Fibrocell Science, Inc. Form 10-Q August 11, 2014 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended June 30, 2014

OR

o 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 (Do not check if a smaller reporting company)

Smaller reporting company o

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 August 4, 2014, issuer had 40,856,815 shares issued and outstanding of common stock, par value \$0.001.

## Table of Contents

## TABLE OF CONTENTS

			PAGE
Part I.	Financial Information		
	Item 1.	Financial Statements	
		Consolidated Balance Sheets as of June 30, 2014 (unaudited) and December 31, 2013	1
		Consolidated Statements of Operations (unaudited) For the three and six months ended June 30, 2014 and 2013	2
		Consolidated Statement of Stockholders Equity For the six months ended June 30, 2014 (unaudited)	3
		Consolidated Statements of Cash Flows (unaudited) For the six months ended June 30, 2014 and 2013	4
		Notes to Consolidated Financial Statements (unaudited)	5
	<u>Item 2.</u>	<u>Management</u> s <u>Discussion and Analysis of Financial Condition and Results of Operations</u>	13
	Item 3.	Quantitative and Qualitative Disclosures about Market Risk	19
	Item 4.	Controls and Procedures	20
Part II.	Other Information		
	Item 1.	<u>Legal Proceedings</u>	21
	Item 1A.	Risk Factors	21
	Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
	Item 3.	<u>Defaults upon Senior Securities</u>	23
	Item 4.	Mine Safety Disclosure	23
	Item 5.	Other Information	23
	Item 6.	<u>Exhibits</u>	23
	Signature Page		24

## PART I. FINANCIAL INFORMATION

## ITEM 1. Financial Statements.

## Fibrocell Science, Inc.

## **Consolidated Balance Sheets**

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

	June 30, 2014 (unaudited)	I	December 31, 2013
Assets	,		ĺ
Current assets:			
Cash and cash equivalents	\$ 49,536	\$	60,033
Accounts receivable, net of allowance for doubtful accounts of \$22 and \$5, respectively	14		28
Inventory	476		597
Prepaid expenses and other current assets	706		1,202
Total current assets	50,732		61,860
Property and equipment, net of accumulated depreciation of \$911 and \$735, respectively	1,736		1,701
Intangible assets, net of accumulated amortization of \$1,378 and \$1,102, respectively	4,962		5,238
Other assets	1		215
Total assets	\$ 57,431	\$	69,014
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	\$ 1,368	\$	2,958
Accrued expenses	1,600		487
Deferred revenue	280		148
Total current liabilities	3,248		3,593
Warrant liability	14,258		15,216
Other long term liabilities	632		539
Total liabilities	18,138		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	142,586		136,694
Accumulated deficit	(103,334)		(87,068)
Total stockholders equity	39,293		49,666
Total liabilities and stockholders equity	\$ 57,431	\$	69,014

## Fibrocell Science, Inc.

## **Consolidated Statements of Operations**

## (unaudited)

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

	 hree months ended une 30, 2014	Three months ended June 30, 2013	Six months ended June 30, 2014	Six months ended June 30, 2013
Revenue from product sales	\$ 58	\$ 62	\$ 104	\$ 88
Cost of sales	547	2,104	1,340	4,317
Gross loss	(489)	(2,042)	(1,236)	(4,229)
Selling, general and administrative expense	3,487	2,294	6,302	4,504
Research and development expense	2,620	1,478	10,058	2,985
Operating loss	(6,596)	(5,814)	(17,596)	(11,718)
Other income (expense):				
Warrant revaluation and other finance income (expense)	4,008	(8,818)	958	(7,480)
Other income	330		370	
Interest income	1		2	
Loss from continuing operations before income taxes	(2,257)	(14,632)	(16,266)	(19,198)
Deferred tax benefit				
Loss from continuing operations, net of tax	(2,257)	(14,632)	(16,266)	(19,198)
Loss from discontinued operations, net of tax		(5)		(9)
Net loss	\$ (2,257)	\$ (14,637)	\$ (16,266)	\$ (19,207)
Per Share Information:				
Loss from continuing operations, net of tax basic	\$ (0.06)	\$ (0.63)	\$ (0.40)	\$ (0.73)
Loss from discontinued operations, net of tax basic				
Net loss per common share basic	\$ (0.06)	\$ (0.63)	\$ (0.40)	\$ (0.73)
Loss from continuing operations, net of tax diluted	\$ (0.09)	\$ (0.63)	\$ (0.43)	\$ (0.74)
Loss from discontinued operations, net of tax diluted				
Net loss per common share diluted	\$ (0.09)	\$ (0.63)	\$ (0.43)	\$ (0.74)
Weighted average number of common shares outstanding				
- Basic	40,856,815	23,260,802	40,720,958	26,230,358
- Diluted	41,250,886	23,260,802	40,917,993	26,437,817

