

Fibrocell Science, Inc.
Form 10-Q
November 07, 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 September 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 ☒ No ☐

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 ☒ No ☐

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 ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

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 ☒ No ☐

As of October 31, 2014, issuer had 40,856,815 shares issued and outstanding of common stock, par value \$0.001.

Table of Contents

TABLE OF CONTENTS

	PAGE
<u>Part I.</u>	
<u>Financial Information</u>	
<u>Item 1.</u>	
<u>Financial Statements</u>	
<u>Consolidated Balance Sheets (unaudited) as of September 30, 2014 and December 31, 2013</u>	1
<u>Consolidated Statements of Operations (unaudited) For the three and nine months ended September 30, 2014 and 2013</u>	2
<u>Consolidated Statement of Stockholders' Equity (unaudited) For the nine months ended September 30, 2014</u>	3
<u>Consolidated Statements of Cash Flows (unaudited) For the nine months ended September 30, 2014 and 2013</u>	4
<u>Notes to Consolidated Financial Statements (unaudited)</u>	5
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 4.</u>	
<u>Controls and Procedures</u>	21
<u>Part II.</u>	
<u>Other Information</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	21
<u>Item 1A.</u>	
<u>Risk Factors</u>	21
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
<u>Item 3.</u>	
<u>Defaults upon Senior Securities</u>	23
<u>Item 4.</u>	
<u>Mine Safety Disclosure</u>	23
<u>Item 5.</u>	
<u>Other Information</u>	23
<u>Item 6.</u>	
<u>Exhibits</u>	23
<u>Signature Page</u>	24

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements.****Fibrocell Science, Inc.****Consolidated Balance Sheets****(unaudited)****(\$ in thousands, except share and per share data)**

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,215	\$ 60,033
Accounts receivable, net of allowance for doubtful accounts of \$20 and \$5, respectively	2	28
Inventory	610	597
Prepaid expenses and other current assets	480	1,202
Total current assets	45,307	61,860
Property and equipment, net of accumulated depreciation of \$994 and \$735, respectively	1,749	1,701
Intangible assets, net of accumulated amortization of \$1,516 and \$1,102, respectively	4,824	5,238
Other assets	1	215
Total assets	\$ 51,881	\$ 69,014
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,054	\$ 2,958
Accrued expenses	2,041	487
Deferred revenue	479	148
Total current liabilities	3,574	3,593
Warrant liability	14,081	15,216
Other long term liabilities	679	539
Total liabilities	18,334	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	142,852	136,694
Accumulated deficit	(109,346)	(87,068)
Total stockholders' equity	33,547	49,666
Total liabilities and stockholders' equity	\$ 51,881	\$ 69,014

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

Table of Contents**Fibrocell Science, Inc.****Consolidated Statements of Operations****(unaudited)****(\$ in thousands, except share and per share data)**

	Three months ended		Three months ended		Nine months ended		Nine months ended	
	September 30,		September 30,		September 30,		September 30,	
	2014		2013		2014		2013	
Product sales	\$	20	\$	68	\$	124	\$	156
Cost of sales		512		1,792		1,852		6,109
Gross loss		(492)		(1,724)		(1,728)		(5,953)
Selling, general and administrative expense		2,810		2,746		9,112		7,250
Research and development expense		2,889		8,651		12,947		11,636
Operating loss		(6,191)		(13,121)		(23,787)		(24,839)
Other income (expense):								
Warrant revaluation and other finance income (expense)		177		6,520		1,135		(960)
Other income						370		
Interest income		2				4		
Loss from continuing operations before income taxes		(6,012)		(6,601)		(22,278)		(25,799)
Deferred tax benefit								
Loss from continuing operations, net of tax		(6,012)		(6,601)		(22,278)		(25,799)
Loss from discontinued operations, net of tax				(4)				(13)
Net loss	\$	(6,012)	\$	(6,605)	\$	(22,278)	\$	(25,812)
Per Share Information:								
Loss from continuing operations, net of tax basic	\$	(0.15)	\$	(0.24)	\$	(0.55)	\$	(0.97)
Loss from discontinued operations, net of tax basic								
Net loss per common share basic	\$	(0.15)	\$	(0.24)	\$	(0.55)	\$	(0.97)
Loss from continuing operations, net of tax diluted	\$	(0.17)	\$	(0.31)	\$	(0.60)	\$	(1.04)
Loss from discontinued operations, net of tax diluted								
Net loss per common share diluted	\$	(0.17)	\$	(0.31)	\$	(0.60)	\$	(1.04)
Weighted average number of common shares outstanding								
- Basic		40,856,815		27,158,394		40,766,741		26,543,099
- Diluted		41,300,105		27,802,557		41,045,861		26,896,268

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

Table of Contents

Fibrocell Science, Inc.

