or above product revenue for the foreseeable future and, thus, we anticipate that we will continue to report gross losses from sales of LAVIV® for the aesthetic indication for the foreseeable future.

Selling, General and Administrative Expense. Selling, general and administrative expense was comprised of the following:

	Three mor Marc		Increase (Decrease)		
(\$ in thousands)	2014		2013	\$	%
Compensation and related expense	\$ 1,287	\$	973	\$ 314	32.3%
External services consulting	83		20	63	315.0%
Marketing expense	22		127	(105)	-82.7%
Legal expense	160		193	(33)	-17.1%
Facilities and related expense and other	1,263		897	366	40.8%
Total selling, general and administrative expense	\$ 2,815	\$	2,210	\$ 605	27.4%

Selling, general and administrative expense increased by approximately \$0.6 million, or 27%, to \$2.8 million for the three months ended March 31, 2014 as compared to \$2.2 million for the three months ended March 31, 2013. Compensation and related expense increased \$0.3 million due to additional salary costs. Marketing expense decreased \$0.1 million as the focus shifted away from our commercial product LAVIV®. Facilities and related expense and other increased \$0.4 million due to an increase in office costs. External services consulting and license fees and legal expenses remained relatively constant year over year.

## Research and Development Expense.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, pre-clinical and clinical development costs. Indirect expenses include regulatory, lab costs, personnel, facility, stock compensation and other overhead costs that are not attributable to any one program. We expect research and development costs to continue to be significant for the foreseeable future as a result of our clinical trials and our collaboration with Intrexon.

Research and development expense was comprised of the following:

	Three me	onths end	ed		Increase	
	Mai	(Decrease)				
(\$ in thousands)	2014		2013		\$	%
Direct costs:						
Restrictive Burn Scarring	\$ 132	\$	63	\$	69	109.5%
Vocal Cord Scarring	123		54		69	127.8%
Recessive Dystrophic Epidermolysis						
Bullosa	701		183		518	283.1%
Morphea Profunda/ Linear Scleroderma	92				92	100.0%
Cutaneous Eosinophilias	92				92	100.0%
azficel-T	58		363		(305)	-84.0%
Tenascin-X	5,161				5,161	100.0%
Other	149		179		(30)	-16.8%
Total direct costs	6,508		842		5,666	672.9%

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Indirect costs:				
Regulatory costs	204	258	(54)	-20.9%
Intangible amortization	138	138		
Indirect lab costs	515	201	314	156.2%
Compensation and related expense	73	68	5	7.4%
Total indirect costs	930	665	265	39.8%
Total research and development expense	\$ 7,438	\$ 1,507	\$ 5.931	393.6%

Total research and development expense increased \$5.9 million to approximately \$7.4 million for the three months ended March 31, 2014 as compared to \$1.5 million for the three months ended March 31, 2013. The increase is due primarily to stock issuance costs of approximately \$5.2 million and a \$0.4 million increase in consulting fees related to research and development costs incurred in the three months ended March 31, 2014, both in connection with our collaboration with Intrexon, as well as a \$0.3 million increase in other spending.

Direct research and development expense by major clinical and pre-clinical development program were as follows:

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<u>Recessive Dystrophic Epidermolysis Bullosa (RDEB</u>) Costs increased approximately \$0.5 million compared to the three months ended March 31, 2013 due to the expansion of our preclinical development program for RDEB during the three months ended March 31, 2014.

<u>Azficel-T</u> Costs decreased approximately \$0.3 million compared to the three months ended March 31, 2013 due to the reduction in our process development program for azficel-T during the three months ended March 31, 2014.

<u>Tenascin-X</u> - This program began in 2014 and costs were approximately \$5.2 million due to the cost of the 2014 supplemental stock issuance in connection with the Second Amendment to the Channel Agreement with Intrexon.

Our other research and development expense related to our other clinical and pre-clinical development programs were relatively constant year over year.