## Fibrocell Science, Inc.

## Consolidated Statements of Stockholders Equity

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

Common Stock									
	Shares		Amount	_	Additional id-in capital	A	Accumulated deficit	,	Fotal Equity
Balance, December 31, 2013	39,832,225	\$	40	\$	136,694	\$	(87,068)	\$	49,666
Stock-based compensation expense					739				739
Issuance of common stock	1,024,590		1		5,153				5,154
Net loss							(16,266)		(16,266)
Balance, June 30, 2014 (unaudited)	40,856,815	\$	41	\$	142,586	\$	(103,334)	\$	39,293

## Fibrocell Science, Inc.

## **Consolidated Statements of Cash Flows**

## (unaudited)

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

	Six months ended June 30, 2014		Six months ended June 30, 2013
Cash flows from operating activities:			
	\$ (16,2)	66) \$	(19,207)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	7	39	209
Stock issued for supplemental stock issuance agreement	5,1	54	
Warrant revaluation and other finance (income) expense	(9	58)	7,480
Depreciation and amortization	4	52	456
Provision for doubtful accounts		16	
Change in operating assets and liabilities:			
Accounts receivable		(2)	(10)
Inventory	1	21	(144)
Prepaid expenses and other current assets	4	96	537
Other assets	2	14	
Accounts payable	(1,5	90)	221
Accrued expenses and other liabilities	1,2	ე6	30
Deferred revenue	1	32	11
Net cash used in operating activities	(10,2	86)	(10,417)
Cash flows from investing activities:			
Purchase of property and equipment	(2	11)	(122)
Net cash used in investing activities	(2	11)	(122)
Cash flows from financing activities:			
Subscriptions received			4
Net cash provided by financing activities			4
Effect of exchange rate changes on cash balances			(1)
Net decrease in cash and cash equivalents	(10,4	97)	(10,536)
Cash and cash equivalents, beginning of period	60,0	33	31,346
Cash and cash equivalents, end of period	\$ 49,5	36 \$	20,810

#### **Table of Contents**

#### Fibrocell Science, Inc.

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

(unaudited)

#### Note 1. Business and Organization

Fibrocell Science, Inc. (as used herein, we, us, our, Fibrocell or the Company) is the parent company of Fibrocell Technologies (Fibrocell 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 focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases 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 is collaboration with Intrexon Corporation (NYSE:XON) (Intrexon), a leader in synthetic biology, includes using genetically-modified fibroblasts for treating rare and serious skin and connective tissue diseases for which there are no currently approved products. Fibrocell is ongoing scientific research collaboration with UCLA has yielded discoveries and technologies related to stem cells and regenerative cells in human skin. The technologies from this collaboration and our exclusive license agreements with UCLA enable Fibrocell to expand its proprietary personalized biologics platform which uses human fibroblasts and stem cells from skin to create localized therapies that are compatible with the unique biology of each patient.

#### 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 discussed below) 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, filed with the Securities and Exchange Commission (SEC) as discussed below. 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 May 6, 2014, the Audit Committee of the Company s Board of Directors, 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 should no longer be relied upon. On June 2, 2014, the Company restated all affected interim and annual periods in its Annual Report on Form 10-K/A (Amendment No. 2) for the fiscal year ended December 31, 2013 in an SEC approved omnibus filing. As such, the comparative information provided for the year ended December 31, 2013 and the three and six months ended June 30, 2013 contained in the preceding financial statements and the accompanying footnotes reflect these previously restated amounts.

The prior year financial statements contain certain reclassifications to the results of operations for the three and six months ended June 30, 2013 to conform to the presentation for the three and six months ended June 30, 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.

For the three and six months ended June 30, 2014, amortization expense of approximately \$0.1 million and \$0.3 million, respectively, was included in research and development expense on the Consolidated Statements of Operations. For the three and six months ended June 30, 2013, amortization expense of approximately \$0.1 million and \$0.3 million, respectively, was reclassed from cost of sales to research and development expense on the Consolidated Statements of Operations to conform to the current presentation. For the three and six months ended June 30, 2014, Food and Drug Administration (FDA) license fees related to the Company s Biologics License Application (BLA) of approximately \$0.2 million and \$0.3 million, respectively, were included in research and development expense on the Consolidated Statements of Operations. For the three and six months ended June 30, 2013, FDA license fees of approximately \$0.2 million and \$0.3 million, respectively, were reclassified from selling, general and administrative expense to research and development expense on the Consolidated Statements of Operations to conform to the current presentation.

