

Fibrocell Science, Inc.  
Form 10-Q  
May 05, 2016

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended March 31, 2016

OR

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

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Commission File Number 001-31564

Fibrocell Science, Inc.

(Exact name of registrant as specified in its Charter)

Delaware 87-0458888

(State or other jurisdiction of incorporation) (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  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

As of April 29, 2016, there were 43,898,785 outstanding shares of the registrant's common stock, par value \$0.001.



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Unless the context otherwise requires, all references in this Form 10-Q to the "Company," "Fibrocell," "we," "us," and "our" include Fibrocell Science, Inc. and its subsidiaries.

Trademark Notice

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, among others, statements relating to:

- the sufficiency of our cash and cash equivalents to fund our operations into the fourth quarter of 2016;
  - our plans to obtain additional capital and the potential consequences of failing to do so;
  - future expenses and capital expenditures;
  - the expected announcement of primary endpoint results of our Phase II clinical trial for azficel-T in June 2016;
  - the expected initiation of the Phase I portion of our Phase I/II clinical trial of FCX-007 in June 2016;
  - the anticipated submission of an Investigational New Drug application (IND) for FCX-013 to the United States Food and Drug Administration (FDA) in 2017;
  - our expectations with respect to the collaboration that we entered into with Intrexon Corporation (Intrexon) in December 2015;
  - the potential benefits of orphan drug and pediatric rare disease designations; and
  - the potential advantages of our product candidates and technologies;
- as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-Q entitled “Item 1—Financial Statements,” and “Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by words such as “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “scheduled” and similar expressions, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based upon current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (2015 Form 10-K) and in particular, the risks and uncertainties discussed under “Item 1A—Risk Factors” of our 2015 Form 10-K. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-Q represent our views only as of the date of this Form 10-Q (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the periodic and current reports that we file with the Securities and Exchange Commission (SEC).

This Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements.

Fibrocell Science, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

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

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,095	\$ 29,268
Inventory	475	482
Prepaid expenses and other current assets	1,036	1,244
Total current assets	14,606	30,994
Property and equipment, net of accumulated depreciation of \$1,321 and \$1,242, respectively	1,576	1,582
Intangible assets, net of accumulated amortization of \$2,342 and \$2,204, respectively	3,998	4,136
Other assets	30	—
Total assets	\$ 20,210	\$ 36,712
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 893	\$ 499
Related party payable	1,078	10,720
Accrued expenses	636	1,779
Deferred revenue	462	457
Warrant liability, current	282	1,910
Total current liabilities	3,351	15,365
Warrant liability, long term	2,736	6,365
Deferred rent	782	779
Total liabilities	6,869	22,509
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; 43,898,785 shares issued and outstanding	44	44
Additional paid-in capital	161,975	161,330
Accumulated deficit	(148,678)	(147,171)
Total stockholders' equity	13,341	14,203
Total liabilities and stockholders' equity	\$ 20,210	\$ 36,712

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

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

	Three Months Ended	
	March 31,	
	2016	2015
Revenue from product sales	\$12	\$ 113
Collaboration revenue	4	81
Total revenue	16	194
Cost of product sales	17	144
Cost of collaboration revenue	1	3
Total cost of revenue	18	147
Gross (loss) profit	(2	) 47
Research and development expense	2,602	2,246
Research and development expense - related party	1,324	1,741
Selling, general and administrative expense	2,740	2,924
Operating loss	(6,668	) (6,864 )
Other income (expense):		
Warrant revaluation income (expense)	5,257	(1,663 )
Interest income	4	2
Loss before income taxes	(1,407	) (8,525 )
Income tax benefit	—	—
Net loss	\$(1,407)	\$(8,525 )
Per Share Information:		
Net loss:		
Basic	\$(0.03	) \$(0.21 )
Diluted	\$(0.08	) \$(0.21 )
Weighted average number of common shares outstanding:		
Basic	43,898,784	40,861,329
Diluted	43,970,854	40,861,329

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

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Fibrocell Science, Inc.  
 Condensed 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, 2015	43,898,785	\$ 44	\$ 161,330	\$(147,171 )	\$ 14,203
Cumulative effect from adoption of new accounting standard (Note 3)	—	—	100	(100 )	—
Stock-based compensation expense	—	—	545	—	545
Net loss	—	—	—	(1,407 )	(1,407 )
Balance, March 31, 2016	43,898,785	\$ 44	\$ 161,975	\$(148,678 )	\$ 13,341

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



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Fibrocell Science, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(\$ in thousands)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(1,407 )	\$(8,525 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	545	240
Warrant revaluation (income) expense	(5,257 )	1,663
Depreciation and amortization	217	140
Provision for (recovery of) doubtful accounts	(10 )	—
Decrease (increase) in operating assets:		
Accounts receivable	10	1
Inventory	7	27
Prepaid expenses and other current assets	299	201
Other assets	(30 )	—
Increase (decrease) in operating liabilities:		
Accounts payable	338	293
Related party payable	(9,642 )	936
Accrued expenses and deferred rent	(1,138 )	614
Deferred revenue	5	172
Net cash used in operating activities	(16,063 )	(4,238 )
Cash flows from investing activities:		
Purchase of property and equipment	(58 )	(108 )
Net cash used in investing activities	(58 )	(108 )
Cash flows from financing activities:		
Payment of deferred offering costs	(50 )	—
Proceeds from the exercise of stock options	—	152
Principle payments on capital lease obligations	(2 )	—
Net cash (used in) provided by financing activities	(52 )	152
Net decrease in cash and cash equivalents	(16,173 )	(4,194 )
Cash and cash equivalents, beginning of period	29,268	37,495
Cash and cash equivalents, end of period	\$13,095	\$33,301
Supplemental Cash Flow Disclosures:		
Non Cash Investing and Financing Activities:		
Property and equipment in accounts payable	\$15	\$—
Deferred offering costs in accounts payable	\$41	\$—

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

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 1. Business and Organization

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 International, S.A., a company organized under the laws of Switzerland (Isolagen Switzerland). The Company’s international activities are currently immaterial.

Effective April 1, 2016, Fibrocell Hong Kong was dissolved. As this entity had no historical financial or operational activities, the impact of the dissolution did not, and is not expected to have, a material impact on the Company’s present or future consolidated financial statements.

