Fibrocell Science, Inc.
Form 10-Q
November 03, 2016

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

FORM 10-Q

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

For the quarterly period ended September 30, 2016

OR

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

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

Indicate by check mark whether the registrant is shell company (as defined in Rule 12b-2of the Exchange Act)

Yes o No ý

As of November 1, 2016, there were 43,978,326 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
Fibrocell®, Fibrocell Science®, the Fibrocell logo and LAVIV® are trademarks of Fibrocell Science, Inc. (Exton, PA). All other trademarks, service marks or trade names appearing in this Form 10-Q are the property of their respective

owners.

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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 potential advantages of our product candidates and technologies;
- our expectation to dose the first subject in the Phase I portion of our Phase I/II clinical trial of FCX-007 at the end of 2016, to have three-month data for the Phase I portion of the trial in the third quarter of 2017 and to initiate the Phase II portion of the trial in the fourth quarter of 2017;
- our expectation to initiate a preclinical dose ranging study for FCX-013 in November 2016 to be followed by a toxicology/biodistribution study and submission of an Investigational New Drug application (IND) for FCX-013 to the United States Food and Drug Administration (FDA) in the fourth quarter of 2017;
- our product development goals under our collaboration with Intrexon Corporation for arthritis and related conditions;
- the potential benefits of orphan drug and pediatric rare disease designations;
- our expectation that our existing cash resources will be sufficient to enable us to fund our operations into the fourth quarter of 2017;
- expected costs associated with the wind-down of azficel-T (including LAVIV) operations at our Exton, PA facility including future cash expenditures to decommission our azficel-T manufacturing facility and to terminate and wind-down our contractual and other obligations relating to our azficel-T operations, as well as potential non-cash charges related to future impairments of the carrying values of equipment used in our azficel-T operations;
- future expenses and capital expenditures;
- our plans to address our future capital requirements and the consequences of failing to do so; and
- our plans to resolve our noncompliance with the minimum bid price requirement of The Nasdaq Capital Market listing rules and the consequences of failing to do so;

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," "c "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 this Form 10-Q and 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 the caption "Item 1A—Risk Factors". 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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 21,283	$ 29,268
Inventory, net	—	482
Prepaid expenses and other current assets	374	1,244
Total current assets	21,657	30,994
Property and equipment, net of accumulated depreciation of $1,486 and $1,242, respectively	1,492	1,582
Intangible assets, net of accumulated amortization of $0 and $2,204, respectively	—	4,136
Other assets	64	—
Total assets	$ 23,213	$ 36,712
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 361	$ 499
Related party payable	341	10,720
Accrued expenses	1,715	1,779
Interest payable	46	—
Deferred revenue	—	457
Warrant liability, current	—	1,910
Total current liabilities	2,463	15,365
Convertible promissory notes, net of debt discount of $18,088 and $0, respectively (see Note 5)	—	—
Warrant liability, long term	7,400	6,365
Derivative liability	1,524	—
Deferred rent	788	779
Total liabilities	12,175	22,509
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares outstanding as of September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized, 43,898,785 shares issued and outstanding as of September 30, 2016; 100,000,000 shares authorized, 43,898,785 shares issued and outstanding as of December 31, 2015	44	44
Additional paid-in capital	170,063	161,330
Accumulated deficit	(159,069)	(147,171)
Total stockholders' equity	11,038	14,203
Total liabilities and stockholders' equity	$ 23,213	$ 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue from product sales	$215	$ 49	$300	$217
Collaboration revenue	—	30	18	193
Total revenue	215	79	318	410
Cost of product sales	287	62	696	283
Cost of collaboration revenue	—	142	1	230
Total cost of revenue	287	204	697	513
Gross loss	(72)	(125)	(379)	(103)
Research and development expense	1,645	2,394	6,599	7,208
Research and development expense - related party	534	1,827	2,783	4,694
Selling, general and administrative expense	2,723	2,477	8,003	9,041
Intangible asset impairment expense	—	—	3,905	—
Restructuring costs	43	—	335	—
Operating loss	(5,017)	(6,823)	(22,004)	(21,046)
Other income (expense):				
Warrant revaluation income	3,007	5,301	10,518	4,240
Derivative revaluation expense	(251)	—	(251)	—
Interest expense	(46)	—	(46)	—
Other income (expense), net	8	1	(15)	4
Loss before income taxes	(2,299)	(1,521)	(11,798)	(16,802)
Income tax benefit	—	—	—	—
Net loss	$(2,299)	$ (1,521)	$(11,798)	$ (16,802)
Per Share Information:				
Net loss:				
Basic	$(0.05)	$ (0.04)	$(0.27)	$ (0.40)
Diluted	$(0.05)	$ (0.07)	$(0.31)	$ (0.44)
Weighted average number of common shares outstanding:				
Basic	43,898,785	43,021,121	43,898,785	41,598,632
Diluted	43,898,785	43,712,918	43,922,808	41,829,231