Table	e of	Cont	ents

#### Fibrocell Science, Inc.

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

(unaudited)

Note 3. Summary of S	ignificant A	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.

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 transitioned our business strategy 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 was 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 and six months ended June 30, 2014 was immaterial to the results on the Consolidated Statements 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 or target 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.

6

**Table of Contents** 

#### Fibrocell Science, Inc.

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

(unaudited)

#### **Note 3. Summary of Significant Accounting Policies (continued)**

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 either the three or six months ended June 30, 2014 or 2013.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, Income Taxes ( ASC 740 ), which provides for reporting of amounts that are currently payable and also for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2013 and June 30, 2014, the Company did not have any uncertain tax positions.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ( ASU ) No. 2014-09, Revenue from Contracts with Customers, under ASC Topic 606 which supersedes the current revenue recognition requirements under ASC Topic 605, Revenue Recognition. The standard is core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. It also provides a five step approach to achieve this principle. For public entities, the new guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. Based on the Company is current financial operations, the Company anticipates the potential impact of ASU No. 2014-09 to be immaterial to its financial statements.

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.

## Note 4. Inventory

Inventories consisted of the following as of:

(\$ in thousands)	June 30 2014	,	December 31, 2013
Raw materials	\$	383	\$ 511
Work in process		93	86
Inventory	\$	476	\$ 597

7

#### **Table of Contents**

#### Fibrocell Science, Inc.

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

(unaudited)

#### Note 5. 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 or 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:

Number of Warrants							
		December 31,		Exercise	Expiration		
Liability-classified warrants	June 30, 2014	2013		Price	Dates		
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 six months ended June 30, 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 statements of operations in each subsequent period. The change in the estimated fair value of our warrant liability for the three and six months ended June 30, 2014 resulted in non-cash income of approximately \$4.0 million

and \$1.0 million, respectively. The change in the estimated fair value of our warrant liability for the three and six months ended June 30, 2013 resulted in non-cash expense of approximately \$8.8 million and \$7.5 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 will 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 other assumptions used by the Company are summarized in the following table:

	June 30, 2014	June 30, 2013
Weighted average remaining expected life (years)	3.0	3.6
Interest rate	0.9%	1.0%
Dividend yield		
Volatility	73%	64%

8

## Fibrocell Science, Inc.

## **Notes to Consolidated Financial Statements**

#### (unaudited)

#### **Note 6. 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 June 30, 2014 and December 31, 2013:

	Fair value measurement using						
			Significant other		gnificant bservable		
	Quot	ed prices in	observable		inputs		
(\$ in thousands)	active ma	rkets (Level 1)	inputs (Level 2)	(1	Level 3)		Total
Balance at June 30, 2014							
Assets:							
Cash and cash equivalents	\$	49,536	\$	\$		\$	49,536
Liabilities:							
Warrant liability	\$		\$	\$	14,258	\$	14,258

Fair value measurement using								
		Significant	Si	ignificant				
		other	un	observable				
Quo	ted prices in	observable		inputs				
active m	arkets (Level 1)	inputs (Level 2)	(	(Level 3)		Total		
\$	60,033	\$	\$		\$	60,033		
\$		\$	\$	15,216	\$	15,216		
	active m	¢	Significant other  Quoted prices in active markets (Level 1)  \$ 60,033 \$	Significant other under the state of the sta	Significant other Significant unobservable inputs active markets (Level 1) inputs (Level 2) (Level 3)  \$ 60,033 \$ \$	Significant other Significant unobservable inputs active markets (Level 1) inputs (Level 2) (Level 3)  \$ 60,033 \$ \$ \$		

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

(\$ in thousands)	Warrant Liability
Balance at December 31, 2013	\$ 15,216
Exercise of warrants	
Change in fair value of warrant liability	(958)
Balance at June 30, 2014	\$ 14,258

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 5 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.

#### Fibrocell Science, Inc.

## **Notes to Consolidated Financial Statements**

(unaudited)

#### **Note 7. Share-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 5,600,000 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 3,384,286 options available for grant as of June 30, 2014.

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

	Three moi	nths end e 30,	led	Six months ended June 30,			
(\$ in thousands)	2014		2013		2014		2013
Stock option compensation expense for employees and							
directors	\$ 436	\$	33	\$	736	\$	206
Equity awards for nonemployees issued for services			3		3		3
Total stock-based compensation expense	\$ 436	\$	36	\$	739	\$	209

(\$ in thousands except share and per share data)	Number of shares	Weighted- average exercise price	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2013	2,068,720	\$ 7.93	8.4	\$ 544
Granted	333,000	4.25		
Exercised				
Forfeited	(3,883)	5.89		
Expired	(120)	15.50		
Outstanding at June 30, 2014	2,397,717	\$ 7.42	8.3	\$ 507
Exercisable at June 30, 2014	883,517	\$ 13.09	7.3	\$ 73

The total fair value of shares vested during the six months ended June 30, 2014 was approximately \$0.5 million. As of June 30, 2014, there was approximately \$3.0 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 4.2 years. As of June 30, 2014, there was no unrecognized compensation expense related to performance-based, non-vested non-employee options.