Consolidated Statements of Stockholders' Equity

(unaudited)

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

	Common Stock		Additional		Accumulated		Total Equity
	Shares	Amount		paid-in capital		deficit	
Balance, December 31, 2013	39,832,225	\$ 40	\$	136,694	\$	(87,068)	\$ 49,666
Stock-based compensation expense				1,005			1,005
Issuance of common stock	1,024,590		1	5,153			5,154
Net loss						(22,278)	(22,278)
Balance, September 30, 2014	40,856,815	\$ 41	\$	142,852	\$	(109,346)	\$ 33,547

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

Table of Contents
Fibrocell Science, Inc.
Consolidated Statements of Cash Flows
(unaudited)
(\$ in thousands, except share and per share data)

	Nine months ended September 30, 2014	Nine months ended September 30, 2013
Cash flows from operating activities:		
Net loss	\$ (22,278)	\$ (25,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,005	928
Stock issued for supplemental stock issuance agreement	5,154	6,406
Warrant revaluation and other finance (income) expense	(1,135)	960
Depreciation and amortization	673	693
Provision for doubtful accounts	15	(7)
Change in operating assets and liabilities:		
Accounts receivable	11	23
Inventory	(13)	(97)
Prepaid expenses and other current assets	722	(133)
Other assets	214	(214)
Accounts payable	(1,904)	248
Accrued expenses and other long-term liabilities	1,693	973
Deferred revenue	331	(7)
Net cash used in operating activities	(15,512)	(16,039)
Cash flows from investing activities:		
Purchase of property and equipment	(307)	(162)
Net cash used in investing activities	(307)	(162)
Cash flows from financing activities:		
Subscriptions received		2,004
Deferred equity costs		(274)
Net cash provided by financing activities		1,730
Effect of exchange rate changes on cash balances	1	
Net decrease in cash and cash equivalents	(15,818)	(14,471)
Cash and cash equivalents, beginning of period	60,033	31,346
Cash and cash equivalents, end of period	\$ 44,215	\$ 16,875

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

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

The Company 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. Fibrocell's lead orphan drug program is in late-stage pre-clinical development for the treatment of RDEB (recessive dystrophic epidermolysis bullosa) and DDEB (dominant dystrophic epidermolysis bullosa). The Company's collaboration with Intrexon Corporation (NYSE:XON) (Intrexon), a leader in synthetic biology, includes using genetically-modified autologous fibroblast cells to express target proteins that are inactive or missing from patients with rare genetic skin and connective tissue disorders. The Company is also pursuing medical applications for azficel-T, the Company's proprietary autologous fibroblast technology, for vocal cord scarring and restrictive burn scarring. Both indications are currently in Phase II clinical trials. The Company's ongoing scientific research collaboration with the University of California, Los Angeles (UCLA) has yielded discoveries and technologies related to stem cells and regenerative cells in human skin. The technologies from this collaboration and the Company's exclusive license agreements with UCLA enable the Company 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.

On August 18, 2014, the Company notified the NYSE MKT of its intention to delist its common stock from the NYSE MKT and to list on The NASDAQ Capital Market of The NASDAQ Stock Market LLC (NASDAQ). The Company's securities ceased trading on the NYSE MKT effective at the close of business on August 28, 2014 and commenced trading on NASDAQ on August 29, 2014 when the market opened. The Company's common stock continues to trade under its current trading symbol FCSC.

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.

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

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 nine months ended September 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 nine months ended September 30, 2013 to conform to the presentation for the three and nine months ended September 30, 2014 in this Form 10-Q. These reclassifications were made in conjunction with the Company's de-emphasis on its commercial product LAVIV® and towards further research and development of the underlying azficel-T process as well as on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

For the three and nine months ended September 30, 2014, amortization expense of approximately \$0.1 million and \$0.4 million, respectively, was included in research and development expense on the Consolidated Statements of Operations. For the three and nine months ended September 30, 2013, amortization expense of approximately \$0.1 million and \$0.4 million, respectively, was reclassified from cost of sales to research and development expense on the Consolidated Statements of Operations to conform to the current

Table of Contents

Fibrocell Science, Inc.