Business Overview

Fibrocell is an autologous cell and gene therapy company translating personalized biologics into medical breakthroughs. The Company is focused on discovering and developing therapies for the localized treatment of diseases affecting the skin, connective tissue and joints. All of the Company’s product candidates incorporate its proprietary autologous fibroblast technology. Currently, all of the Company’s research and development efforts focus on gaining regulatory approvals and commercialization of its product candidates in the United States.

Liquidity and Financial Condition

The Company expects to continue to incur losses and will require additional capital to advance its product candidates through development to commercialization. As of March 31, 2016, we had cash and cash equivalents of approximately \$13.1 million and working capital of approximately \$11.3 million. The Company believes that its cash and cash equivalents at March 31, 2016 will be sufficient to fund operations into the fourth quarter of 2016. The Company will require additional capital to fund operations beyond that point. To meet its capital needs, the Company intends to raise additional capital through debt or equity financings, collaborations, partnerships or other strategic transactions. However, there can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company’s business, results of operations and financial condition. These conditions raise substantial doubt about its ability to continue as a going concern. Consequently, the audit report prepared by the Company’s independent registered public accounting firm relating to its Consolidated Financial Statements for the year ended December 31, 2015 included a going concern explanatory paragraph.

Note 2. Basis of Presentation

General

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 and accompanying notes should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 (2015 Form 10-K), filed with the Securities and Exchange Commission (SEC). The Company's significant accounting policies are described in the Notes to Consolidated Financial Statements in the 2015 Form 10-K and updated, as necessary, in Note 3 in this Form 10-Q. 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.

All intercompany accounts and transactions have been eliminated in consolidation. The Company's international operations are immaterial and it has no unrealized gains or losses from the sale of investments. As a result, it does not have any items that would be classified as other comprehensive income in such a statement.

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 2. Basis of Presentation (continued)

Reclassifications

The prior year Condensed Consolidated Financial Statements contain certain reclassifications made to the Condensed Consolidated Balance Sheet and Condensed Consolidated Statement of Cash Flows to conform to the current year's presentation. Specifically, related party payables were reclassified from accounts payable and accrued expenses as of March 31, 2015.

Note 3. Summary of Significant Accounting Policies

Accounts Receivable

Accounts receivable arising from product sales represent amounts due from physicians. We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against a reserve. Accounts receivable, net of allowance for doubtful accounts of \$2 thousand and \$12 thousand as of March 31, 2016 and December 31, 2015, respectively, were zero at the end of both periods.

Stock-Based Compensation

The Company follows Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, Compensation – Stock Compensation (ASC 718), or ASC 505-50, Equity – Equity Based Payments to Non-Employees, where applicable. The Company accounts for stock-based awards to employees using the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. In addition, the Company accounts for stock-based compensation to non-employees in accordance with the accounting guidance for equity instruments that are issued to entities or persons other than employees. The Company uses a Black-Scholes option-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, expected stock price volatility and expected term of the options. The value of the award that is ultimately expected to vest based on the achievement of a performance condition (i.e., service period) is recognized as expense on a straight-line basis over the requisite service period. See Note 7 for additional details.

Previously, ASC 718 required forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. During the three months ended March 31, 2016, the Company adopted FASB Accounting Standards Update (ASU) 2016-09 which allows an entity to elect as an accounting policy either to continue to estimate the total number of awards for which the requisite service period will not be rendered or to account for forfeitures when they occur. In connection with the adoption of this ASU, the Company made an accounting policy election to account for forfeitures as they occur. See "Recently Adopted Accounting Pronouncements" below for additional details.

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, 2016 and 2015, 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, 2016 or December 31, 2015 because it maintained a full valuation allowance 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. As of March 31, 2016 and December 31, 2015, the Company had no uncertain tax positions.

#### Recently Issued Accounting Pronouncements

##### Amendments to ASC Topic 606, Revenue from Contracts with Customers (ASC 606)

In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net). In April 2016, the FASB also issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing. These amendments include

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

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

targeted improvements based on input the FASB received from the FASB/International Accounting Standards Boards' Joint Transition Resource Group for Revenue Recognition and other stakeholders, but do not change the core principles in Topic 606. The ASUs seek to clarify the guidance within the applicable subtopics of ASC 606, including amendments to the implementation guidance and illustrations intended to improve the operability and understandability of the implementation guidance. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early adoption permitted. Management is currently evaluating the effect that the updated standard will have on the Company's consolidated financial statements.

## Recently Adopted Accounting Pronouncements

## Amendments to ASC 718, Compensation – Stock Compensation

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update simplifies several aspects of accounting for share-based payment award transactions and includes accounting for income taxes, forfeitures, statutory tax withholding requirements and the classification of awards as either equity or liabilities, as well as the classification on the statement of cash flows. The guidance is effective for public companies with annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is permitted. The Company elected to early adopt ASU 2016-09 during the three months ended March 31, 2016. In connection with the adoption of this ASU, the Company elected to account for forfeitures as they occur and applied this change in accounting policy on a modified retrospective basis. As a result, the Company recorded a cumulative-effect adjustment to retained earnings which resulted in an increase to accumulated deficit of \$0.1 million with an offsetting increase to additional paid-in capital (zero net total equity impact) as of the date of adoption, principally related to additional stock compensation expense that would have been recognized on unvested outstanding options unadjusted for estimated forfeitures. Other provisions of ASU 2016-09 had no impact on the Company's Condensed Consolidated Financial Statements during the current period or previously reported periods but may in the future.

## Other Recently Issued Guidance

Management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC did or is expected to have a material impact on the Company's present or future consolidated financial statements.

## Note 4. Inventory

Inventories consist of raw materials and work-in-process intended for use in the manufacture of LAVIV, which was approved by the FDA in 2011 for the improvement of nasolabial fold wrinkles in adults. However, raw materials may be used for clinical trials and are charged to research and development (R&D) expense when consumed.