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 paid-in capital	Accumulated deficit	Total Equity
	Shares	Amount			
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)	—
Intrinsic value of beneficial conversion feature, net of issuance costs	—	—	7,017	—	7,017
Stock-based compensation expense	—	—	1,616	—	1,616
Net loss	—	—	—	(11,798)	(11,798)
Balance, September 30, 2016	43,898,785	$ 44	$ 170,063	$ (159,069)	$ 11,038

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)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(11,798)	$(16,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,616	1,550
Warrant liability revaluation income	(10,518)	(4,240)
Derivative liability revaluation expense	251	—
Depreciation and amortization of long-lived assets	476	554
Recovery of doubtful accounts	(12)	(5)
Intangible asset impairment	3,905	—
Loss on disposal or impairment of property and equipment	64	—
Decrease (increase) in operating assets:		
Accounts receivable	12	9
Inventory	482	5
Prepaid expenses and other current assets	1,045	812
Other assets	(64)	—
Increase (decrease) in operating liabilities:		
Accounts payable	(212)	898
Related party payable	(10,379)	434
Accrued expenses and deferred rent	(53)	248
Interest payable	46	—
Deferred revenue	(457)	57
Net cash used in operating activities	(25,596)	(16,480)
Cash flows from investing activities:		
Purchase of property and equipment	(187)	(208)
Proceeds from the sale of property and equipment	1	—
Net cash used in investing activities	(186)	(208)
Cash flows from financing activities:		
Proceeds from private placement offering, net	17,933	—
Proceeds from common stock offering, net	—	15,872
Payment of deferred offering costs	(134)	—
Proceeds from the exercise of stock options	—	255
Principle payments on capital lease obligations	(2)	(3)
Net cash provided by financing activities	17,797	16,124
Net decrease in cash and cash equivalents	(7,985)	(564)
Cash and cash equivalents, beginning of period	29,268	37,495
Cash and cash equivalents, end of period	$21,283	$36,931
Supplemental Cash Flow Disclosures:		
Non Cash Investing and Financing Activities:		
Property and equipment in accounts payable	$33	$31
Deferred offering costs in accounts payable	$41	$—
Reduction of warrant liability upon issuance of shares	$—	$82

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

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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). 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 Science Hong Kong Limited (Fibrocell Hong Kong), a company organized under the laws of Hong Kong and former subsidiary of Fibrocell, 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 and connective tissue. All of the Company's product candidates incorporate its proprietary autologous fibroblast technology. The Company's research and development efforts focus on gaining regulatory approvals 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 September 30, 2016, the Company had cash and cash equivalents of approximately $21.3 million and working capital of approximately $19.2 million. The Company believes that its cash and cash equivalents at September 30, 2016 will be sufficient to fund operations into the fourth quarter of 2017. 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 related to its Consolidated Financial Statements for the year ended December 31, 2015 included a going concern explanatory paragraph.

On October 5, 2016, the Company received a notice (the Notice) from The Nasdaq Stock Market LLC (NASDAQ) that the Company is not currently in compliance with the $1.00 minimum closing bid requirements of NASDAQ Listing Rule 5550(a)(2). The Notice indicated that, consistent with NASDAQ Listing Rule 5810(c)(3)(A), the Company has until April 3, 2017 to regain compliance with the minimum bid price requirement by having the closing bid price of the Company's common stock meet or exceed $1.00 per share for at least ten consecutive business days. During that time, the Company's common stock will continue to trade on The Nasdaq Capital Market under the symbol "FCSC".

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Notes to Condensed Consolidated Financial Statements
(unaudited)

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.
Reclassifications

The prior year Condensed Consolidated Balance Sheet, Condensed Consolidated Statement of Operations and Condensed Consolidated Statement of Cash Flows presented in this Form 10-Q contain certain reclassifications for purposes of disclosing related party transactions and balances separately.
Note 3. Summary of Significant Accounting Policies

Intangible Assets

Intangible assets were research and development assets related to the Company's primary study on azficel-T that were capitalized on the balance sheet upon emergence from bankruptcy. The portion of the reorganization value which was attributed to identifiable intangible assets was $6.3 million. Azficel-T had two current or target indications: the Company's FDA-approved product LAVIV® and a clinical development program for azficel-T for the treatment of vocal cord scarring resulting in chronic or severe dysphonia. Effective January 1, 2012, the Company launched LAVIV and as a result, the research and development intangible assets related to the Company's primary study were considered to be finite-lived intangible assets and began amortizing over 12 years, the estimated useful life of the assets which is analogous with the exclusivity period granted to the Company under the BLA.