Notes to Consolidated Financial Statements

(unaudited)

Note 2. Basis of Presentation (continued)

presentation. For the three and nine months ended September 30, 2014, the Company's Food and Drug Administration (FDA) license fees related to its Biologics License Application (BLA) of approximately \$0.2 million and \$0.5 million, respectively, were included in research and development expense on the Consolidated Statements of Operations. For the three and nine months ended September 30, 2013, FDA license fees of approximately \$0.2 million and \$0.5 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.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

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

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 the Company's 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 the Company changed corporate strategy in late 2013 to de-emphasize sales of LAVIV® into the aesthetic markets, and towards further research and development of the underlying azficel-T process as well as on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

Research and Development Expenses

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

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 manufacture product for clinical trial use and 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:

Table of Contents**Fibrocell Science, Inc.****Notes to Consolidated Financial Statements****(unaudited)****Note 3. Summary of Significant Accounting Policies (continued)**

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 Topic 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 nine months ended September 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 vocal cord scarring and a clinical development program for restrictive burn 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 the 12 year period of exclusivity, commencing in June 2011, granted by the FDA.

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 the FASB's *ASC Subtopic 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 nine months ended September 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

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

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 September 30, 2014, the Company did not have any uncertain tax positions.

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements Going Concern (ASC Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern . This ASU requires that an entity's management shall evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Implementation of this ASU is effective for the annual and interim periods ending after December 15, 2016 and early application is permitted.

In May 2014, the FASB issued 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's core principle is

Table of Contents**Fibrocell Science, Inc.****Notes to Consolidated Financial Statements****(unaudited)****Note 3. Summary of Significant Accounting Policies (continued)**

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. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated 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)	September 30, 2014	December 31, 2013
Raw materials	\$ 327	\$ 511
Work in process	283	86
Inventory	\$ 610	\$ 597

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 ASC 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

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

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		Exercise Price	Expiration Dates
	September 30, 2014	December 31, 2013		
Liability-classified warrants				
Issued in March 2010 and Series A, B and D Preferred Stock offerings	2,640,534	2,640,534	\$ 6.25	Oct 2015-Dec 2016
Issued in B, D and E 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 nine months ended September 30, 2014.

Table of Contents

Fibrocell Science, Inc.

Notes to Consolidated Financial Statements

(unaudited)

Note 5. Warrants (continued)

Liability-classified Warrants

The foregoing warrants are recorded as liabilities at their estimated fair value at the date of issuance, with 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 the Company's warrant liability for the three and nine months ended September 30, 2014 resulted in non-cash income of approximately \$0.2 million and \$1.1 million, respectively. The change in the estimated fair value of the Company's warrant liability for the three and nine months ended September 30, 2013 resulted in a non-cash impact of approximately \$6.5 million of income and \$1.0 million of expense, 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:

	September 30, 2014	September 30, 2013
Weighted average remaining expected life (years)	2.8	3.8
Interest rate	0.9%	0.8%
Dividend yield		
Volatility	71%	63%

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 September 30, 2014 and December 31, 2013:

Table of Contents**Fibrocell Science, Inc.****Notes to Consolidated Financial Statements****(unaudited)****Note 6. Fair Value Measurements (continued)**

(\$ in thousands)	Quoted prices in active markets (Level 1)	Fair value measurement using		Total
		Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Balance at September 30, 2014				
Assets:				
Cash and cash equivalents	\$ 44,215	\$	\$	\$ 44,215
Liabilities:				
Warrant liability	\$	\$	\$ 14,081	\$ 14,081

(\$ in thousands)	Quoted prices in active markets (Level 1)	Fair value measurement using		Total
		Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Balance at December 31, 2013				
Assets:				
Cash and cash equivalents	\$ 60,033	\$	\$	\$ 60,033
Liabilities:				
Warrant liability	\$	\$	\$ 15,216	\$ 15,216

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

(\$ in thousands)	Warrant Liability
Balance at December 31, 2013	\$ 15,216
Exercise of warrants	
Change in fair value of warrant liability	(1,135)
Balance at September 30, 2014	\$ 14,081

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 the Company's current assets and current liabilities approximate their reported carrying amounts. There were no transfers between Level 1, 2 and 3 during the periods presented.

Note 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. The Company issued 206,000 options 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 of Directors 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 3,374,803 options available for grant as of September 30, 2014.