Inventories consisted of the following as of:

(\$ in thousands)	March 31, 2016	December 31, 2015
Raw materials (LAVIV and product candidates)	\$ 276	\$ 338
Work in process (LAVIV)	199	144
Total Inventory	\$ 475	\$ 482

Note 5. Warrants

The Company accounts for common stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. As of March 31, 2016 and December 31, 2015, all of the Company's outstanding common stock warrants were classified as derivative liabilities and accounted for based on the guidance in ASC 815, Derivatives and Hedging as the warrants contain "down-round protection" or other terms that could potentially require "net

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

## Note 5. Warrants (continued)

cash settlement” and hence were determined not to be indexed to the Company’s own stock. The warrants will continue to be classified as a liability, regardless of the likelihood that such instruments will ever be settled in cash, until they 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:

Liability-classified warrants	Number of Warrants		Exercise Price	Expiration Dates
	March 31, 2016	December 31, 2015		
Issued in Series B and D Preferred Stock offerings	1,970,594	1,970,594	\$6.25	Jul 2016 - Dec 2016
Issued in March 2010 financing	—	319,789	\$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 E Preferred Stock offering	60,000	60,000	\$2.50	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	5,346,990	5,666,779		

The table below is a summary of the Company’s warrant activity during the three months ended March 31, 2016:

	Number of warrants	Weighted-average exercise price
Outstanding at December 31, 2015	5,666,779	\$ 7.14
Granted	—	—
Exercised	—	—
Expired	(319,789 )	6.25
Outstanding at March 31, 2016	5,346,990	\$ 7.20

## Accounting for 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 or expense in the Company’s Condensed Consolidated Statements of Operations in each subsequent period. The change in the estimated fair value of the warrant liability for the three months ended March 31, 2016 and 2015 resulted in non-cash income of approximately \$5.3 million and non-cash expense of approximately \$1.7 million, respectively. The Company utilizes a Monte Carlo simulation valuation method to value its liability-classified warrants.

## Assumptions Used In Determining Fair Value of Warrants

The estimated fair value of warrants is determined using Level 2 and Level 3 inputs. Inherent in the Monte Carlo simulation valuation method are the following assumptions:



Volatility. The Company estimates volatility based on the Company's historical volatility over a period that matches the expected remaining life of the warrants.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the valuation date commensurate with the expected remaining life assumption.

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

## Note 5. Warrants (continued)

Expected remaining life. The expected life of the warrants is assumed to be equivalent to their remaining contractual term.

Dividend rate. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.

Scenarios. The probability of complex features of the warrants being triggered is subjective (no observable inputs or available market data) and based on internal and external information known to management at the valuation date.

The following table summarizes the calculated aggregate fair values, along with the inputs and assumptions utilized in each calculation:

(\$ in thousands except per share data)	March 31, 2016		December 31, 2015	
Calculated aggregate value	\$ 3,018		\$ 8,275	
Weighted average exercise price per share	\$ 7.20		\$ 7.14	
Closing price per share of common stock	\$ 2.50		\$ 4.55	
Volatility	93.3	%	85.2	%
Weighted average remaining expected life	1 year, 6 months		1 year, 8 months	
Risk-free interest rate	0.66	%	0.98	%
Dividend yield	—		—	

## Note 6. Fair Value Measurements

## Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company uses the accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires fair value measurements be classified and disclosed in one of the following three categories within the hierarchy:

• 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).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period.



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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

## Note 6. Fair Value Measurements (continued)

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:

(\$ in thousands)	March 31, 2016			Total
	Level 1	Level 2	Level 3	
Assets:				
Cash and cash equivalents	\$ 13,095	\$ —	\$ —	\$ 13,095
Liabilities:				
Warrant liability	\$ —	\$ —	\$ —3,018	\$ 3,018

(\$ in thousands)	December 31, 2015			Total
	Level 1	Level 2	Level 3	
Assets:				
Cash and cash equivalents	\$ 29,268	\$ —	\$ —	\$ 29,268
Liabilities:				
Warrant liability	\$ —	\$ —	\$ —8,275	\$ 8,275

## Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis - Common Stock Warrants

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, 2015	\$ 8,275
Expiration of warrants <sup>(1)</sup>	(62 )
Change in fair value of warrant liability	(5,195 )
Balance at March 31, 2016	\$ 3,018

Represents the fair value as of the beginning of the year for warrants expiring during the year and has been (1) recorded to warrant revaluation income (expense) in the Condensed Consolidated Statement of Operations for the three months ended March 31, 2016.

## Effect of Fibrocell's Stock Price and Volatility Assumptions on the Calculation of Fair Value of Warrant Liabilities

The fair value of the warrant liability is based on Level 3 inputs. As discussed in Note 5, the Company uses a Monte Carlo simulation valuation method to value its liability-classified warrants. The determination of fair value as of the reporting date is affected by Fibrocell's stock price as well as assumptions regarding a number of subjective variables that do not have observable inputs or available market data to support the fair value. These variables include, but are not limited to, expected stock price volatility over the term of the warrants and the risk-free interest rate. The primary factors affecting the fair value of the warrant liability are the Company's stock price and volatility as well as certain assumptions by the Company as to the likelihood of provisions to the underlying warrant agreements being triggered. The methods described above and in Note 5 may produce a fair value calculation that may not be indicative of net

realizable value or reflective of future fair values. Furthermore, while the Company believes its valuation method is appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value could result in a different fair value measurement at the reporting date.

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 6. Fair Value Measurements (continued)

Fair Value of Certain Financial Assets and Liabilities

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

Note 7. Stock-Based Compensation

2009 Equity Incentive Plan

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 equity-based incentives. The Plan allows for the issuance of up to 5,600,000 shares of the Company's common stock. In addition, there were 206,000 options issued outside of the Plan to consultants in prior years.

The types of awards that may be granted under the Plan include 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 at the time each award is granted, provided that the terms of options do not exceed ten years. Vesting schedules for stock options vary, but generally vest 25% per year over four years. The Plan had 1,552,409 shares available for future grants as of March 31, 2016.

Accounting for Stock-Based Compensation

The Company recognizes non-cash compensation expense for stock-based awards based on their grant date fair value, determined using the Black-Scholes option-pricing model. During the three months ended March 31, 2016 and 2015, the weighted average fair market value for options granted was and \$1.74 and \$3.39, respectively.

Total stock-based compensation expense recognized using the straight-line attribution method and included in operating expenses in the Condensed Consolidated Statements of Operations was approximately \$0.5 million and \$0.2 million, for the three months ended March 31, 2016 and 2015, respectively.

Assumptions Used In Determining Fair Value of Stock Options

Inherent in the Black-Scholes option-pricing model are the following assumptions:

**Volatility.** The Company estimates volatility based on the Company's historical stock volatility over a period that matches the expected term of the stock options.

