Fibrocell Science, Inc.
Form 10-Q
May 08, 2015

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 March 31, 2015

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	001-31564	87-0458888
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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 ý No o

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

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

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

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

As of May 1, 2015, issuer had 40,888,065 shares issued and outstanding of common stock, par value $0.001.

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements.

Fibrocell Science, Inc.
Consolidated Balance Sheets
(unaudited)
($ in thousands, except share and per share data)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$33,301	$37,495
Accounts receivable, net of allowance for doubtful accounts of $17 and $17, respectively	3	4
Inventory	544	571
Prepaid expenses and other current assets	1,078	1,279
Total current assets	34,926	39,349
Property and equipment, net of accumulated depreciation of $1,053 and $1,051, respectively	1,704	1,598
Intangible assets, net of accumulated amortization of $1,791 and $1,653, respectively	4,549	4,687
Total assets	$41,179	$45,634
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,898	$1,124
Accrued expenses	2,697	1,675
Deferred revenue	588	416
Warrant liability, current	851	278
Total current liabilities	6,034	3,493
Warrant liability, long term	12,098	11,008
Other long term liabilities	771	724
Total liabilities	18,903	15,225
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; 40,888,065 and 40,856,815 shares issued and outstanding, respectively	41	41
Additional paid-in capital	143,478	143,086
Accumulated deficit	(121,243)	(112,718)
Total stockholders' equity	22,276	30,409
Total liabilities and stockholders' equity	$41,179	$45,634

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

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

	Three months ended March 31, 2015	Three months ended March 31, 2014
Product sales	$113	$46
Collaboration revenue	81	—
Total revenues	194	46
Cost of revenues	147	793
Gross profit (loss)	47	(747)
Research and development expense	3,987	7,915
Selling, general and administrative expense	2,924	2,338
Operating loss	(6,864)	(11,000)
Other income (expense):		
Warrant revaluation and other finance expense	(1,663)	(3,050)
Other income	—	40
Interest income	2	1
Loss before income taxes	(8,525)	(14,009)
Deferred tax benefit	—	—
Net loss	$(8,525)	$(14,009)
Per Share Information:		
Net loss:		
Basic and diluted	$(0.21)	$(0.35)
Weighted average number of common shares outstanding		
Basic and diluted	40,861,329	40,583,591

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

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Fibrocell Science, Inc.
Consolidated Statement of Stockholders' Equity
(unaudited)
($ in thousands, except share data)

	Common Stock		Additional	Accumulated	Total Equity
	Shares	Amount	paid-in capital	deficit	
Balance, December 31, 2014	40,856,815	$41	$143,086	$(112,718)	$30,409
Stock-based compensation expense	—	—	240	—	240
Exercise of stock options	31,250	—	152	—	152
Net loss	—	—	—	(8,525)	(8,525)
Balance, March 31, 2015	40,888,065	$41	$143,478	$(121,243)	$22,276

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

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Fibrocell Science, Inc.
Consolidated Statements of Cash Flows
(unaudited)
($ in thousands)

	Three months ended March 31, 2015	Three months ended March 31, 2014
Cash flows from operating activities:		
Net loss	$(8,525)	$(14,009)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	240	303
Stock issued for supplemental stock issuance agreement	—	5,154
Warrant revaluation and other finance expense	1,663	3,050
Depreciation and amortization	140	222
Provision for doubtful accounts	—	5
Change in operating assets and liabilities:		
Accounts receivable	1	(35)
Inventory	27	91
Prepaid expenses and other current assets	201	317
Other assets	—	72
Accounts payable	774	(2,055)
Accrued expenses and other long-term liabilities	1,069	931
Deferred revenue	172	1
Net cash used in operating activities	(4,238)	(5,953)
Cash flows from investing activities:		
Purchase of property and equipment	(108)	(79)
Net cash used in investing activities	(108)	(79)
Cash flows from financing activities:		
Proceeds from the issuance of common stock	152	—
Net cash provided by financing activities	152	—
Net decrease in cash and cash equivalents	(4,194)	(6,032)
Cash and cash equivalents, beginning of period	37,495	60,033
Cash and cash equivalents, end of period	$33,301	$54,001

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

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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.