During the six months ended June 30, 2014 and 2013, the weighted average fair market value of the options granted was \$2.74 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 six months ended as of the dates indicated:

	June 30, 2014	June 30, 2013
Expected life (years)	6.25 years	5.0 years
Interest rate	2.0%	0.9%
Dividend yield		
Volatility	70%	69%

## Fibrocell Science, Inc.

## **Notes to Consolidated Financial Statements**

(unaudited)

#### Note 8. Loss Per Share

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.

(\$ in thousands except share and per	For the three mo		nded June	For the six mon		ded June
share data)	2014	,	2013	2014	,	2013
Loss per share - basic:						
Numerator for basic loss per share	\$ (2,257)	\$	(14,637) \$	(16,266)	\$	(19,207)
Denominator for basic loss per share	40,856,815		23,260,802	40,720,958		26,230,358
Basic loss per common share	\$ (0.06)	\$	(0.63) \$	(0.40)	\$	(0.73)
Loss per share - diluted:						
Numerator for diluted loss per share	\$ (2,257)	\$	(14,637) \$	(16,266)	\$	(19,207)
Add back: Fair value of in the money warrants						
outstanding	1,284			1,284		315
Net loss attributable to common share	\$ (3,541)	\$	(14,637) \$	(17,550)	\$	(19,522)
Denominator for basic loss per share	40,856,815		23,260,802	40,720,958		26,230,358
Plus: Incremental shares underlying in the money						
warrants outstanding	394,071			197,035		207,459
Denominator for diluted loss per share	41,250,886		23,260,802	40,917,993		26,437,817
Diluted net loss per common share	\$ (0.09)	\$	(0.63) \$	(0.43)	\$	(0.74)

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 en	ded June 30,	Six months ended June 30,		
	2014	2013	2014	2013	
In the money stock options	852,000	214,000	852,000	214,000	
Out of the money stock options	1,545,717	529,406	1,545,717	592,406	
In the money warrants		1,276,698		1,320	
Out of the money warrants	4,831,352	4,831,352	4,831,352	4,831,352	

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 June 30, 2014 or December 31, 2013.

<b>7D 1</b>	1			c.	$\sim$			
Tal	٦I	$\boldsymbol{e}$	$\cap$ 1	1		۱n	tei	ntc

#### Fibrocell Science, Inc.

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

(unaudited)

**Note 9. Equity (continued)** 

Common stock

In connection with the execution of the Second Amendment to the Exclusive Channel Collaboration Agreement (the Second Amendment ) on January 10, 2014 between the Company and Intrexon Corporation (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). 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 the Company s collaboration with Intrexon, see Note 11.

#### Note 10. Income Taxes

In accordance with ASC Topic No. 270 Interim Reporting and ASC Topic No. 740 Income Taxes , the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the six months ended June 30, 2014 and 2013, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company had not recorded its net deferred tax asset as of either June 30, 2014 or December 31, 2013, because it maintains a full valuation against all deferred tax assets as management has determined that it is not more likely than not that the Company will realize these future tax benefits.

#### Note 11. 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.

Pursuant to the Channel Agreement and Amendments, the Company engaged Intrexon for support services for the development of new products covered under the Channel Agreement and Amendments, and will reimburse Intrexon for its fully-loaded cost for time and materials for transgenes, cell processing, or other work performed by Intrexon for such research and manufacturing. For the three and six months ended June 30, 2014, the Company incurred expenses of \$0.7 million and \$1.8 million, respectively, for work performed. For the three and six months ended June 30, 2013, the Company incurred expenses of \$0.6 million and \$1.0 million, respectively, for work performed. As of June 30, 2014 and December 31, 2013, the Company had outstanding trade payables with Intrexon of \$0.2 million and \$1.3 million, respectively.