**Risk-free interest rate.** The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption.

**Expected term.** The expected term of stock options granted is based on an estimate of when options will be exercised in the future. The Company applied the simplified method of estimating the expected term of the options, as described in the SEC's Staff Accounting Bulletins 107 and 110, as the historical experience is not indicative of the expected behavior in the future. The expected term, calculated under the simplified method, is applied to groups of stock options that have similar contractual terms. Using this method, the expected term is determined using the average of

the vesting period and the contractual life of the stock options granted.

Forfeitures. The Company accounts for forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

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## Note 7. Stock-Based Compensation (continued)

The fair market value of these stock options at the date of grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the three months ended:

	March 31, 2016	March 31, 2015
Expected term	6 years, 3 months	6 years, 2 months
Interest rate	1.44	% 1.48
Dividend yield	—	—
Volatility <sup>(1)</sup>	93.5	% 106.3

For the three months ended March 31, 2016, the Company estimated expected volatility based on the historical (1) volatility of its own common stock on a stand-alone basis. Prior to January 1, 2016, including the three months ended March 31, 2015, the Company estimated expected volatility based on the historical volatility of a peer group.

## Stock Option Activity

The following table summarizes stock option activity for the three months ended March 31, 2016:

(\$ in thousands except share and per share data)	Number of shares	Weighted- average exercise price	Weighted- average remaining contractual term	Aggregate intrinsic value
Outstanding at December 31, 2015	3,134,094	\$ 6.23	8 years	\$ 1,630
Granted	875,000	2.27		
Exercised	—	—		
Forfeited	(750)	4.24		
Expired	—	—		
Outstanding at March 31, 2016 <sup>(1)</sup>	4,008,344	\$ 5.37	8 years, 3 months	\$ 201
Exercisable at March 31, 2016	1,683,556	\$ 7.96	7 years	\$ —

(1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

The total fair value of options vested during the three months ended March 31, 2016 was approximately \$0.7 million. Additionally, as of March 31, 2016, there was approximately \$5.3 million of unrecognized compensation expense related to non-vested stock options which is expected to be recognized over a weighted-average period of 3.0 years.

## Note 8. Related Party Transactions

The Company and Intrexon Corporation (Intrexon) are parties to two distinct exclusive channel collaboration agreements including the Exclusive Channel Collaboration Agreement entered into in October 2012 and amended in June 2013 and January 2014 (as amended, the 2012 ECC) and the Exclusive Channel Collaboration Agreement entered into in December 2015 (the 2015 ECC). Pursuant to these agreements, the Company engages Intrexon for support services for the research and development of product candidates covered under the respective agreements and reimburses Intrexon for its cost for time and materials for such work.

For the three months ended March 31, 2016 and 2015, the Company incurred total expenses of \$1.3 million and \$1.7 million, respectively, with Intrexon, for work performed under the 2012 ECC. During the same periods, no expenses were incurred for work performed under the 2015 ECC. Of the \$1.3 million incurred during the 2016 period, \$0.5 million related to direct expenses for work performed by Intrexon and \$0.8 million related to pass-through costs. Of



the \$1.7 million incurred

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Fibrocell Science, Inc.

Notes to Consolidated Financial Statements

(unaudited)

## Note 8. Related Party Transactions (continued)

during the 2015 period, \$0.9 million related to direct expenses for work performed by Intrexon and \$0.8 million related to pass-through costs.

As of March 31, 2016 and December 31, 2015, the Company had outstanding payables to Intrexon of \$1.1 million and \$10.7 million, respectively. In connection with the 2015 ECC, in consideration for the license and the other rights that the Company receives under the agreement, the Company paid Intrexon an up-front technology access fee of \$10 million in cash in January 2016.

Randal J. Kirk is the chairman of the board and chief executive officer of Intrexon and, together with his affiliates, owns more than 50% of Intrexon's common stock. Affiliates of Randal J. Kirk (including Intrexon) own approximately 38% of our common stock. Additionally, two of our directors, Julian Kirk (who is the son of Randal J. Kirk) and Marcus Smith, are employees of Third Security, LLC, which is an affiliate of Randal J. Kirk.

## Note 9. Loss Per Share

Basic loss per share is computed by dividing net loss for the period by the weighted-average number of shares of common stock outstanding during that period. The diluted loss per share calculation gives effect to dilutive stock options, warrants and other potentially dilutive common stock equivalents 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 based on the average market price during the period. Common stock equivalents have been excluded where their inclusion would be anti-dilutive.

Details in the computation of basic and diluted loss per share is as follows:

(\$ in thousands except share and per share data)	Three months ended	
	March 31,	2015
	2016	2015
Loss per share - basic:		
Numerator for basic loss per share	\$(1,407)	\$(8,525)
Denominator for basic loss per share	43,898,785	40,861,329
Basic loss per common share	\$(0.03)	\$(0.21)
Loss per share - diluted:		
Numerator for diluted loss per share	\$(1,407)	\$(8,525)
Adjustment for income (expense) for change in fair value of warrant liability for dilutive warrants	1,958	—
Net loss attributable to common share	\$(3,365)	\$(8,525)
Denominator for basic loss per share	43,898,785	40,861,329
Plus: Incremental shares underlying dilutive "in the money" warrants outstanding	72,068	—
Denominator for diluted loss per share	43,970,853	40,861,329
Diluted net loss per common share	\$(0.08)	\$(0.21)

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Fibrocell Science, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

## Note 9. Loss Per Share (continued)

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

	Three months ended	
	March 31,	
	2016	2015
“In the money” stock options	875,000	1,555,300
“Out of the money” stock options	3,133,344	1,230,200
“In the money” warrants	—	1,201,698
“Out of the money” warrants	4,161,412	4,831,352

Other securities excluded from the calculation of diluted loss per share:

Stock options with performance condition	—	100,000
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Note 10. Equity

## Common Stock - “At-The-Market” Equity Program

On January 21, 2016, the Company entered into a Controlled Equity Offering™ Sales Agreement (the ATM Agreement) with Cantor Fitzgerald & Co. (Cantor Fitzgerald) to implement an "At-The-Market" (ATM) equity program under which the Company, from time to time, may offer and sell shares of its common stock having an aggregate offering price of up to \$50.0 million (the Shares) through Cantor Fitzgerald.