Fibrocell is an autologous cell and gene therapy company primarily focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. Our most advanced drug candidate, azficel-T, uses the Company's Food and Drug Administration ("FDA") approved proprietary autologous fibroblast technology and is in a Phase II clinical trial for the treatment of chronic dysphonia resulting from vocal cord scarring or atrophy. In collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology, Fibrocell is also developing gene therapies for orphan skin diseases using gene-modified autologous fibroblasts. The Company’s lead orphan gene-therapy drug candidate, FCX-007, is in late stage pre-clinical development for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"). Fibrocell is also in pre-clinical development of FCX-013, a second gene-therapy drug candidate, for the treatment of linear scleroderma.

Note 2. Basis of Presentation

The accompanying unaudited condensed consolidated 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) 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, 2014, filed with the Securities and Exchange Commission (“SEC”). 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.

There have been certain reclassifications made to the prior year’s results of operations to conform to the current year’s presentation. Compensation and related expenses for manufacturing and facilities personnel of $0.5 million were reclassed from selling, general and administrative expense to research and development expense for the three months ended March 31, 2014.

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.

Revenue Recognition

Product Sales. The FDA approved the Company's Biologics License Application ("BLA") in June of 2011 for the aesthetic indication of azficel-T, commercial name LAVIV®. The Company recognizes revenue over the period LAVIV® is shipped for injection in accordance with Accounting Standards Codification ("ASC") 605 Revenue Recognition (“ASC 605”). In general, ASC 605 requires that four basic criteria must be met before revenue can be

recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collectability is reasonably assured. One full course of LAVIV® therapy includes three series of injections. Corresponding revenue is recognized on a prorata basis as each of the three series of injections is shipped to the physician. The Company no longer actively promotes this product.

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Notes to Consolidated Financial Statements
(unaudited)

Note 3. Summary of Significant Accounting Policies (continued)
Collaboration Revenue. The Company's collaboration agreements may contain multiple elements, such as fees to perform proof of concept studies, product development, aid in obtaining U.S. patents and trademarks, and royalties based upon future commercial sales. The deliverables under such an arrangement are evaluated under ASC 605-25, Revenue Recognition: Multiple-Element Arrangements. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has “stand-alone value” to the customer. The arrangement’s consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Collaboration revenue is recognized on a gross basis, in accordance with the criteria set forth in ASC 605-45, Revenue Recognition: Principal Agent Considerations. Collaboration revenue for the quarter ended March 31, 2015 is related to a research and development agreement that the Company has with an unrelated third party to investigate potential new non-pharmaceutical applications for the Company's conditioned fibroblast media technology. Revenue recognized from this collaboration relates to an upfront license fee and a proof of concept study currently underway.
Cost of Revenues
Cost of revenues includes expenses related to product sales and collaboration revenue.
Costs Related to Product Sales. Costs include the processing of cells for LAVIV®, including direct and indirect costs. Cost of product 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.
Costs Related to Collaboration Revenue. Costs directly related to deliverables in a revenue-generating collaboration are charged to cost of revenues as incurred.
Income Taxes
In accordance with ASC 270, Interim Reporting and ASC 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 three months ended March 31, 2015 and 2014, 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 March 31, 2015 or December 31, 2014, 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. For each of the three months ended March 31, 2015 and 2014, the Company had no uncertain tax positions.
Loss Per Share Data
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 and warrants, assuming the exercise of all in-the-money stock options and warrants. Common share equivalents have been excluded where their inclusion would be anti-dilutive.
For all periods present, diluted net loss per common share was the same as basic net loss per common share as the effects of the Company’s potential common stock equivalents were antidilutive. Total antidilutive securities were 8,918,550 and 8,306,770 at March 31, 2015 and 2014, respectively, and consisted of stock options and warrants.

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Note 3. Summary of Significant Accounting Policies (continued)
Recently Issued Accounting Pronouncements
There have been no recently issued accounting pronouncements that the Company believes will have a material impact on its consolidated results of operations, cash flows or financial position upon adoption that have not been previously disclosed.
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, which were solely related to LAVIV®, consisted of the following as of:

($ in thousands)	March 31, 2015	December 31, 2014
Raw materials	$355	$357
Work in process	189	214
Inventory	$544	$571

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 an equity instrument. Since "down-round protection" is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require "net cash settlement" in the absence of express language precluding such settlement or 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 liability-classified warrants to purchase common stock as of:

	Number of Warrants			
Liability-classified warrants	March 31, 2015	December 31, 2014	Exercise Price	Expiration Dates
Issued in Series A, B and D Preferred Stock offerings	2,247,118	2,247,118	$6.25	Oct 2015 - Dec 2016
Issued in March 2010 financing	393,416	393,416	$6.25	Mar 2016
Issued in June 2011 financing	6,113	6,113	$22.50	Jun 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	$13.635	Aug 2016
Issued in Series B, D and E Preferred Stock offerings	76,120	76,120	$2.50	Nov 2015 - Dec 2017
Issued with Convertible Notes	1,125,578	1,125,578	$2.50	Jun 2018
Issued in Series E Preferred Stock offering	1,568,823	1,568,823	$7.50	Dec 2018

Total	6,033,050	6,033,050

There were no warrants exercised or canceled during the three months ended March 31, 2015.

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Note 5. Warrants (continued)

Liability-classified Warrants

The foregoing warrants were recorded as derivative liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in other income (expense) in the Company's consolidated statement of operations in each subsequent period. The change in the estimated fair value of the Company's warrant liability for the three months ended March 31, 2015 and 2014 resulted in non-cash expense of approximately $1.7 million and $3.1 million, respectively. The Company utilizes the Monte Carlo simulation valuation method to value its 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 following table summarizes the calculated aggregate fair values, along with the assumptions utilized in each calculation:

($ in thousands)	March 31, 2015	December 31, 2014
Calculated aggregate value	$12,949	$11,286
Weighted average exercise price per share	$7.08	$7.08
Closing price per share of common stock	$4.51	$2.59
Volatility	78.5 %	67.6 %
Weighted average remaining expected life	2 years, 4 months	2 years, 7 months
Risk-free interest rate	0.63 %	0.86 %
Dividend yield	—	—

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 liabilities measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014:

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Note 6. Fair Value Measurements (continued)

($ in thousands)	Fair value measurement using Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Balance at March 31, 2015				
Assets:				
Cash and cash equivalents	$33,301	$—	$—	$33,301
Liabilities:				
Warrant liability	$—	$—	$12,949	$12,949

($ in thousands)	Fair value measurement using Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Balance at December 31, 2014				
Assets:				
Cash and cash equivalents	$37,495	$—	$—	$37,495
Liabilities:				
Warrant liability	$—	$—	$11,286	$11,286

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

($ in thousands)	Warrant Liability
Balance at December 31, 2014	$11,286
Exercise of warrants	—
Change in fair value of warrant liability	1,663
Balance at March 31, 2015	$12,949

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 advisers 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 stock options (both non-qualified 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 2,700,253 options available for grant as of March 31, 2015.

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Note 7. Share-Based Compensation (continued)
Total share-based compensation expense recognized using the straight-line attribution method in the consolidated statements of operations is as follows:

	Three months ended March 31,	
($ in thousands)	2015	2014
Stock option compensation expense for employees and directors	$240	$300
Equity awards for non-employees issued for services	—	3
Total stock-based compensation expense	$240	$303

($ 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 ($ in thousands)
Outstanding at December 31, 2014	2,086,450	$7.43	8 years	$—
Granted	830,300	4.13		
Exercised	(31,250)	4.86		
Forfeited	—	—		
Expired	—	—		
Outstanding at March 31, 2015	2,885,500	$6.51	8 years, 4 months	$1,510
Exercisable at March 31, 2015	1,162,250	$10.25	7 years, 3 months	$349

The total fair value of shares vested during the three months ended March 31, 2015 was approximately $0.2 million. As of March 31, 2015, there was approximately $4.1 million of total unrecognized compensation cost, related to time-based and performance-based non-vested stock options. That cost is expected to be recognized over a weighted-average period of 3.26 years. As of March 31, 2015, there was no unrecognized compensation expense related to non-vested non-employee options.
During the three months ended March 31, 2015 and 2014, the weighted average fair market value of the options granted was $3.39 and $2.88, 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 three months ended as of the dates indicated:

	March 31, 2015		March 31, 2014	
Expected life	6 years, 2 months		6 years, 3 months	
Interest rate	1.48	%	1.99	%
Dividend yield	—		—	
Volatility	106.3	%	71.0	%

The Company uses a peer group to determine historical stock price volatility as it has not had enough standalone trading to satisfy the "look-back" requirements of ASC 718, Compensation: Stock Compensation. For grants issued during the first quarter of 2015, the Company reassessed those companies it would include in its peer group, resulting in an increase in volatility as compared to the first quarter of 2014.
Note 8. 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.