## 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:

•	the progress and results of our clinical trials of our cell therapy applications, including 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	s, and such other target 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 advance	ced into human clinical trials;

- the cost of manufacturing related to our pre-clinical and 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;
- the costs, timing and outcome of regulatory review of our product engines;
- 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;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our cell therapy applications;
- the number and development requirement of other product engines that we pursue;

•	the emergence of competing technologies and other adverse market developments;
•	the extent to which we acquire or invest in businesses, products and technologies;
•	our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators;
• maintainin	any adverse claims relating to our intellectual property and the costs of preparing, filing and prosecuting patent applications and g, enforcing and defending intellectual property related claims; and
•	our dependence on physicians to correctly follow our established protocols for the safe and optimal administration of our product.
reliance or in the forw Factors of actual resu	ot actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue in our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed vard-looking statements we make. We have included important factors in the cautionary statements included in Part I Item 1A Risk of the Annual Report on Form 10-K, as amended on June 2, 2014, for the year ended December 31, 2013 that we believe could cause alts or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.
	d read this quarterly report on Form 10-Q in conjunction with the documents that we reference herein. We do not assume any to update any forward-looking statements.
General	
	autologous cell therapy company primarily focused on developing first-in-class treatments for rare and serious skin and connective ases with high unmet medical needs. Based on our proprietary autologous fibroblast technology, we are
	13

## Table of Contents

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.

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. 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 on June 2, 2014, other than those discussed below.

On May 6, 2014, the Audit Committee of the Company s Board of Directors, 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 should no longer be relied upon. On June 2, 2014, the Company restated all affected interim and annual periods in its Annual Report on Form 10-K/A (Amendment No. 2) for the fiscal year ended December 31, 2013 in an SEC approved omnibus filing. As such, the comparative information provided for the three and six months ended June 30, 2013 contained in the results of operations discussed below reflect these previously restated amounts. In addition, there have been other reclassifications made to the prior year s results of operations to conform to the current year s presentation.

Warrant Liability: We account 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. We 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 June 30, 2014 and 2013

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

		Three mon	ded	Increase		
		June	e <b>30</b> ,		(Decrease)	
(\$ in thousands)	20	14		2013	\$	%
Total revenue	\$	58	\$	62 \$	(4)	-0.06%
Cost of sales		547		2,104	(1,557)	-74.0%
Gross loss	\$	(489)	\$	(2,042) \$	1,553	-76.0%

Revenue was immaterial for each of the three months ended June 30, 2014 and 2013. Revenue is booked based on the shipment of LAVIV® to patients.

Cost of sales was approximately \$0.5 million and \$2.1 million for the three months ended June 30, 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 \$1.6 million is primarily due to the transition away from the aesthetic market (LAVIV®) and to a focus on research and development as evidenced by a reduction in the number of biopsies and injections performed during the three months ended June 30, 2014 as compared to the three months ended June 30, 2013.

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. 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	nths ende	ed	Increase (Decrease	
(\$ in thousands)	2014		2013	\$	%
Compensation and related					
expense	\$ 1,352	\$	643	\$ 709	110.3%

Edgar Filing: Fibrocell Science, Inc. - Form 10-Q

Professional fees	670	266	404	151.9%
Marketing expense	59	134	(75)	-56.0%
Legal expense	307	209	98	46.9%
Facilities and related expense				
and other	1,099	1,042	57	5.5%
Total selling, general and				
administrative expense	\$ 3,487	\$ 2,294 \$	1,193	52.0%

Selling, general and administrative expense increased by approximately \$1.2 million, or 52%, to \$3.5 million for the three months ended June 30, 2014 as compared to \$2.3 million for the three months ended June 30, 2013. Compensation and related expense increased \$0.7 million due to additional costs for salaries, bonuses and stock compensation. Professional fees increased \$0.4 million and legal costs increased \$0.1 million due to the costs of our warrant restatement project in the second quarter of 2014. Marketing expense decreased \$0.1 million as our strategic focus has shifted away from our commercial product LAVIV®. Facilities and related expense and other increased \$0.1 million due to an increase in office costs.

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.

## Table of Contents

Research and development expense was comprised of the following:

	Three mon		Increase (Decrease)		
(\$ in thousands)	2014		2013	\$	%
Direct costs:					
Restrictive Burn Scarring	\$ 202	\$	60	\$ 142	236.7%
Vocal Cord Scarring	150		53	97	183.0%
Recessive Dystrophic Epidermolysis Bullosa	863		345	518	150.1%
Morphea Profunda/ Linear Scleroderma	73			73	100.0%
Cutaneous Eosinophilias	73			73	100.0%
azficel-T	193		403	(210)	-52.1%
Ehlers-Danlos Syndrome hypermobility type	8			8	100.0%
Other	37		150	(113)	-75.3%
Total direct costs	1,599		1,011	588	58.2%
Indirect costs:					
Regulatory costs	227		226	1	0.40%
Intangible amortization	138		138		
Indirect lab costs	581		38	543	1428.9%
Compensation and related expense	75		65	10	15.4%
Total indirect costs	1,021		467	554	118.6%
Total research and development expense	\$ 2,620	\$	1,478	\$ 1,142	77.3%

Total research and development expense increased \$1.1 million to approximately \$2.6 million for the three months ended June 30, 2014 as compared to \$1.5 million for the three months ended June 30, 2013. The overall increase is due to a \$0.1 million increase related to research and development costs in connection with our collaboration with Intrexon, increased costs of \$0.2 million related to enrollment of our phase II clinical trials, increased manufacturing and laboratory costs of \$0.5 million, and an increase of \$0.3 million in other spending.