Change in Revaluation of Warrant Liability. During the three months ended March 31, 2014 and 2013, we recorded non-cash warrant expense of \$3.1 million and non-cash warrant income of \$1.3 million in our statements of operations, respectively.

*Net Loss.* Net loss for the three months ended March 31, 2014 and March 31, 2013 was \$14.0 million and \$4.6 million, respectively, representing an increase of approximately \$9.4 million. The change is primarily due to the approximately \$5.2 million in costs for the 2014 supplemental stock issuance in connection with the Second Amendment to the Channel Agreement with Intrexon and to a \$4.4 million change in the non-cash warrant expense related to the revaluation of the warrant liability.

#### **Liquidity and Capital Resources**

The following table summarizes our cash flows from operating, investing and financing activities for the three months ended March 31, 2014 and 2013:

Statement of Cash Flows Data:	T	Three months Ended March 31,				
(\$ in thousands)	20	2014		2013		
Cash used in operating activities	\$	(5,953)	\$	(5,059)		
Cash used in investing activities	\$	(79)	\$	(100)		
Cash provided by financing activities	\$		\$			

*Operating Activities.* Cash used in operating activities during the three months ended March 31, 2014 was approximately \$6.0 million, an increase of \$0.9 million over the three months ended March 31, 2013. The increase in cash used in operating activities over the comparable quarter in the prior year is due to changes in operating assets and liabilities, mostly related to cash used to reduce accounts payable offset by cash

provided by an increase in accrued expenses and other liabilities.

*Investing Activities.* Cash used in investing activities amounted to \$0.1 million for each of the three months ended March 31, 2014 and March 31, 2013, due to the purchase of equipment for the laboratory facility in Exton, Pennsylvania.

Financing Activities. There was no cash used in or provided by financing activities for the three months ended March 31, 2014 and March 31, 2013.

Working Capital

As of March 31, 2014, we had cash and cash equivalents of \$54.0 million and working capital of \$53.0 million. We expect to have sufficient cash to operate for at least the next twelve months. In addition, we expect we will require additional financing prior to our business achieving significant net cash from operations. We would likely raise such additional capital through the issuance of our equity or equity-linked securities, which may result in dilution to our investors, or by entering into strategic partnerships. Our ability to raise additional capital is dependent on, among other things, the state of the financial markets at the time of any proposed offering. To secure funding through strategic partnerships, it may be necessary to partner one or more of our technologies at an earlier stage of development, which could cause us to share a greater portion of the potential future economic value of those programs with our partners. There is no assurance that additional funding, through any of the aforementioned means, will be available on acceptable terms, or at all. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations could be materially negatively impacted.

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#### **Contractual Obligations**

On April 6, 2005, the Company entered into a non-cancellable operating lease (the Lease) for its office, warehouse and laboratory facilities in Exton, Pennsylvania. The lease agreement had a term of 8 years. On February 17, 2012, the Company entered into an amended and restated lease (the Amended Lease) for an additional term of 10 years through the year 2023. At March 31, 2014, our minimum lease payments under the Amended Lease total approximately \$12.0 million.

During the three month period ended March 31, 2014, there have been no material changes to our other contractual obligations outside the ordinary course of business from those specified in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2013.

#### **Recently Issued Accounting Pronouncements**

There have been no recently issued accounting pronouncements that we believe will have a material impact on our consolidated results of operations, cash flows or financial position upon adoption.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange rates or interest rates

Our exposure to interest rate risk is limited to our cash. The goals of our investment policy are preservation of capital and fulfillment of our working capital requirements. To achieve our goals, we maintain our cash in interest-bearing bank accounts, which are subject to minimal interest rate risk.

We do not believe that we have significant foreign exchange rate risk at March 31, 2014.

We do not enter into derivatives or other financial instruments for trading or speculative purposes.

#### Item 4. Controls and Procedures.

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934), as of the end of the period covered by this report. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on their evaluation, including the existence of the material weakness in our internal control over financial reporting referenced below, our management, including our Chief Executive Office and Chief Financial Officer, concluded that our disclosure controls and procedures were not effective to provide reasonable assurance as of March 31, 2014.