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Fibrocell Science, Inc.
Notes to Consolidated Financial Statements
(unaudited)

Note 8. Collaboration Agreement with Related Party (continued)
For the three months ended March 31, 2015 and 2014, the Company incurred expenses of $1.7 million and $1.1 million, respectively, for work performed under the Company's exclusive channel collaboration agreement, as amended, with Intrexon. As of March 31, 2015 and December 31, 2014, the Company had outstanding payables to Intrexon of $1.9 million and $1.0 million, respectively.

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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, ar 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 pre-clinical studies and human clinical trials of our cell and gene-therapy drug candidates, including, in particular, those for chronic dysphonia caused by vocal cord scarring or atrophy, recessive dystrophic epidermolysis bullosa and linear scleroderma, and such other target indications as we may identify and pursue, can be conducted within the timeframe that we expect, whether such studies and 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 drug candidates;
- the dependence on our facility in Exton, Pennsylvania for the research, development and manufacturing operations of our cell therapy products, and the potential that such facility is damaged or if we are otherwise required to discontinue research, development and production at such facility;
- the dependence on our third party facility in Mountainview, California for the research, development and manufacturing operations of our gene-therapy products, and the potential that such facility is damaged or if we are otherwise required to discontinue research, development and production at such facility;
- whether our collaboration with Intrexon can be advanced with positive results within the timeframe and budget that we expect;
- our dependence on suppliers for cell and gene-therapy products which are critical to the completion of our gene-therapy applications;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our cell and gene-therapy applications;
- the number and development requirements of other product candidates 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, for the year ended December 31, 2014 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.

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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.

General

We are an autologous cell and gene therapy company primarily focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. Our most advanced drug candidate, azficel-T, uses our FDA-approved proprietary autologous fibroblast technology and is in a Phase II clinical trial for the treatment of chronic dysphonia, a reduction in vocal capacity resulting from vocal cord scarring or atrophy. We expect to complete the Phase II clinical trial and announce efficacy results in the first half of 2016. Dysphonia is defined as a reduction in vocal capacity and is caused by damage to the fibroblast layer of the vocal cords which limits airflow and results in severe and significant limitations in voice quality, including, in some cases, the loss of voice altogether. Our lead orphan gene-therapy drug candidate, FCX-007, is in late stage pre-clinical development for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"), a devastating, rare, congenital, painful, progressive blistering skin disease that typically leads to premature death. We are also in pre-clinical development of our second gene-therapy drug candidate, FCX-013, for the treatment of linear scleroderma, an excess production of extracellular matrix characterized by skin fibrosis and linear scars. The linear areas of skin thickening may extend to underlying tissue and muscle in children which may impair growth and development.

Depending on the severity of dysphonia, a patient's resulting voice is hoarse or raspy and is perceived by sufferers as a communication disorder. Severe cases can lead to a loss of voice. Vocal fold scarring or atrophy due to age can lead to dysphonic conditions. When scarred vocal folds vibrate, there is decreased or non-existent mucosal pliability. For subjects with age-related atrophy of vocal fold tissue (presbylaryngis), the viscoelasticity of the vocal fold has declined with age partially due to a decrease in extracellular membrane that makes up the lamina propria layer of the vocal fold tissue. No long-term effective therapy is presently available, and rehabilitation of subjects (for example, with voice therapy) is difficult. Our clinical focus is on subjects with age-related dysphonia or dysphonia resulting from chronic idiopathic causes.

Working in collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology, we are genetically modifying autologous fibroblast cells to express type VII collagen ("COL7"), a protein that is missing or mis-formed in subjects with RDEB. COL7 is responsible for forming fibrils which attach the epidermis and the dermis layers of the skin, and the lack of or mis-formed COL7 is the underlying cause of this disease. We expect to file our investigational new drug ("IND") application for FCX-007 with the FDA by mid-2015 and to initiate the Phase I portion of our Phase I/II clinical trial in the second half of 2015.

Linear scleroderma is a localized autoimmune skin disorder that manifests as excess production of extracellular matrix characterized by fibrosis and linear scars. Lesions appearing across joints can be painful, impair motion and may be permanent. Current treatments only address symptoms, including systemic or topical corticosteroids, UVA light therapy and physical therapy.