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

Restrictive Burn Scarring (RBS) Costs increased approximately \$0.1 million compared to the three months ended June 30, 2013 due to additional costs related to our phase II clinical trials currently in enrollment.

<u>Vocal Cord Scarring ( VCS</u> ) Costs increased approximately \$0.1 million compared to the three months ended June 30, 2013 due to additional costs related to our phase II clinical trials currently in enrollment.

Recessive Dystrophic Epidermolysis Bullosa (RDEB) Costs increased approximately \$0.5 million compared to the three months ended June 30, 2013 due to the expansion of our pre-clinical development program for RDEB during the three months ended June 30, 2014.

Morphea Profunda/ Linear Scleroderma This program began in the second half of 2013. Costs during the three months ended June 30, 2014 were approximately \$0.1 million and related to early stage pre-clinical development.

<u>Cutaneous Eosinophilias</u> This program began in the second half of 2013. Costs during the three months ended June 30, 2014 were approximately \$0.1 million and related to early stage pre-clinical development.

<u>Azficel-T</u> Costs decreased approximately \$0.2 million compared to the three months ended June 30, 2013 due to the reduction in our process development program for azficel-T during the three months ended June 30, 2014.

Ehlers-Danlos Syndrome hypermobility type No substantive work has yet begun on the development of this pre-clinical program.

Change in Revaluation of Warrant Liability. During the three months ended June 30, 2014 and 2013, we recorded non-cash warrant income of approximately \$4.0 million and non-cash warrant expense of \$8.8 million in our statements of operations, respectively.

*Other Income.* During the three months ended June 30, 2014, we recorded approximately \$0.3 million of other income related to a settlement agreement with one of our suppliers. There was no such income during the three months ended June 30, 2013.

*Net Loss.* Net loss for the three months ended June 30, 2014 and June 30, 2013 was \$2.3 million and \$14.6 million, respectively, representing a decrease of approximately \$12.4 million. The change is primarily due to a decrease of \$12.8 million in the non-cash revaluation of the warrant liability offset by an increase in other income of \$0.3 million.

#### Comparison of Six Months Ended June 30, 2014 and 2013

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

		Six mont June		d	Increase (Decrease)	
(\$ in thousands)	2	2014	,	2013	\$	%
Total revenue	\$	104	\$	88	\$ 16	18.2%
Cost of sales		1,340		4,317	(2,977)	-69.0%
Gross loss	\$	(1,236)	\$	(4,229)	\$ 2,993	-70.8%

Revenue was immaterial for each of the six months ended June 30, 2014 and 2013. Revenue is booked based on the shipment of LAVIV® to patients.

Cost of sales was approximately \$1.3 million and \$4.3 million for the six months ended June 30, 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 \$2.9 million is primarily due to the transition away from the aesthetic market (LAVIV®) and to a focus on research and development as evidenced by a reduction in the number of biopsies and injections performed during the six months ended June 30, 2014 as compared to the six months ended June 30, 2013.

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. 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:

		Six months ended June 30,				Increase (Decrease)		
(\$ in thousands)	2	014		2013		\$	<b>%</b>	
	\$	2,638	\$	1,616	\$	1,022	63.2%	

Edgar Filing: Fibrocell Science, Inc. - Form 10-Q

Compensation and related				
expense				
Professional fees	1,002	449	553	123.2%
Marketing expense	81	244	(163)	-66.8%
Legal expense	467	402	65	16.2%
Facilities and related expense				
and other	2,114	1,793	321	17.9%
Total selling, general and				
administrative expense	\$ 6,302	\$ 4,504	\$ 1,798	39.9%

Selling, general and administrative expense increased by approximately \$1.8 million, or 40%, to \$6.3 million for the six months ended June 30, 2014 as compared to \$4.5 million for the six months ended June 30, 2013. Compensation and related expense increased \$1.0 million due to additional costs for salaries, bonuses and stock compensation. Professional fees increased \$0.6 million and legal costs increased \$0.1 million primarily due to the costs of our warrant restatement project in the second quarter of 2014 as well as increase in other consulting expenses. Marketing expense decreased \$0.2 million as our strategic focus has shifted away from our commercial product LAVIV®. Facilities and related expense and other increased \$0.3 million due to an increase in office costs.