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

Table of Contents**Fibrocell Science, Inc.****Notes to Consolidated Financial Statements****(unaudited)****Note 7. Share-Based Compensation (continued)**

(\$ in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Stock option compensation expense for employees and directors	\$ 266	\$ 620	\$ 1,002	\$ 826
Equity awards for nonemployees issued for services		99	3	102
Total stock-based compensation expense	\$ 266	\$ 719	\$ 1,005	\$ 928

(\$ 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	348,000	4.19		
Exercised				
Forfeited	(144,883)	4.05		
Expired	(5,637)	13.94		
Outstanding at September 30, 2014	2,266,200	\$ 7.59	8.3	\$ 1
Exercisable at September 30, 2014	1,096,250	\$ 11.46	7.5	\$

The total fair value of shares vested during the nine months ended September 30, 2014 was approximately \$1.1 million. As of September 30, 2014, there was approximately \$2.7 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 4.0 years. As of September 30, 2014, there was no unrecognized compensation expense related to performance-based, non-vested non-employee options.

During the nine months ended September 30, 2014 and 2013, the weighted average fair market value of the options granted was \$2.64 and \$3.47, respectively. The fair market value of these options was computed using the Black-Scholes option-pricing model with the following key weighted average assumptions for the nine months ended as of the dates indicated:

	September 30, 2014	September 30, 2013
Expected life (years)	5.9	5.6
Interest rate	1.9%	1.4%
Dividend yield		
Volatility	70%	71%

Note 8. Loss Per Share

Basic loss per share is computed by dividing 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.

Table of Contents**Fibrocell Science, Inc.****Notes to Consolidated Financial Statements****(unaudited)****Note 8. Loss Per Share (continued)**

(\$ in thousands except share and per share data)	For the three months ended September 30,		For the nine months ended September 30,	
	2014	2013	2014	2013
Loss per share - basic:				
Numerator for basic loss per share	\$ (6,012)	\$ (6,605)	\$ (22,278)	\$ (25,812)
Denominator for basic loss per share	40,856,815	27,158,394	40,766,741	26,543,099
Basic loss per common share	\$ (0.15)	\$ (0.24)	\$ (0.55)	\$ (0.97)
Loss per share - diluted:				
Numerator for diluted loss per share	\$ (6,012)	\$ (6,605)	\$ (22,278)	\$ (25,812)
Add back: Fair value of in the money warrants outstanding	1,098	1,887	2,364	2,202
Net loss attributable to common share	\$ (7,110)	\$ (8,492)	\$ (24,642)	\$ (28,014)
Denominator for basic loss per share	40,856,815	27,158,394	40,766,741	26,543,099
Plus: Incremental shares underlying in the money warrants outstanding	443,290	644,163	279,120	353,169
Denominator for diluted loss per share	41,300,105	27,802,557	41,045,861	26,896,268
Diluted net loss per common share	\$ (0.17)	\$ (0.31)	\$ (0.60)	\$ (1.04)

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
In the money stock options	15,000	198,000	15,000	198,000
Out of the money stock options	2,392,200	1,070,720	2,392,200	1,070,720
In the money warrants				
Out of the money warrants	4,831,352	4,831,352	4,831,352	4,831,352

Note 9. Equity*Preferred stock*

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

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 September 30, 2014 or December 31, 2013.

Table of Contents

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 1,024,590 shares issued to Intrexon as a technology access fee. The 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 270 Interim Reporting* and *ASC Topic 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 nine months ended September 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 September 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 Agreement with Related Party

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

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

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 September 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, as amended, the Company engaged Intrexon for support services for the development of new products covered under the Channel Agreement, as amended, 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 nine months ended September 30, 2014, the Company incurred expenses of \$1.2 million and \$3.0 million, respectively, for work performed. For the three and nine months ended September 30, 2013, the Company incurred expenses of \$1.4 million and \$2.4 million, respectively, for work performed. As of September 30, 2014 and December 31, 2013, the Company had outstanding payables to Intrexon of \$0.9 million and \$1.3 million, respectively.

Table of Contents

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

This report contains certain forward-looking statements relating to us 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 vocal cord scars, restrictive burn scars and genetically-modified orphan indications, 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 advanced into human clinical trials;
- the cost of manufacturing related to our pre-clinical studies and clinical trials;
- our ability to meet requisite regulations or receive regulatory approvals in the United States and in Europe, our ability to retain any regulatory approvals that we may obtain and the absence of adverse regulatory developments in the United States and Europe;
- the costs, timing and outcome of regulatory review of our product engines;
- the dependence on our 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 research, development and production at such facility;
- our dependence on one supplier for genetically-modified products which are critical to the completion of the Company's cell therapy applications;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our cell therapy applications;

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

- the number and development requirements 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;
- any adverse claims relating to our intellectual property and the costs of preparing, filing and prosecuting patent applications and maintaining, 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.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in Part I Item 1A Risk Factors 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 actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

You should read this quarterly report on Form 10-Q in conjunction with the documents that we reference herein. We do not assume any obligation to update any forward-looking statements.