Subject to the terms and conditions of the ATM Agreement, Cantor Fitzgerald will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company’s instructions. The Company has no obligation to sell any of the Shares, and may at any time suspend sales under the ATM Agreement or terminate the ATM Agreement. Cantor Fitzgerald will be entitled to a fixed commission of up to 3.0% of the gross proceeds from Shares sold. Through March 31, 2016, no Shares have been sold through the ATM equity program.

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

The following discussion and analysis should be read in conjunction with:

our unaudited Condensed Consolidated Financial Statements and accompanying notes included in Part I, Item 1 of this Form 10-Q; and

our audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for 2015 (2015 Form 10-K), as well as the information contained under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2015 Form 10-K.

Overview

We are an autologous cell and gene therapy company focused on translating personalized biologics into medical breakthroughs. Our approach to personalized biologics is distinctive and the foundation of our personalized biologics platform is our proprietary autologous fibroblast technology. Fibroblasts are the most common cell in skin and connective tissue and are responsible for synthesizing extracellular matrix proteins, including collagen and other growth factors, that provide structure and support. Because fibroblasts naturally reside in the localized environment of the skin and connective tissue, they represent an ideal therapeutic agent for the treatment of diseases affecting the skin, connective tissue and joints. We target the underlying cause of disease by using fibroblast cells from a patient's skin to create localized therapies—with or without genetic modification—that are compatible with the unique biology of the patient (i.e., autologous).

We are focused on discovering and developing localized therapies for diseases affecting the skin, connective tissue and joints, where there are high unmet needs, to improve the lives of patients and their families. In that regard, we commit significant resources to our research and development programs. Currently, all of our research and development operations and focus are on gaining regulatory approvals to commercialize our product candidates in the United States, however, we may seek to expand into international markets in the future.

Our current pre-clinical and clinical development program pipeline consists of the following product candidates:

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### Intrexon Collaborations

We collaborate with Intrexon Corporation (Intrexon), a related party, through two distinct exclusive channel collaboration agreements including the Exclusive Channel Collaboration Agreement entered into in October 2012 and amended in June 2013 and January 2014 (as amended, the 2012 ECC) and the Exclusive Channel Collaboration Agreement entered into in December 2015 (the 2015 ECC). Pursuant to these agreements, we engage Intrexon for support services for the research and development of product candidates covered under the respective agreements and reimburses Intrexon for its cost for time and materials for such work. We are developing FCX-007 and FCX-013 under the 2012 ECC and we are in the research phase for an arthritis treatment under the 2015 ECC. For additional details, see Note 8 in the accompanying Notes to the Condensed Consolidated Financial Statements included in this Form 10-Q and additional disclosures included in our 2015 Form 10-K.

### Development Programs

#### azfichel-T for Vocal Cord Scarring

Vocal cord scarring is caused by damage to the fibroblast layer of the vocal cords which reduces vocal cord elasticity and airflow, affecting voice tone and volume. This reduction in vocal capacity is referred to as dysphonia, severe cases of which can lead to a total loss of voice. Current treatments for vocal cord scarring, including voice therapy and surgery through the use of injection (collagen, fat, calcium, hyaluronic acid) or implant (PTFE, silastic), only address the symptoms of vocal cord scarring and have inconsistent efficacy.

Azfichel-T is in development to treat patients suffering from vocal cord scarring that is either idiopathic or age-related, of which we estimate there to be approximately 64,000 in the U.S. We believe azfichel-T restores the extracellular matrix to repair damage to the fibroblast layer of the vocal cords, thereby improving voice quality. This program is being conducted under an Investigational New Drug application (IND) that cross-references our U.S. Food and Drug Administration (FDA) approved Biologics License Application (BLA) for LAVIV, our FDA-approved product, which allows us to leverage the safety, chemistry and manufacturing data contained in the BLA.

#### Phase I Trial

In our Phase I open label clinical trial of azfichel-T for the treatment of vocal cord scarring resulting in chronic or severe dysphonia, we examined the safety and efficacy of azfichel-T injections for subjects who had failed to improve following currently available treatments. Five subjects were treated in the clinical trial. The voice quality of each subject was evaluated using Mucosal Wave Grade assessment, Voice Handicap Index and patient-assessed voice quality prior to treatment and at 4 and 12 months following treatment. The data from this trial showed a positive trend of sustained improvement in a majority of the subjects in the Mucosal Wave Grade assessment and Voice Handicap Index and no serious adverse events were reported, as more fully described in our 2015 Form 10-K.

#### Phase II Trial

Our Phase II clinical trial that is currently in progress is a double-blind, randomized, placebo-controlled trial that is designed to test the safety and efficacy of azfichel-T injections in subjects with chronic dysphonia caused by vocal cord scarring or atrophy. In this clinical trial, subjects were administered the same dose at the same time intervals as in the Phase I clinical trial. We have completed dosing for all 21 subjects currently enrolled in the trial. Efficacy endpoints were assessed on three different scales: Voice Handicap Index, Mucosal Wave Grade, and GRBAS (grade, roughness, breathiness, asthenia & strain). Our last subject visit for primary endpoint analysis occurred in April 2016. We expect to report primary endpoint results in June 2016. As of April 29, 2016, no treatment-related serious adverse events have been reported.

FCX-007 for Recessive Dystrophic Epidermolysis Bullosa

Recessive dystrophic epidermolysis bullosa (RDEB) is the most severe form of dystrophic epidermolysis bullosa (DEB), a congenital, progressive, devastatingly painful and debilitating genetic disorder that often leads to death. RDEB is caused by a mutation of the COL7A1 gene, the gene which encodes for type VII collagen (COL7), a protein that forms anchoring fibrils. Anchoring fibrils hold together the layers of skin, and without them, skin layers separate causing severe blistering, open wounds and scarring in response to any kind of friction, including normal daily activities like rubbing or scratching. Children who inherit this condition are often called “butterfly children” because their skin can be as fragile as a butterfly’s wings. We estimate that there are approximately 1,100 - 2,500 RDEB patients in the U.S. Currently, treatments for RDEB address only the sequelae, including daily bandaging, hydrogel dressings, antibiotics, feeding tubes and surgeries.

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Our lead orphan gene-therapy product candidate, FCX-007, is in clinical development for the treatment of RDEB. In addition to having orphan drug designation from the FDA's Office of Orphan Products Development (OOPD), FCX-007 also was granted pediatric rare disease designation. FCX-007 is a genetically-modified autologous fibroblast that encodes COL7 for localized treatment of RDEB and is being developed in collaboration with Intrexon. By genetically modifying autologous fibroblasts, ex vivo, to produce COL7, culturing them and then treating blisters and wounds locally via injection, FCX-007 offers the potential to address the underlying cause of the disease by providing high levels of COL7 directly to the affected areas, thereby avoiding systemic treatment.