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:

		hs ended e 30,		Increase (Decrease)	
(\$ in thousands)	2014		2013	\$	%
Direct costs:					
Restrictive Burn Scarring	\$ 334	\$	123	\$ 211	171.5%
Vocal Cord Scarring	273		107	166	155.1%
Recessive Dystrophic					
Epidermolysis Bullosa	1,564		528	1,036	196.2%
Morphea Profunda/ Linear					
Scleroderma	165			165	100.0%
Cutaneous Eosinophilias	165			165	100.0%
azficel-T	251		766	(515)	-67.2%
Ehlers-Danlos Syndrome					
hypermobility type	5,169			5,169	100.0%
Other	187		329	(142)	-43.2%
Total direct costs	8,108		1,853	6,255	337.6%
Indirect costs:					
Regulatory costs	431		484	(53)	-11.0%
Intangible amortization	276		276		
Indirect lab costs	1,095		239	856	358.2%
Compensation and related					
expense	148		133	15	11.3%
Total indirect costs	1,950		1,132	818	72.3%
Total research and development					
expense	\$ 10,058	\$	2,985	\$ 7,073	237.0%

Total research and development expense increased \$7.1 million to approximately \$10.1 million for the six months ended June 30, 2014 as compared to \$3.0 million for the six months ended June 30, 2013. The increase is due primarily to stock issuance costs of approximately \$5.2 million and a \$0.8 million increase related to research and development costs incurred in the six months ended June 30, 2014, both in connection with our collaboration with Intrexon. In addition, there was a \$0.9 million increase in manufacturing and laboratory costs and an increase of \$0.2 million in other spending.

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

Restrictive Burn Scarring (RBS) Costs increased approximately \$0.2 million compared to the six months ended June 30, 2013 due to additional costs related to our phase II clinical trials currently in enrollment.

<u>Vocal Cord Scarring ( VCS</u> ) Costs increased approximately \$0.2 million compared to the six months ended June 30, 2013 due to additional costs related to our phase II clinical trials currently in enrollment.

Recessive Dystrophic Epidermolysis Bullosa (RDEB) Costs increased approximately \$1.0 million compared to the six months ended June 30, 2013 due to the expansion of our pre-clinical development program for RDEB during the six months ended June 30, 2014.

Morphea Profunda/ Linear Scleroderma This program began in the second half of 2013. Costs during the six months ended June 30, 2014 were approximately \$0.2 million and related to early stage pre-clinical development.

<u>Cutaneous Eosinophilias</u> This program began in the second half of 2013. Costs during the six months ended June 30, 2014 were approximately \$0.2 million and related to early stage pre-clinical development.

<u>Azficel-T</u> Costs decreased approximately \$0.5 million compared to the six months ended June 30, 2013 due to the reduction in our process development program for azficel-T during the six months ended June 30, 2014.

Ehlers-Danlos Syndrome hypermobility type Costs to date are approximately \$5.2 million and represent the cost of the 2014 supplemental stock issuance in connection with the second amendment to the exclusive channel collaboration agreement with Intrexon. No substantive work has yet begun on the development of this pre-clinical program.

Change in Revaluation of Warrant Liability. During the six months ended June 30, 2014 and 2013, we recorded non-cash warrant income of approximately \$1.0 million and non-cash warrant expense of \$7.5 million in our statements of operations, respectively.

*Other Income.* During the six months ended June 30, 2014, we recorded approximately \$0.4 million of other income, primarily due to a settlement agreement with one of our suppliers. There was no such income during the six months ended June 30, 2013.

#### Table of Contents

Net Loss. Net loss for the six months ended June 30, 2014 and June 30, 2013 was \$16.3 million and \$19.2 million, respectively, representing a decrease of approximately \$3.0 million. The change is primarily due to a decrease of \$8.4 million in the non-cash revaluation of the warrant liability, offset by \$5.2 million in costs during the first quarter for the 2014 supplemental stock issuance in connection with the Second Amendment to the Channel Agreement with Intrexon

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

The following table summarizes our cash flows from operating, investing and financing activities for the six months ended June 30, 2014 and 2013:

Statement of Cash Flows Data: Six months End		ded June 30,		
(\$ in thousands)		2014		2013
Cash used in operating activities	\$	(10,286)	\$	(10,417)
Cash used in investing activities	\$	(211)	\$	(122)
Cash provided by financing activities	\$		\$	4

*Operating Activities*. Cash used in operating activities during the six months ended June 30, 2014 was approximately \$10.3 million, relatively consistent with cash used in operating activities during the six months ended June 30, 2013.