Table of Contents

General

We are an autologous cell therapy company primarily focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. Fibrocell's lead orphan drug program is in late-stage pre-clinical development for the treatment of RDEB (recessive dystrophic epidermolysis bullosa) and DDEB (dominant dystrophic epidermolysis bullosa). Working in collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology, Fibrocell is genetically modifying autologous fibroblast cells to express target proteins that are inactive or missing from patients with rare genetic skin and connective tissue disorders. Fibrocell is also pursuing medical applications for azficel-T, the Company's proprietary autologous fibroblast technology, for vocal cord scarring and restrictive burn scarring. Both indications are currently in Phase II clinical trials. Driving our innovative therapies is our 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 us 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.

Additional collaborations with the University of California, Los Angeles (UCLA) offer significant potential for future discovery and development of autologous cellular therapeutics. In addition, UCLA has discovered a media supplement that contributes to the genomic stability of induced pluripotent stem cells (iPSCs) while growing in culture. Issues common to genomic stability with iPSC culture has prevented significant advance into clinical trials. This media supplement may allow for the advance in this technology.

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 our 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 our warrants, our 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, we restated all affected interim and annual periods in our 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 nine months ended September 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

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

fair value of the warrants, the warrants cannot be considered indexed to our 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.

Table of Contents

Results of Operations

Comparison of Three Months Ended September 30, 2014 and 2013

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

(\$ in thousands)	Three months ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
Total revenue	\$ 20	\$ 68	\$ (48)	(70.6)%
Cost of sales	512	1,792	(1,280)	(71.4)%
Gross loss	\$ (492)	\$ (1,724)	\$ (1,232)	71.5%

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

Cost of sales was approximately \$0.5 million and \$1.8 million for the three months ended September 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 \$1.3 million is primarily due to a reallocation of manufacturing costs related to research and development expense, increased production efficiency and yield as well as a de-emphasis on commercial sales in the aesthetic market (LAVIV®).

The principal reason for the relatively small level of revenue as compared to the cost of sales is that we changed corporate strategy in late 2013 to de-emphasize commercial sales of azficel-T into the aesthetic markets, and strategically 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:

(\$ in thousands)	Three months ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
Compensation and related expense	\$ 1,145	\$ 1,277	\$ (132)	(10.3)%

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

Severance		170	(170)	(100.0)%
Professional fees	108	58	50	86.2%
Marketing expense	56	2	54	2700.0%
Legal expense	374	114	260	228.1%
Facilities and related expense and other	1,127	1,125	2	0.2%
Total selling, general and administrative expense	\$ 2,810	\$ 2,746	\$ 64	2.3%

Selling, general and administrative expense increased by approximately \$0.1 million, or 2.3%, to \$2.8 million for the three months ended September 30, 2014 as compared to \$2.7 million for the three months ended September 30, 2013. Total compensation expense decreased \$0.3 million overall, \$0.1 million due to lower salaries and \$0.2 million due to lower severance costs. Legal costs increased \$0.3 million due to negotiations with respect to our corporate contracts. Professional fees, marketing expense, and facilities and related expense and other expenses were comparable for the three months ended September 30, 2014 and 2013.

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 strategic shift to develop first-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

Table of Contents

Research and development expense was comprised of the following:

(\$ in thousands)	Three months ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
<i>Direct costs:</i>				
Vocal Cord Scarring	\$ 194	\$ 99	\$ 95	96.0%
Restrictive Burn Scarring	204	101	103	102.0%
RDEB / DDEB	1,135	541	594	109.8%
Autoimmune diseases	74	6,798	(6,724)	(98.9)%
azficel-T	46	519	(473)	(91.1)%
Ehlers-Danlos Syndrome hypermobility type	7		7	100.0%
Other	329	156	173	110.9%
<i>Total direct costs</i>	1,989	8,214	(6,225)	(75.8)%
<i>Indirect costs:</i>				
Regulatory costs	246	212	34	16.0%
Intangible amortization	138	138		
Indirect lab costs	505	3	502	16,733.3%
Compensation and related expense	11	84	(73)	(86.9)%
<i>Total indirect costs</i>	900	437	463	105.9%
Total research and development expense	\$ 2,889	\$ 8,651	\$ (5,762)	(66.6)%

Total research and development expense decreased \$5.8 million to approximately \$2.9 million for the three months ended September 30, 2014 as compared to \$8.7 million for the three months ended September 30, 2013. The overall decrease is due primarily to the decrease in research and development consulting fees and stock issuance costs incurred in connection with our collaboration with Intrexon Corporation. We recorded \$6.4 million for the shares issued for the supplemental stock issuance to Intrexon during the three months ended September 30, 2013. This \$6.4 million decrease is offset by an increase in costs related to our RDEB / DDEB pre-clinical study of approximately \$0.6 million for the three months ended September 30, 2014.