### Phase I/II Trial

In April 2016 we received allowance from the FDA to initiate a Phase I/II clinical trial for FCX-007 in adults. We expect to initiate the Phase I portion of the trial in June 2016. The primary objective of this open label trial is to evaluate the safety of FCX-007 in RDEB subjects. Additionally, the trial will evaluate type VII collagen expression and the presence of anchoring fibrils resulting from FCX-007, as well as evidence of wound healing. Six adult subjects are expected to be treated with FCX-007 in the Phase I portion of the trial and six pediatric subjects in the Phase II portion of the trial. Prior to conducting studies on pediatric subjects, we are required to obtain allowance from the FDA and submit evidence of FCX-007 activity in adult subjects and final data from an ongoing toxicology study.

### FCX-013 for Linear Scleroderma

Linear scleroderma, a form of localized scleroderma, is a chronic autoimmune skin disorder that manifests as excess production of extracellular matrix, specifically type I collagen and type III collagen, resulting in thickening of the skin and connective tissue. The localized areas of skin thickening may extend to underlying tissue and muscle in children which can impair growth and development. Lesions appearing across joints can be painful, impair motion and may be permanent. Current treatments for linear scleroderma, which include systemic or topical corticosteroids, UVA light therapy and physical therapy, only address the symptoms of the disorder. We estimate the U.S. population of patients who have linear scleroderma over a major joint and exhibit severe joint pain to be approximately 40,000.

Our second orphan gene-therapy product candidate, FCX-013, is in pre-clinical development for the treatment of linear scleroderma. FCX-013 incorporates Intrexon's proprietary RTS<sup>®</sup> switch, a biologic switch activated by an orally administered compound to control protein expression once the initial fibrosis has been resolved. FCX-013 is designed to be injected under the skin at the location of the fibrosis where the genetically-modified fibroblast cells will produce a protein to break down excess collagen accumulation. The patient takes an oral compound to facilitate protein expression. Once the fibrosis is resolved, the patient will stop taking the oral compound which will stop further production of the subject protein by FCX-013.

We have successfully completed a proof-of-concept study for FCX-013 in which the primary objective was to determine whether FCX-013 had the potential to reduce dermal thickness in fibrotic tissue. In this study, FCX-013 was evaluated in a bleomycin-induced scleroderma model utilizing SCID mice. Data from the study demonstrated that FCX-013 reduced dermal thickness of fibrotic tissue to levels similar to that of the non-treated control and further reduced the thickness of the sub-dermal muscle layer. Based upon these data and the FDA's feedback to our pre-IND briefing package, we are advancing FCX-013 into pre-clinical dose-ranging studies. In April 2016 we received orphan drug designation from the OOPD for FCX-013 for the treatment of localized scleroderma. We expect to submit an IND application for FCX-013 to the FDA in 2017.

### New Gene Therapy Program for Arthritis

Arthritis is a broad term that covers a group of more than 100 different types of diseases that affect the joints, as well as connective tissues and organs, including the skin. According to the Centers for Disease Control and Prevention,

arthritis—characterized by joint inflammation, pain, and decreased range of motion—is the United States’ most common cause of disability affecting more than 52 million adults as well as 300,000 children at a cost exceeding \$120 billion.

Our third gene-therapy program is focused on the treatment of arthritis. This program is in the research phase and is being undertaken in collaboration with Intrexon. Our goal is to deliver a protein therapy locally to the joint to provide sustained efficacy while avoiding key side effects typically associated with systemic therapy.



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## Commercial Program

## LAVIV (azficel-T) for Nasolabial Fold Wrinkles

LAVIV (azficel-T) was approved by the FDA in June 2011 for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults. LAVIV utilizes our proprietary autologous fibroblast technology. In 2013, we shifted our strategic focus away from the aesthetic market and towards developing treatments for diseases affecting the skin, connective tissue and joints. As a result, we no longer actively market or promote LAVIV but we continue to accept prescriptions, from which we expect a nominal amount of revenue during 2016.

A condition to the FDA's approval of LAVIV was that we conduct a 2,700 patient post-marketing study by the end of 2016 to assess the risk of skin cancer (such as basal cell cancer) in the area of LAVIV injections and the risk of immune-mediated hypersensitivity reactions (such as leukocytoclastic vasculitis). We have initiated enrollment in this study and have submitted the required biannual interim reports to the FDA, with the most recent being in January 2016. However, given the limited use of LAVIV, we have experienced difficulties in recruiting a sufficient number of patients for this study. We are actively engaged in discussions with the FDA about how to fulfill the study size requirement in light of the limited population of LAVIV users.

## Results of Operations

## Comparison of Three Months Ended March 31, 2016 and 2015

## Revenue and Cost of Revenue

Revenue and cost of revenue was comprised of the following:

	Three months ended March 31,		Increase (Decrease)		
(\$ in thousands)	2016	2015	\$	%	
Revenue from product sales	\$12	\$113	\$(101)	(89.4)	%(1)
Collaboration revenue	4	81	(77)	(95.1)	%(2)
Total revenue	16	194	(178)	(91.8)	%
Cost of product sales	17	144	(127)	(88.2)	%(3)
Cost of collaboration revenue	1	3	(2)	(66.7)	%
Total cost of revenue	18	147	(129)	(87.8)	%
Gross (loss) profit	\$(2)	\$47	\$(49)	(104.3)	%

Revenue from product sales solely relates to, and is recognized based on, the shipment of LAVIV injections to (1) patients. Although the number of injections can fluctuate from period to period, product revenues continue to be, and are expected to remain, insignificant to our operations.

Collaboration revenue is related to a research and development agreement that we have with a third party to investigate potential new non-pharmaceutical applications for our conditioned fibroblast media technology.

Revenue recognized to date relates to an upfront license fee of approximately \$0.1 million that is being amortized (2) over the estimated total contract period and \$0.2 million for a proof-of-concept study that was completed during the fourth quarter of 2015. Collaboration revenue for the three months ended March 31, 2016 solely relates to amortization of the upfront license fee while collaboration revenue for the three months ended March 31, 2015 includes amortization of both the upfront license fee and proof-of-concept study.