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis. The Company reviews the estimated remaining useful life of its intangible assets on an annual basis with any changes, if applicable, accounted for prospectively. In accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 360-10-35, Impairment or Disposal of Long-Lived Assets, the Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In June 2016, based on its failure to achieve primary efficacy endpoints for its Phase II clinical trial of azficel-T for the treatment of vocal cord scarring, the Company determined to wind-down its azficel-T operations as more fully described in Note 10. As a result,

management concluded that the Company's intangible assets had become fully impaired. Accordingly, a non-cash impairment charge of approximately $3.9 million was recorded during the second quarter of 2016 and is included in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2016.

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Note 3. Summary of Significant Accounting Policies (continued)

Warrant Liability

The Company accounts for stock warrants as either equity instruments, derivative liabilities, or liabilities in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480), depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with ASC 815, Derivatives and Hedging (ASC 815) if the stock warrants contain "down-round protection" or other terms that could potentially require "net cash settlement" and therefore, do not meet the scope exception for treatment as a derivative. Since "down-round protection" is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under ASC 815. Warrant instruments that could potentially require "net cash settlement" in the absence of express language precluding such settlement and those which include "down-round provisions" are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to classify the fair value of the warrants that contain "down-round protection" and "net cash settlement" as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. Warrants that the Company may be required to redeem through payment of cash or other assets outside its control are classified as liabilities pursuant to ASC 480 and are initially and subsequently measured at their estimated fair values. For additional discussion on warrants, see Note 6.

Debt Issued with Warrants

The Company considers guidance within ASC 470-20, Debt (ASC 470), ASC 480, and ASC 815 when accounting for the issuance of convertible debt with detachable warrants. As described above under the caption "Warrant Liability", the Company classifies stock warrants as either equity instruments, derivative liabilities, or liabilities depending on the specific terms of the warrant agreement. In circumstances in which debt is issued with liability-classified warrants, the proceeds from the issuance of convertible debt are first allocated to the warrants at their full estimated fair value and established as both a liability and a debt discount. The remaining proceeds, as further reduced by discounts created by the bifurcation of embedded derivatives and a beneficial conversion feature, is allocated to the debt. The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from the allocation of proceeds, to interest expense using the effective interest method over the expected term of the debt instrument pursuant to ASC 835, Interest (ASC 835).

Embedded Derivatives. The Company considers whether there are any embedded features in debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC 815. Embedded derivatives are initially and subsequently measured at fair value. See Note 5 for additional discussion on the embedded derivatives associated with the Company's convertible notes.

Beneficial Conversion Feature. If the amount allocated to the convertible debt results in an effective per share conversion price less than the fair value of the Company's common stock on the commitment date, the intrinsic value of this beneficial conversion feature is recorded as a discount to the convertible debt with a corresponding increase to additional paid-in capital. The beneficial conversion feature discount is equal to the difference between the effective conversion price and the fair value of the Company's common stock at the commitment date, unless limited by the remaining proceeds allocated to the debt. See Note 5 for additional discussion on the beneficial conversion feature associated with the Company's convertible notes.

Debt Issuance Costs. The Company follows the guidance under ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03) for accounting for debt issuance costs. The Company allocates debt issuance costs between the debt and the warrants on the same basis as proceeds were allocated. The Company expenses issuance costs allocated to the warrants and presents the issuance costs allocated to the debt as a direct reduction from the carrying amount of the debt liability in the balance sheet. However, if debt issuance costs exceed the carrying amount of the debt, issuance costs are recorded to additional paid-in capital as a reduction of the beneficial conversion feature. As of September 30, 2016, the Company's debt issuance costs are presented in additional paid-in capital as a reduction of the beneficial conversion feature and will be amortized to interest expense (despite their classification in additional paid-in capital) using the effective interest rate method over the expected term of the debt pursuant to ASC 835.

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Note 3. Summary of Significant Accounting Policies (continued)

Stock-Based Compensation

The Company follows 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 8 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. In the first quarter of 2016, the Company adopted FASB Accounting Standards Update (ASU) 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, 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 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.

Restructuring Costs

Restructuring charges are primarily comprised of severance costs related to workforce reductions, contract termination and wind-down costs, asset impairments and costs of decommissioning the Company’s azficel-T manufacturing facility. In accordance with ASC 420, Exit or Disposal Cost Obligations, the Company recognizes restructuring charges when the liability has been incurred, except for one-time employee termination benefits that are incurred over time. Generally, one-time employee termination benefits (i.e., severance costs) are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments. Other costs, including but not limited to, contract termination and wind-down costs and manufacturing facility decommissioning costs, will be recorded as incurred. Asset impairment charges have been, and will be, recognized when management has concluded that the assets have been impaired in accordance with ASC 360-10-35, Impairment or Disposal of Long-Lived Assets, or other applicable authoritative guidance. See Note 10 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 and nine months ended September 30,

2016 and 2015, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either September 30, 2016 or December 31, 2015 because it maintains 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 September 30, 2016 and December 31, 2015, the Company had no uncertain tax positions.