We also have an ongoing scientific research collaboration with the Regents of the University of California, Los Angeles (“UCLA”) which is focused on discoveries and technologies related to regenerative medicine. The technologies from this collaboration and our exclusive license agreements with UCLA may enable us to expand our biologics platform which uses human fibroblasts to create localized therapies that are compatible with the unique biology of each subject.

Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

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

	Three months ended March 31,		Increase (Decrease)		
($ in thousands)	2015	2014	$	%	
Product sales	$113	$46	$67	145.7	%
Collaboration revenue	81	—	81	100.0	%
Total revenues	194	46	148	321.7	%
Cost of revenues	147	793	(646)	(81.5)	%

Gross profit (loss)	$47	$(747)	$794	(106.3)%

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Total revenues were $0.2 million and less than $0.1 million for each of the three months ended March 31, 2015 and 2014, respectively. Revenue from product sales is recognized based on the shipment of LAVIV® injections to patients. While there were fewer injections performed during the first quarter of 2015, LAVIV® pricing was increased in mid-2014 resulting in $0.1 million of higher product sales for the first quarter of 2015 as compared to the same period in 2014. Collaboration revenue is related to a research and development agreement that we have with an unrelated third party to investigate potential new non-pharmaceutical applications for our conditioned fibroblast media technology. Revenue recognized from our collaboration relates to an upfront license fee and a proof of concept study currently underway.

Cost of revenues was approximately $0.1 million and $0.8 million for the three months ended March 31, 2015 and 2014, respectively, and includes the cost of product sales and the cost of collaboration revenue. Cost of product sales includes the costs related to the processing of cells for LAVIV®, including direct and indirect costs. The decrease of $0.6 million is primarily due to our continued de-emphasis on commercial sales in the aesthetic market (LAVIV®). We believe that cost of product sales will remain at or above product sales for the foreseeable future and, thus, we anticipate that we will continue to report gross losses from product sales of LAVIV® for the aesthetic indication for the foreseeable future. Cost of collaboration revenue was immaterial for the three months ended March 31, 2015.

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, laboratory, personnel, facility, stock compensation and other overhead costs that we do not allocate to any specific program. We expect research and development costs to continue to be significant for the foreseeable future as we continue in our efforts to develop first-in-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:

	Three months ended March 31,		Increase (Decrease)	
($ in thousands)	2015	2014	$	%
Direct costs:				
azficel-T for chronic dysphonia	$288	$88	$200	227.3 %
FCX-007	1,322	705	617	87.5 %
FCX-013	450	184	266	144.6 %
Ehlers-Danlos Syndrome (hypermobility type)	—	5,154	(5,154)	(100.0)%
Other	38	109	(71)	(65.1)%
Total direct costs	2,098	6,240	(4,142)	(66.4)%
Indirect costs:				
Regulatory costs	241	165	76	46.1 %
Intangible amortization	138	138	—	—
Compensation and related expense	235	72	163	226.4 %
Process development	20	42	(22)	(52.4)%
Other indirect R&D costs	1,255	1,258	(3)	(0.2)%
Total indirect costs	1,889	1,675	214	12.8 %
Total research and development expense	$3,987	$7,915	$(3,928)	(49.6)%

Total research and development expense decreased $3.9 million to approximately $4.0 million for the three months ended March 21, 2015 as compared to $7.9 million for the three months ended March 31, 2014. The overall decrease is due primarily to $5.2 million of supplemental stock issuance costs incurred in 2014 related to our Ehlers-Danlos Syndrome (hypermobility type) program in connection with the second amendment to the exclusive channel collaboration agreement with Intrexon. This up-front licensing cost did not recur in 2015. That decrease was offset by increased costs during the 2015 period of $0.2 million for our azficel-T for chronic dysphonia Phase II clinical trial, $0.6 million for pre-clinical development of FCX-007 and $0.3 million for pre-clinical development of FCX-013.

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

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azficel-T for chronic dysphonia — Costs increased approximately $0.2 million as compared to the three months ended March 31, 2014 due to costs for enrollment and clinical site fees related to our Phase II clinical trial which did not begin enrollment until the second quarter of 2014.

FCX-007 — Costs increased approximately $0.6 million as compared to the three months ended March 31, 2014 due to the progression of our pre-clinical development program, specifically our animal studies and pre-clinical product manufacturing costs.