Cost of product sales includes direct and indirect costs related to the processing of cells for LAVIV. For the three (3) months ended March 31, 2016 compared to the same period in 2015, cost of product sales experienced a decrease as a result of lower product sales volume.

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## Research and Development Expense

For each of our research and development programs, we incur both direct and indirect expenses. We track direct research and development expenses by program, which include third party costs such as contract research, consulting and pre-clinical and clinical development costs. We do not allocate indirect research and development expenses, which may include regulatory, laboratory (equipment and supplies), personnel, facility, process development and other overhead costs (including depreciation and amortization), to specific programs, as these expenses are to be deployed across all of our product candidates. We expect research and development costs to continue to be significant for the foreseeable future as a result of our pre-clinical studies and clinical trials, as well as our ongoing collaborations with Intrexon.

Research and development expense was comprised of the following:

(\$ in thousands)	Three months ended		Increase (Decrease)		
	March 31, 2016	March 31, 2015	\$	%	
Direct costs:					
azficel-T for vocal cord scarring	\$35	\$288	\$(253)	(87.8)	%(1)
FCX-007	1,023	1,322	(299)	(22.6)	%(2)
FCX-013	310	450	(140)	(31.1)	%(3)
Other	34	38	(4)	(10.5)	%(4)
Total direct costs	1,402	2,098	(696)	(33.2)	%(5)
Indirect costs:					
Regulatory costs	175	241	(66)	(27.4)	%(6)
Intangible amortization	138	138	—	—	%(7)
Compensation and related expense	1,096	928	168	18.1	%(8)
Process development	598	20	578	2,890.0	%(9)
Other indirect R&D costs	517	562	(45)	(8.0)	%(10)
Total indirect costs	2,524	1,889	635	33.6	%(11)
Total research and development expense	\$3,926	\$3,987	\$(61)	(1.5)	%(12)

(1) Costs for our azficel-T for vocal cord scarring program decreased approximately \$0.3 million, or 87.8%, for the quarter ended March 31, 2016 as compared to the same period in 2015 as dosing in the Phase II trial was complete as of December 31, 2015. Therefore, no patient enrollment or clinical manufacturing costs were incurred in the current period.

Through March 31, 2016, we have incurred approximately \$2.4 million in direct research and development costs related to this program, life-to-date. These costs include the author and review of clinical trial protocols, recruiting investigator sites, the cost to manufacture clinical trial material, recruiting patients and executing our Phase I and II clinical trials. Going forward, research and development investments for this program are expected to support the completion of our Phase II clinical trial as well as clinical product manufacturing, statistical analyses, report generation and future clinical trial costs.

(2) Costs for our FCX-007 program decreased approximately \$0.3 million, or 22.6%, for the quarter ended March 31, 2016 due to the completion of pre-clinical development activities in the first quarter of 2016 that were ongoing during the first quarter of 2015.

Through March 31, 2016, we have incurred approximately \$18.2 million in direct research and development costs related to this program, life-to-date, which include non-cash expenses of \$6.9 million in stock issuance costs

associated with the 2012 ECC with Intrexon. Other costs include product and assay development, key opinion leader development, pre-clinical studies and manufacturing and design of the Phase I/II clinical trial protocol. Going forward, research and development investments for this program are expected to support clinical product manufacturing, statistical analyses, report generation and future clinical trial costs.

Costs for our FCX-013 program decreased approximately \$0.1 million, or 31.1%, for the quarter ended March 31, (3)2016 due to the completion of our proof-of-concept study in the first quarter of 2016, as compared to early product development expenses incurred in the first quarter of 2015.

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Through March 31, 2016, we have incurred approximately \$9.5 million in direct research and development costs related to this program, life-to-date, which include non-cash expenses of \$6.4 million in stock issuance costs with the 2012 ECC with Intrexon. Other costs include product and assay development and pre-clinical work, including execution of our proof-of concept study. Going forward, research and development investments for this program are expected to support ongoing product and assay development, pre-clinical study execution, key opinion leader development, National Institutes of Health Recombinant DNA Advisory Committee (NIH RAC) meeting preparation expenses and the design and execution of clinical trials.

Compensation and related expense increased approximately \$0.2 million, or 18.1%, for the quarter ended March (4)31, 2016 as compared to the same period in 2015, primarily due to increases in salaries, bonus and non-cash stock-based compensation.

Process development costs increased approximately \$0.6 million, or 2,890.0%, for the quarter ended March 31, (5) 2016 as compared to the same period in 2015, primarily due to an increase in internal process development work as additional resources were directed towards optimizing our current manufacturing processes, benefiting several of our ongoing development programs.

## Selling, General and Administrative Expense

Selling, general and administrative expense was comprised of the following:

(\$ in thousands)	Three months ended		Increase (Decrease)		
	March 31, 2016	March 31, 2015	\$	%	
Compensation and related expense	\$1,398	\$887	\$511	57.6	%(1)
Professional fees	584	1,192	(608)	(51.0)	%(2)
Facilities and related expense and other	758	845	(87)	(10.3)	%
Total selling, general and administrative expense	\$2,740	\$2,924	\$(184)	(6.3)	%

Compensation and related expense increased approximately \$0.5 million, or 57.6%, for the quarter ended March (1)31, 2016 as compared to the same period in 2015 primarily due to additional employees and increases in salaries, bonus and non-cash stock-based compensation.

Professional fees decreased approximately \$0.6 million, or 51.0%, for the quarter ended March 31, 2016 as (2) compared to the same period in 2015. The decrease is primarily due to legal fees related to litigation and contract negotiation that were incurred in the prior year and did not recur in 2016. Additionally, in the second quarter of 2015, we hired in-house general counsel which further reduced legal costs incurred with outside vendors.

## Warrant Revaluation Income (Expense)

During the three months ended March 31, 2016 and 2015, we recorded non-cash income of approximately \$5.3 million and non-cash expense of approximately \$1.7 million for warrant revaluation charges in our Condensed Consolidated Statements of Operations, respectively. Due to the nature and inputs of the model used to assess the fair value of our outstanding warrants, it is not abnormal to experience significant fluctuations from period to period. These fluctuations are due to a variety of factors including changes in our stock price, changes in the remaining contractual life of the warrants, and changes in management's estimated probability of certain events occurring that would impact the warrants. The primary reason for the significant change between the warrant revaluation charges noted above is the significant decrease in our stock price during the three months ended March 31, 2016 compared to the significant increase in our stock price experienced during the three months ended March 31, 2015.