#### **Material Weakness**

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on this assessment using the COSO criteria, management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2013, because of a material weakness relating to accounting for warrants. Specifically, we did not maintain effective controls over the identification and proper accounting treatment of certain terms and conditions in our warrant agreements. This material weakness resulted in a misstatement of our liabilities, non-cash expense relating to the changes in fair value of common stock warrants, accumulated deficit accounts and related financial disclosures. This condition also resulted in the restatement of our consolidated financial statements for the years ended December 31, 2013, 2012 and 2011, and each of the quarterly periods beginning with September 30, 2011 through September 30, 2013 as discussed below and in Note 3 to these consolidated financial statements included in this Quarterly Report on Form 10-Q.

#### **Restatement of Consolidated Financial Statements**

On May 6, 2014, Company management, in consultation with its Audit Committee, revised its prior position on accounting for warrants and concluded that its previously issued consolidated financial statements for all periods beginning with the quarterly period ended September 30, 2011 through December 31, 2013 (collectively, the Affected Periods) should not be relied on because of a misapplication in the guidance on accounting for Warrants (as defined in Note 3 of these consolidated financial statements). However, the non-cash adjustments to the financial statements, in all of the Affected Periods, do not impact the amounts previously reported for the Company s cash and cash equivalents, total assets, revenue, or cash flows.

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#### **Changes in Internal Control over Financial Reporting**

There were no significant changes in our internal control over financial reporting that occurred during the three months ended March 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **PART II - OTHER INFORMATION**

Item 1. Legal Proceedings

None

Item 1A. Risk Factors

Investing in our company involves a high degree of risk. Before investing in our company you should carefully consider the following risks, together with the financial and other information contained in this Form 10-Q as well as the Form 10-K, as amended for the year ended December 31, 2013. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be adversely affected. In that case, the trading price of our common stock would likely decline and you may lose all or a part of your investment.

We have identified a material weakness in our internal control over financial reporting that resulted in the restatement of certain of our previously issued consolidated financial statements. This material weakness could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. generally accepted accounting principles (GAAP). Our management is also required, on a quarterly basis, to disclose any change in internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the internal control over financial weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a Company s annual or interim financial statements will not be prevented or detected on a timely basis.

As described elsewhere in this Quarterly Report on Form 10-Q, in connection with the restatement process, we identified a material weakness in our internal control regarding our process and procedures related to our prior interpretation of ASC 815 and our initial classification and subsequent accounting of warrants as either liabilities or equity instruments. As a result of this material weakness, our management concluded

that our internal control over financial reporting was not effective as of December 31, 2013. This material weakness resulted in a misstatement of our liabilities, non-cash expense relating to the changes in fair value of common stock warrants, accumulated deficit accounts and related financial disclosures as discussed herein and in Note 3 to the consolidated financial statements included in this Quarterly Report on Form 10-Q. See Part I, Item 4, Controls and Procedures.

To respond to the material weakness, we have and plan to continue to devote significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and intelligently apply developments in accounting, we plan to enhance these processes to better evaluate our research and understanding of the nuances of increasingly complex accounting standards. Our plans at this time include providing enhanced access to accounting literature, research materials and documents and increased communication among our finance personnel and third party professionals with whom we consult regarding complex legal and accounting applications. The elements of our remediation plan can only be accomplished over time and we can offer no assurance that these initiatives will ultimately have the intended effects.

Any failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and NYSE, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

#### The Company faces risks in connection with the expansion of its business in China.

In April 2010, we entered into a letter of intent with Chinese company Heifei Meifu Bio-Tech Limited Co. to form a joint venture to commercialize autologous fibroblast therapies in Asia (excluding Japan) and to produce and develop such therapies in China. This letter of intent was intended to serve as the template for a joint venture agreement between the Company and Heifei Meifu, which would expand the scope of the Company's operations to China and Asia more broadly. However, to date we and Heifei Meifu have not received Chinese governmental approval to form the proposed joint venture and we are considering alternative business structures to develop our business in Asia (excluding Japan). As the Company furthers its commitment to China, it is increasingly exposed to risks in that region. These risks include changes in laws and regulations, currency fluctuations, increased competition and changes in economic conditions, including those related to consumer spending. Adverse developments in these areas could cause the Company to lose some or all of its future investment in China and could cause the Company to fail to achieve anticipated growth.