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

Vocal Cord Scarring (VCS) Costs increased approximately \$0.1 million compared to the three months ended September 30, 2013 due to additional costs for enrollment and clinical site fees related to our phase II clinical trial.

Restrictive Burn Scarring (RBS) Costs increased approximately \$0.1 million compared to the three months ended September 30, 2013 due to additional costs for enrollment and clinical site fees related to our phase II clinical trial.

RDEB /DDEB Costs for the Recessive and Dominant Dystrophic Epidermolysis Bullosa program increased approximately \$0.6 million compared to the three months ended September 30, 2013 due to the expansion of our pre-clinical development program and pre-clinical manufacturing costs.

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

Autoimmune diseases The Morphea Profunda/ Linear Scleroderma program began in the second half of 2013. Costs during the three months ended September 30, 2014 were less than \$0.1 million and related to early stage pre-clinical development. The majority of the costs during the three months ended September 30, 2013 is the \$6.4 million cost of the 2013 supplemental stock issuance in connection with the first amendment to the exclusive channel collaboration agreement with Intrexon. The cutaneous eosinophilias indication is no longer being targeted.

Azficel-T Costs decreased approximately \$0.5 million compared to the three months ended September 30, 2013 due to the reduction in our process development program for azficel-T during the three months ended September 30, 2014.

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

Indirect lab costs increased by \$0.5 million primarily due to the 2014 implementation of a standard cost system. A portion of our operational and overhead costs not related to commercial sales were allocated to research and development expense. Similar costs would have been included in cost of sales for the three months ended September 30, 2013.

Warrant Revaluation and Other Finance Income (Expense). During the three months ended September 30, 2014 and 2013, we recorded non-cash warrant income of approximately \$0.2 million and \$6.5 million in our statements of operations, respectively, related to the change in the fair value of our warrants.

Table of Contents

Net Loss. Net loss for the three months ended September 30, 2014 and 2013 was \$6.0 million and \$6.6 million, respectively, representing a decreased loss of approximately \$0.6 million. The change is due to a reduction of \$6.3 million in the non-cash warrant revaluation income offset by a \$5.8 million decrease in research and development expense. The research and development expense decrease is related to the \$6.4 million cost of the 2013 supplemental stock issuance, in connection with the first amendment to the exclusive channel collaboration agreement with Intrexon, offset by \$0.5 million of higher indirect lab expenses and \$0.1 million additional spending on various development programs.

Comparison of Nine Months Ended September 30, 2014 and 2013

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

(\$ in thousands)	Nine months ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
Total revenue	\$ 124	\$ 156	\$ (32)	(20.5)%
Cost of sales	1,852	6,109	(4,257)	(69.7)%
Gross loss	\$ (1,728)	\$ (5,953)	\$ 4,225	(71.0)%

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

Cost of sales was approximately \$1.9 million and \$6.1 million for the nine months ended September 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 \$4.3 million is due to a reallocation of manufacturing costs related to research and development expense, increased production efficiency and yield as well as a de-emphasis on commercial sales in the aesthetic market (LAVIV®).

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:

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

(\$ in thousands)	Nine months ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
Compensation and related expense	\$ 3,784	\$ 2,893	\$ 891	30.8%
Severance		170	(170)	(100.0)%
Professional fees	1,110	113	997	882.3%
Marketing expense	137	290	(153)	(52.8)%
Legal expense	841	517	324	62.7%
Facilities and related expense and other	3,240	3,267	(27)	(0.8)%
Total selling, general and administrative expense	\$ 9,112	\$ 7,250	\$ 1,862	25.7%

Selling, general and administrative expense increased by approximately \$1.9 million, or 26%, to \$9.1 million for the nine months ended September 30, 2014 as compared to \$7.2 million for the nine months ended September 30, 2013. Total compensation expense increased \$0.7 million overall, \$0.9 million due to additional costs for salaries, bonuses and stock compensation offset by a \$0.2 million decrease due to lower severance costs. Professional fees increased \$1.0 million, primarily due to the costs of our warrant restatement project in the second quarter of 2014, higher audit fees, project expenses and temporary staffing costs. Legal costs increased \$0.3 million due to negotiations with respect to our corporate contracts and the warrant restatement project. Marketing expense decreased \$0.2 million due to our de-emphasis on sales of our commercial product, LAVIV®. Facilities and related expense and other remained relatively constant.