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## Financial Condition, Liquidity and Capital Resources

## Financial Condition

We have experienced losses since our inception. As of March 31, 2016, we had an accumulated deficit of \$148.7 million. The process of developing and commercializing our product candidates requires significant research and development efforts and clinical trial work, as well as significant manufacturing and process development. These activities, together with our selling, general and administrative expenses, are expected to continue to result in significant operating losses for the foreseeable future.

Our financial condition is summarized below as of the following dates:

	March	December	Change	
(\$ in thousands)	31, 2016	31, 2015	\$	%
Cash and cash equivalents	\$13,095	\$29,268	\$(16,173)	(55.3)%
Working capital:				
Total current assets	\$14,606	\$30,994	\$(16,388)	(52.9)%
Total current liabilities	(3,351)	(15,365)	12,014	(78.2)%
Net working capital	\$11,255	\$15,629	\$(4,374)	(28.0)%

## Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents of \$13.1 million as of March 31, 2016. As of March 31, 2016, we had net working capital of \$11.3 million. Net working capital decreased approximately \$4.4 million, or 28.0%, from December 31, 2015 to March 31, 2016. This decrease is the result of a one-time, up-front technology access fee of \$10 million cash paid in January 2016 to Intrexon in connection with the 2015 ECC, as well as a net consumption of cash used in operations to further our development programs (for which future funding requirements are described below). We believe that our existing cash and cash equivalents will be sufficient to fund our operations into the fourth quarter of 2016; however, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. We will require additional capital to fund operations beyond that point and prior to our business achieving significant net cash from operations. Our future capital requirements may be substantial, and will depend on many factors, including, but not limited to:

- the cost of clinical activities and outcomes related to our Phase I/II clinical trial for FCX-007, the Phase I portion of which we expect to initiate in June 2016;
- the costs of pre-clinical activities and outcomes related to FCX-013, for which we expect to file an IND with the FDA in 2017;
- the costs and outcomes relating to our ongoing clinical program for azficel-T for the treatment of vocal cord scarring resulting in chronic or severe dysphonia, for which we expect to announce primary endpoint results in June 2016;
- the cost of additional clinical trials in order to obtain regulatory approvals for our product candidates;
- the cost of regulatory submissions, as well as the preparation, initiation and execution of clinical trials in potential new clinical indications;
- the cost of maintaining an adequate and compliant manufacturing facility; and
- the cost of filing, surveillance around, prosecuting, defending and enforcing patent claims.

To meet our capital needs, we are considering multiple alternatives, including but not limited to, equity financings, debt financings, corporate collaborations, partnerships and other strategic transactions and funding opportunities. If we raise additional funds by issuing equity 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 or equity financing that we complete may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration or partnership arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Additionally, there can be no assurance that we will be able to complete any such financings or capital-raising transactions on acceptable terms or otherwise.



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If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs and modify our business strategy which may require us to, among other things: significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives; seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; sell or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or seek bankruptcy protection which may result in the termination of agreements pursuant to which we license certain intellectual property rights including our exclusive channel collaboration agreements with Intrexon.

These factors raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its audit report on our Consolidated Financial Statements for the year ended December 31, 2015 related to our ability to continue as a going concern.

Also, see Risks Related to Our Financial Position and Need for Additional Capital included within Part I, Item 1A, "Risk Factors" of our 2015 Form 10-K.

## Cash Flows

Our cash flow activity is summarized below for the following periods:

(\$ in thousands)	Three months ended	
	March 31,	
	2016	2015
Net cash flows (used in) provided by:		
Operating activities	\$(16,063)	\$(4,238)
Investing activities	\$(58 )	\$(108 )
Financing activities	\$(52 )	\$152

**Operating Activities.** Cash used in operating activities during the three months ended March 31, 2016 was approximately \$16.1 million, an increase of \$11.8 million as compared to the same period last year, primarily due to the \$10 million up-front technology access fee payment to Intrexon in January 2016 in connection with the 2015 ECC and the payment of employee bonuses and professional fees in the first quarter of 2016.

**Investing Activities.** Cash used in investing activities during both the three months ended March 31, 2016 and 2015 was insignificant and related solely to equipment purchases.

**Financing Activities.** Cash used in financing activities during the three months ended March 31, 2016 was related to payments of deferred offering costs in connection with our "at-the-market" equity offering program. Cash provided by financing activities during the same period in 2015 related to employee stock option exercises. See Note 10 in the accompanying Notes to the Condensed Consolidated Financial Statements for additional information regarding our "at-the-market" offering program. To date, no shares of common stock have been sold, and thus no proceeds have been received, from this program.

## Contractual Obligations

During the three months ended March 31, 2016, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our 2015 Form 10-K.



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### Critical Accounting Policies

Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon our Condensed Consolidated Financial Statements, which have been prepared in conformity with U.S. generally accepted accounting principles (GAAP). Preparing financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. These estimates and assumptions are affected by the application of our accounting policies. Critical accounting policies and practices are both important to the portrayal of a company's financial condition and results of operations, and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. Actual results could differ from such estimates due to changes in economic factors or other conditions that are outside the control of management.

Our summary of significant accounting policies is described in Note 3 to our Consolidated Financial Statements contained in our 2015 Form 10-K. However, please refer to Note 3 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q for updated policies and estimates, if applicable, that could impact our results of operations, financial position, and cash flows.

### Recently Issued Accounting Pronouncements

See Note 3 in the accompanying Notes to the Condensed Consolidated Financial Statements of this Form 10-Q for discussion on recently issued accounting pronouncements.

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

There have been no material changes to our market risk since December 31, 2015.

### Item 4. Controls and Procedures.

#### Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer, concluded that, as of March 31, 2016, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarterly period ended March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



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PART II. OTHER INFORMATION

Item 6. Exhibits.

See the Exhibit Index following the signature page of this Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

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SIGNATURES

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  
Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: May 5, 2016

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EXHIBIT INDEX

EXHIBIT NO. IDENTIFICATION OF EXHIBIT

10.1	Controlled Equity Offering <sup>TM</sup> Sales Agreement, dated January 21, 2016, by and between Fibrocell Science, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 to Fibrocell's Form 8-K filed on January 21, 2016)
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.