FCX-013 — Costs increased approximately $0.3 million as compared to the three months ended March 31, 2014 due to the advancement of our pre-clinical work related to linear scleroderma, specifically for gene screening and selection, construct build and optimization, vector optimization, assay development, RheoSwitch® and ligand optimization and some early animal model work. RheoSwitch® refers to Intrexon's proprietary RheoSwitch Therapeutic System® technology which is a biologic switch activated by a small molecule ligand that provides the ability to control level and timing of protein expression in those diseases where such control is critical.

Ehlers-Danlos Syndrome (hypermobility type) — Costs decreased approximately $5.2 million due to the 2014 supplemental stock issuance in connection with the second amendment to the exclusive channel collaboration agreement with Intrexon. No substantive work has yet begun on this program.

Indirect research and development expense increased by $0.2 million as compared to the three months ended March 31, 2014. This increase is primarily due to additional compensation and related expense of our clinical personnel of $0.2 million.

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

	Three months ended March 31,		Increase (Decrease)	
($ in thousands)	2015	2014	$	%
Compensation and related expense	$887	$966	$(79)	(8.2)%
Professional fees	370	444	(74)	(16.7)%
Legal expense	822	160	662	413.8 %
Facilities and related expense and other	845	768	77	10.0 %
Total selling, general and administrative expense	$2,924	$2,338	$586	25.1 %

Selling, general and administrative expense increased by approximately $0.6 million, or 25.1%, to $2.9 million for the three months ended March 31, 2015 as compared to $2.3 million for the three months ended March 31, 2014. The primary driver of increased expense was a $0.7 million increase in legal expense due to negotiations with respect to our corporate contracts as well as increased litigation costs. Compensation and related expense, professional fees, and facilities and related expense and other were comparable for the three months ended March 31, 2015 and 2014.

Warrant Revaluation and Other Finance Expense. During the three months ended March 31, 2015 and 2014, we recorded non-cash warrant expense of approximately $1.7 million and $3.1 million in our consolidated statements of operations, respectively, related to the change in the fair value of our warrants.

Net Loss. Net loss for the three months ended March 31, 2015 and 2014 was $8.5 million and $14.0 million, respectively, representing a decreased net loss of approximately $5.5 million. The decrease was primarily driven by the non-cash supplemental stock issuance costs of $5.2 million incurred in the 2014 period that did not recur in 2015, offset by increases in 2015 in our legal expenses of $0.7 million and our pre-clinical program expense for FCX-007 of $0.6 million.

Liquidity and Capital Resources

The following table summarizes our cash flows from operating, investing and financing activities for the three months ended March 31, 2015 and 2014:

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Statement of Cash Flows Data:	Three months ended March 31,	
($ in thousands)	2015	2014
Cash used in operating activities	$(4,238)	$(5,953)
Cash used in investing activities	$(108)	$(79)
Cash provided by financing activities	$152	$—

Operating Activities. Cash used in operating activities during the three months ended March 31, 2015 was approximately $4.2 million, a decrease of $1.7 million as compared to the three months ended March 31, 2014, due largely to $3.0 million in cash provided by an increase in accounts payable and accrued expenses at March 31, 2015 as compared to March 31, 2014.

Investing Activities. Cash used in investing activities, attributable primarily to the purchase of equipment, remained relatively flat.

Financing Activities. Cash provided by financing activities, $0.2 million for the three months ended March 31, 2015, relates to cash received for the exercise of stock options.

Working Capital

As of March 31, 2015, we had cash and cash equivalents of approximately $33.3 million and working capital of approximately $28.9 million. We believe that our existing cash and cash equivalents will be sufficient to fund our operations through June 2016. The additional capital that will be required to fund our operations beyond that point will depend largely on the timing and outcomes of our clinical and pre-clinical drug candidate programs and the amount of capital investment we choose to make in our manufacturing facility, as well as on the number of other drug candidates we choose to develop and other factors.

To address our capital needs, we will consider a range of possibilities, including raising additional capital through the issuance of equity or equity-linked securities, 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. There is no assurance that additional capital, 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.

If we raise additional funds by issuing equity or equity-linked securities, our stockholders will experience dilution. Debt financing, if available, will result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to our stockholders. If we raise additional capital through corporate collaborations, partnerships or other strategic transactions, it may be necessary to relinquish valuable rights to our drug candidates, our technologies or future revenue streams or to grant licenses or sell assets on terms that may not be favorable to us.