Table of Contents

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 strategic shift to develop first-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

Research and development expense was comprised of the following:

(\$ in thousands)	Nine months ended September 30,		Increase (Decrease)	
	2014	2013	\$	%
<i>Direct costs:</i>				
Vocal Cord Scarring	\$ 467	\$ 206	\$ 261	126.7%
Restrictive Burn Scarring	538	224	314	140.2%
RDEB / DDEB	2,699	1,069	1,630	152.5%
Autoimmune diseases	404	6,798	(6,394)	(94.1)%
azficel-T	297	1,285	(988)	(76.9)%
Ehlers-Danlos Syndrome hypermobility type	5,176		5,176	100.0%
Other	515	485	30	6.2%
<i>Total direct costs</i>	10,096	10,067	29	0.3%
<i>Indirect costs:</i>				
Regulatory costs	677	696	(19)	(2.7)%
Intangible amortization	414	414		
Indirect lab costs	1,601	240	1,361	567.1%
Compensation and related expense	159	219	(60)	(27.4)%
<i>Total indirect costs</i>	2,851	1,569	1,282	81.7%
Total research and development expense	\$ 12,947	\$ 11,636	\$ 1,311	11.3%

Total research and development expense increased \$1.3 million to approximately \$12.9 million for the nine months ended September 30, 2014 as compared to \$11.6 million for the nine months ended September 30, 2013. The increase is due primarily to the \$1.3 million increase in indirect lab costs. The first quarter 2014 stock issuance costs of approximately \$5.2 million and the \$3.0 million in research and development costs incurred with Intrexon in the nine months ended September 30, 2014 were approximately \$0.6 million lower than the third quarter 2013 stock issuance costs of approximately \$6.4 million and \$2.4 million research and development costs incurred with Intrexon for the nine months ended September 30, 2013. However, these lower costs in 2014 were offset by increased expenses for the Vocal Cord Scarring and Restrictive Burn Scarring programs.

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

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

Vocal Cord Scarring (VCS) Costs increased approximately \$0.3 million compared to the nine months ended September 30, 2013 due to additional costs for enrollment and clinical site fees related to our phase II clinical trial.

Restrictive Burn Scarring (RBS) Costs increased approximately \$0.3 million compared to the nine months ended September 30, 2013 due to additional costs for enrollment and clinical site fees related to our phase II clinical trial.

RDEB / DDEB Costs for the Recessive and Dominant Dystrophic Epidermolysis Bullosa program increased approximately \$1.6 million compared to the nine months ended September 30, 2013 due to our pre-clinical development program and pre-clinical manufacturing costs during the nine months ended September 30, 2014.

Autoimmune diseases The Morphea Profunda/ Linear Scleroderma program began in the second half of 2013. The majority of the costs during the nine months ended September 30, 2013 is the \$6.4 million cost of the 2013 supplemental stock issuance in connection with the first amendment to the exclusive channel collaboration agreement with Intrexon. The cutaneous eosinophilias indication is no longer being targeted.

Azficel-T Costs decreased approximately \$1.0 million compared to the nine months ended September 30, 2013 due to the reduction in our process development program for azficel-T during the nine months ended September 30, 2014.

Table of Contents

Ehlers-Danlos Syndrome hypermobility type Costs to date are approximately \$5.2 million and represent the cost of the first quarter 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.

Indirect lab costs increased by \$1.3 million primarily due to the 2014 implementation of a standard cost system. A portion of our operational and overhead costs not related to commercial sales were allocated to research and development expense. Similar costs would have been included in cost of sales for the nine months ended September 30, 2013.

Warrant Revaluation and Other Finance Income (Expense). During the nine months ended September 30, 2014 and 2013, we recorded non-cash warrant income of approximately \$1.1 million and non-cash warrant expense of approximately \$1.0 million in our statements of operations, respectively, related to the change in the fair value of our warrants. .

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

Net Loss. Net loss for the nine months ended September 30, 2014 and September 30, 2013 was \$22.3 million and \$25.8 million, respectively, representing a decrease of approximately \$3.5 million, or 13.7%. The change is primarily due to a decrease of \$4.3 million in cost of sales offset by an increase of \$2.1 million in non-cash warrant revaluation income and an increase of \$0.4 million in other income attributable to the settlement with a supplier. Selling, general and administrative costs increased \$1.9 million primarily due to \$1.0 million in higher professional fees related to our warrant restatement project, higher audit fees, process improvement expenses and temporary staffing costs. Additionally, total compensation expense increased of \$0.7 million which consisted of a \$0.9 million increase due to additional costs for salaries, bonuses and stock compensation offset by \$0.2 million lower severance costs. Research and development costs increased \$1.3 million primarily due to the 2014 implementation of a standard cost system which allocated a portion of our operational and overhead costs not related to commercial sales to research and development expense. Similar costs would have been included in cost of sales for the nine months ended September 30, 2013.