Moreover, certain risks and uncertainties of doing business in China are solely within the control of the Chinese government, and Chinese law regulates both the scope of the Company s investment in China and the business conducted by it within China. The Company cannot provide assurance that the Chinese government will permit the distribution of the Company s products in China or that the timing of such distribution will be favorable to the Company. There are also uncertainties regarding the interpretation and application of laws and regulations and the enforceability of intellectual property and contract rights in China. If the Company were unable to navigate China s regulatory environment, including with respect to the joint venture, or if the Company were unable to enforce its intellectual property or contract rights in China, the Company s business could be adversely impacted.

Our proposed joint venture with Heifei Meifu Bio-Tech Limited Co., if consummated, may limit our ability to independently develop and commercialize our products in China.

In April 2010, we entered into a letter of intent with Chinese company Heifei Meifu Bio-Tech Limited Co. to form a joint venture to commercialize autologous fibroblast therapies in Asia (excluding Japan) and to produce and develop such

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therapies in China. This letter of intent was intended to serve as the template for a joint venture agreement between the Company and Heifei Meifu. To date, we and Heifei Meifu have not received Chinese governmental approval to form the proposed joint venture and we are considering alternative business structures to develop our business in Asia (excluding Japan). Assuming we receive the necessary approvals and the joint venture is formed or if we enter into an alternative business structure, the joint venture or alternative business structure would establish the exclusive means for us to develop, produce and commercialize autologous fibroblast therapies in Asia (excluding Japan). Assuming we receive the necessary approvals and the joint venture is formed or we enter into an alternative business structure, we expect to grant the joint venture or alternative business structure exclusive licenses under certain of our intellectual property to make and sell joint venture products. As a result of these licenses, we expect to generally no longer have an independent right to make or sell autologous fibroblast therapies in Asia (excluding Japan).

If, for any reason, the joint venture or alternative business structure is not fully supported or is not successful and the joint venture or alternative business structure does not allow us to pursue autologous fibroblast therapies independently, this arrangement could impair our ability to develop and commercialize such products, which could have a material adverse effect on our business and long term prospects. In addition, Heifei Meifu Bio-Tech Limited Co. could take steps that could weaken our intellectual property rights with respect to our autologous fibroblast therapies in China.

#### We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and our or our licensors intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors inventions in all countries outside the U.S., or from selling or importing products made using our and our licensors inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we or our licensors have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our or our licensor s patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and our licensors patents at risk of being invalidated or interpreted narrowly and our and our licensors patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the U.S., and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors

may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

## Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

We had no unregistered sales of equity securities during the period covered by this report that have not been previously reported on Form 8-K.

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Item 3.	Defaults Upon Senior Securities					
None						
Item 4.	Mine Safety Disclosure					
Not Applicable						
Item 5.	Other Information					
On May 12, 2014, the Compensation Committee of the Board of Directors (the Compensation Committee) approved an increase in annual base salary compensation for John Maslowski, Vice President of Operations, Scientific Affairs, to \$250,000 commencing May 16, 2014. In addition, the Compensation Committee granted 20,000 stock options to Mr. Maslowski under the Fibrocell Science, Inc. 2009 Equity Incentive Plan, as amended. Such options vest 25% per year over a four-year period.						
Item 6.	Exhibits					
(a) Exhibits						

* Filed herewith.	•		
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## **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 thereunto duly authorized.

## FIBROCELL SCIENCE, INC.

By: /s/ Gregory Weaver

Gregory Weaver

SVP and Chief Financial Officer

Date: May 19, 2014