*Investing Activities.* Cash used in investing activities amounted to \$0.2 million for the six months ended June 30, 2014 and \$0.1 million for the six months ended June 30, 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 six months ended June 30, 2014. For the six months ended June 30, 2013, cash provided by financing activities amounted to less than \$0.1 million on subscriptions of common stock.

Working Capital

As of June 30, 2014, we had cash and cash equivalents of approximately \$49.5 million and working capital of approximately \$47.5 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 of equity or debt. 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.

#### **Contractual Obligations**

On April 6, 2005, we 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, we entered into an amended and restated lease (the Amended Lease ) for an additional term of 10 years through the year 2023. At June 30, 2014, our minimum lease payments under the Amended Lease total approximately \$11.7 million.

During the six month period ended June 30, 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**

See Note 3 in the accompanying notes to the consolidated financial statements for discussion on recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

None

19

<b>m</b>	. 1		c	$\sim$			
Tα	hl	e	Ωt	Cc	n	tei	าts

Item 4. Controls and Procedures.

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

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 promulgated under the Exchange Act as of June 30, 2014. Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the SEC. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, management is required to apply its judgment in evaluating the benefits of possible disclosure controls and procedures relative to their costs to implement and maintain.

Based on management sevaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

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

Except for the changes described below to remediate the previously reported material weakness, there have been no changes in our internal control over financial reporting during the quarter ended June 30, 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Remediation of Material Weakness

As more fully described in Part II, Item 9A of our Annual Report on Form 10-K, as amended on June 2, 2014, for the year ended December 31, 2013 and as referenced in Note 2 to the consolidated financial statements included in this Quarterly Report on Form 10-Q, a material weakness existed in our internal control over financial reporting. As a result, management concluded that our internal control was not effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for financial reporting in accordance with GAAP as of December 31, 2013 and March 31, 2014. The material weakness was as follows:

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.

Of the Company s 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 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.

The Company has devoted, and plans to continue to devote, significant efforts and resources to the remediation and improvement of its internal control over financial reporting. While the Company has processes to identify and intelligently apply developments in accounting, the Company plans to continue to enhance these processes to better evaluate its research and understanding of the nuances of increasingly complex accounting standards. The Company implemented the following changes in its internal control over financial reporting during the three months ended June 30, 2014:

provided enhanced access to accounting literature, research materials and documents; and

#### Table of Contents

• increased communication among its personnel and third party professionals with whom the Company consults regarding complex accounting applications.

We believe that the controls that we have implemented have remediated this material weakness in our internal control over financial reporting. As we continue to evaluate and work to improve our internal control over financial reporting, we may determine to take additional measures to address the material weakness or determine to supplement or modify certain of the remediation efforts described above.

#### **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 2 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.

#### Table of Contents

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 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

#### Table of Contents

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
None	
Item 3.	Defaults Upon Senior Securities
None	
Item 4.	Mine Safety Disclosure
Not Applicable	
Item 5.	Other Information
None	

Item 6. Exhibits

### (a) Exhibits

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
10.1+	Exclusive License Agreement, dated June 1, 2014, by and between The Regents of the University of California and the
	Company (which we refer to as the BMP2 Agreement )
10.2+	Exclusive License Agreement, dated June 1, 2014, by and between The Regents of the University of California and the
	Company (which we refer to as the Genomic Stability Agreement )
10.3	Fibrocell Science, Inc. 2009 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to our Current
	Report on Form 8-K filed on June 20, 2014)
31.1*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

<sup>+</sup> Confidential treatment has been requested as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.

<sup>\*</sup> Filed or furnished, as applicable herewith.

# 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 thereunto duly authorized.

### FIBROCELL SCIENCE, INC.

/s/ Gregory Weaver Gregory Weaver By:

SVP and Chief Financial Officer

Date: August 11, 2014

# Table of Contents

# INDEX TO EXHIBITS

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
10.1+	Exclusive License Agreement, dated June 1, 2014, by and between The Regents of the University of California and the
	Company (which we refer to as the BMP2 Agreement )
10.2+	Exclusive License Agreement, dated June 1, 2014, by and between The Regents of the University of California and the
	Company (which we refer to as the Genomic Stability Agreement )
10.3	Fibrocell Science, Inc. 2009 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to our Current
	Report on Form 8-K filed on June 20, 2014)
31.1*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

<sup>+</sup> Confidential treatment has been requesteded as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.

<sup>\*</sup> Filed or furnished, as applicable herewith.