Contractual Obligations

On April 6, 2005, we entered into a non-cancellable operating lease (the “Lease”) for our office, warehouse, manufacturing 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 2023. At March 31, 2015, our minimum lease payments under the Amended Lease total approximately $10.9 million.

During the three months ended March 31, 2015, 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 for the year ended December 31, 2014.

Recently Issued Accounting Pronouncements

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

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Item 3. Quantitative and Qualitative Disclosures About Market risk

There have been no material changes to our market risk since December 31, 2014.

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 March 31, 2015. Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the SEC. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, management is required to apply its judgment in evaluating the benefits of possible disclosure controls and procedures relative to their costs to implement and maintain.

Based on management’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

To respond to a material weakness with respect to internal control over management's review of the assumptions used in the valuation modeling of our liability-classified warrants identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, 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. We require additional communication and steps in the process of compiling inputs to the valuation model performed by third parties as well as additional communication and steps in the process of reviewing the outputs of such model provided by any third parties to which we outsource financial modeling to verify that management's assumptions were used as expected during the valuation process. In the past, management has utilized such third parties to assist us and will continue to consider the appropriate selection of its external advisors that will be utilized in the future. The elements of management's remediation plan can only be accomplished over time and management can offer no assurance that these initiatives will ultimately have the intended effects.

There have been no other changes in internal control over financial reporting that have occurred during the quarterly period ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Shandong Fabosaier Bio-Tech Co., Ltd. and Ran Liu v. Fibrocell Science, Inc., Civil Action No. 14-7180 (U.S. Dist. Ct. for the E.D. of PA)

On or about December 19, 2014, Shandong Fabosaier Bio-Tech Co., Ltd. of China (“Shandong”) and Ran Liu of Vancouver, Canada, who is allegedly a director of Shandong, commenced a lawsuit against us in the United States District Court for the Eastern District of Pennsylvania, Case No. 2:14-cv-07180-CMR. The Complaint asserts claims for breach of contract, promissory estoppel, and unjust enrichment against us relating to the marketing of our product “LAVIV®” in China and Vancouver. We vigorously deny and dispute the factual allegations contained in the Complaint and, on February 12, 2015, we filed an amended answer, additional defenses and counterclaims against

Shandong and Ms. Liu. Our counterclaims include counts for trademark infringement, violations of the Lanham Act and the Anti-cybersquatting Consumer Protection Act, unfair

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competition, and tortious interference with contractual relations resulting from Shandong's repeated, unauthorized use of our marks on Shandong's website and in other marketing materials. The court has ordered that all discovery be completed by the end of June 2015. There will also be a settlement conference on May 27, 2015. The court has scheduled the trial for October 2015. At this time, we are unable to state whether an outcome unfavorable to us is either probable or remote nor are we able to estimate the amount or range of loss in the event of an unfavorable outcome.

Item 1A. Risk Factors

None

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

We were notified on May 4, 2015 by LTC Jon Meyerle, MD, of the Uniformed Service University of the Health Sciences ("USUHS") that the grant committee for the Peer Reviewed Orthopaedic Research Program Clinical Trial Award (DoD/CDMRP/PRORP) did not accept our application for funding the amputee prosthetic abandonment program. We announced in November 2014 the allowance of an IND and application for the grant to fund a study evaluating the use of autologous volar skin fibroblasts to treat amputee skin diseases that leads to prosthesis abandonment. The grant committee rated the application as "good" and provided feedback on aspects of the protocol and supporting data for review. Although we do not plan to execute the Phase I protocol at this time, we will continue to seek non-dilutive funding to support this program to develop a product for the treatment of skin disease in amputees for both the military and civilian patient populations.

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Item 6. Exhibits

(a) Exhibits

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
3.1*	Fourth Amended and Restated Bylaws
3.2*	Amendment to the Fourth Amended and Restated Bylaws, effective April 20, 2015
10.1	Employment Agreement, dated March 18, 2015, by and between Fibrocell Science, Inc. and Keith A. Goldan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 18, 2015)
10.2*	Form of Nonqualified Stock Option Agreement for Employee Grants
10.3*	Form of Nonqualified Stock Option Agreement for Director Grants
10.4*	Form of Incentive Stock Option Agreement for Employee Grants
31.1*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
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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.

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SIGNATURE

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

FIBROCELL SCIENCE, INC.

By: /s/ Keith A. Goldan
Keith A. Goldan
SVP and Chief Financial Officer

Date: May 8, 2015

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