Liquidity and Capital Resources

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

Statement of Cash Flows Data: (\$ in thousands)	Nine months Ended September 30,	
	2014	2013
Cash used in operating activities	\$ (15,512)	\$ (16,039)
Cash used in investing activities	\$ (307)	\$ (162)
Cash provided by financing activities	\$	\$ 1,730

Operating Activities. Cash used in operating activities during the nine months ended September 30, 2014 was approximately \$15.5 million or approximately \$0.5 million less than the cash used in operating activities during the nine months ended September 30, 2013, primarily due to a

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

reduced loss of \$0.3 million after non-cash adjustments. In addition, there was a \$0.2 million reduction in working capital uses which reflected reduced prepaid expenses, primarily due to the timing of the prepayment of our annual FDA license fee in the third quarter of 2013 offset by a reduction in trade payables and other current liabilities.

Investing Activities. Cash used in investing activities amounted to \$0.3 million for the nine months ended September 30, 2014 and \$0.2 million for the nine months ended September 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 nine months ended September 30, 2014. For the nine months ended September 30, 2013, cash provided by financing activities amounted to \$2.0 million from subscriptions of common stock received offset by \$0.3 million of equity issuance costs.

Working Capital

As of September 30, 2014, we had cash and cash equivalents of approximately \$44.2 million and working capital of approximately \$41.7 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 or through debt financing. 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

Table of Contents

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 our 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 September 30, 2014, our minimum lease payments under the Amended Lease total approximately \$11.4 million.

During the nine month period ended September 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 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 September 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.

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

Based on management's evaluation, 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

There were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 1A. Risk Factors

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

Table of Contents

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 reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of 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 devoted, 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 NASDAQ, 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.

We face risks in connection with doing business in China.

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

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 us and Heifei Meifu, which would expand the scope of our 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 in Asia (excluding Japan). If we are able to consummate alternative business structures in Asia (excluding Japan), we expect to generally no longer have an independent right to make or sell autologous fibroblast therapies in Asia (excluding Japan). If, however, we are unable to finalize alternative business structures in Asia (excluding Japan), our business could be harmed.

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

Table of Contents

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 licensors' patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the U.S., and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We and our collaborators depend on third parties to conduct our pre-clinical studies and clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our product candidates.

We and our collaborators engage third parties to perform various aspects of our preclinical studies and clinical trials. For instance, one of our collaborators obtains genetically-modified material from a sole source supplier in connection with the pre-clinical development of RDEB. We and our collaborators depend on these third parties to perform these activities on a timely basis in accordance with the protocol, good laboratory practices, good clinical practices, and other regulatory requirements. Our reliance on these third parties for pre-clinical and clinical development activities reduces our control over these activities. Accordingly, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, our pre-clinical studies and clinical trials may be extended, delayed, terminated or our data may be rejected by the FDA. For example, if our collaborator's sole source supplier of genetically-modified material in connection with the pre-clinical development of RDEB were to cease to be able to supply genetically-modified material to our collaborator, or decline to supply genetically-modified material to our collaborator, our RDEB program would be delayed until our collaborator obtained an alternative source, which could take a considerable length of time. If it became necessary to replace a third party that was assisting with one of our pre-clinical studies or clinical trials, we believe that there are a number of other third-party contractors that could be engaged to continue these activities, although it may result in a delay of the applicable pre-clinical study or clinical trial. If there are delays in testing or obtaining regulatory approvals as a result of a third party's failure to perform, our drug discovery and development costs will likely increase, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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	Amendment to Employment Agreement, dated September 2, 2014, by and between the Company and Gregory Weaver (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 3, 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.

* 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.

By: /s/ Kimberly M. Smith
Kimberly M. Smith
Interim Chief Financial Officer

Date: November 7, 2014

Table of Contents

INDEX TO EXHIBITS

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
10.1	Amendment to Employment Agreement, dated September 2, 2014, by and between the Company and Gregory Weaver (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 3, 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	
101.CAL	XBRL Taxonomy Extension Schema Document.
101.LAB	
101.PRE	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	
	XBRL Taxonomy Extension Label Linkbase Document.
	XBRL Taxonomy Extension Presentation Linkbase Document.
	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed or furnished, as applicable herewith.