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Note 3. Summary of Significant Accounting Policies (continued)

Recently Adopted Accounting Pronouncements

In April 2015, the FASB issued ASU 2015-03, to simplify the presentation of debt issuance costs. The new standard requires entities to present debt issuance costs related to a recognized liability in the balance sheet as a direct deduction from that liability, or contra-liability, rather than an asset, consistent with the existing presentation of a debt discount. For public business entities, the amendments in ASU 2015-03 are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company has adopted this guidance during the third quarter of 2016 in connection with the issuance of convertible notes as discussed above under the subheading “Debt Issued with Warrants” within Note 3 and also Note 5.

Recently Issued Accounting Pronouncements

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which provides guidance on the treatment of cash receipts and cash payments for certain types of cash transactions, to eliminate diversity in practice in the presentation of the cash flow statement. For public business entities, the amendments in ASU 2016-15 are effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Earlier application is permitted. While this ASU is not currently material to the Company, given the recent issuance of convertible notes discussed above and in Note 5, this ASU may be applicable in the future.

From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that we adopt as of the specified date. Unless otherwise noted, management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, 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 as such, are charged to research and development (R&D) expense when consumed for such activities.

Inventories consisted of the following as of:

($ in thousands)	September 30, 2016	December 31, 2015
Raw materials (LAVIV and product candidates)	$ —	$ 338
Work in process (LAVIV)	—	144
Total inventory, gross	—	482
Less: Reserve for work in process expiration	—	—
Total inventory, net	$ —	$ 482

As a result of the wind-down of the Company’s azficel-T operations, more fully described in Note 10, the Company wrote off all remaining raw materials and work-in-process inventories as of September 30, 2016. Total inventory write-offs of approximately $0.4 million are included in cost of goods sold for the nine months ended September 30, 2016. Future raw materials purchased for pre-clinical and clinical trials will be charged to R&D expense as incurred.

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Note 5. Convertible Notes

2016 Private Placement

In September 2016, the Company issued an aggregate of $18,087,500 in principal of convertible promissory notes (each, a Note and collectively, the Notes) and accompanying warrants to purchase an aggregate of 18,087,500 shares of common stock (each a Warrant and collectively, the Warrants) in a private placement to institutional and accredited investors (each an Investor and collectively, the Investors).

The Notes bear interest at four percent (4%) per annum. Interest is earned daily and compounded quarterly and, at the election of the Company at the beginning of each quarter, shall accrue or be paid in cash. If the Company elects to have interest accrue, such interest will not be added to the principal amount of the Notes but such interest shall be subject to additional interest at the rate of four percent (4%) per annum, compounded quarterly, and shall be due and payable upon the earliest of the conversion of the Notes, exercise of the Put Right, exercise of the Prepayment Right or the Maturity Date (in each case, as defined below). Additionally, if the Company elects for interest to accrue, then (i) the Company may elect to repay any such accrued and unpaid interest in cash at any time and from time to time and (ii) each Investor may elect to have the Company repay any such accrued and unpaid interest by delivering such number of shares of Common Stock equal to (x) the amount of the accrued and unpaid interest to be repaid, divided by (y) the greater of (i) the last closing bid price of a share of Common Stock as reported on The Nasdaq Capital Market (NASDAQ) on the date of such election and (ii) the Conversion Price (as defined below). As of September 30, 2016, the Company has elected to accrue interest.

All unpaid principal of each Investor’s Note is convertible, at any time and from time to time, at the option of such Investor into shares of Common Stock at the greater of (x) $1.13625 and (y) the last closing bid price of a share of Common Stock as reported on NASDAQ at the time of such Investor’s execution of the Purchase Agreement, plus $0.12625 (as subject to adjustment, the “Conversion Price”) which range from $1.13625 to $1.22625 per share.

The Notes have a maturity date of the earlier of (i) September 7, 2026 and (ii) one-hundred and eighty (180) days after the date on which the Company’s product candidate, FCX-007, is approved by the United States Food and Drug Administration for the treatment of recessive dystrophic epidermolysis bullosa (the Maturity Date). Each Investor has the right to require the Company to repay all or any portion of the unpaid principal and accrued and unpaid interest from time to time on or after September 7, 2021 (such right, a Put Right). Such Put Right must be exercised by such Investor by delivering written notice to the Company no later than one-hundred and eighty (180) days prior to such exercise date of such Put Right. In addition, upon consummation of a specified change of control transaction, each Investor may elect to accelerate the repayment of all unpaid principal and accrued interest under such Investor’s Note. If an Investor does not elect to have the Company prepay its Note upon such change of control transaction, then the Company may prepay the Notes, in an amount equal to one hundred one percent (101%) of the outstanding principal due under the Notes (together with accrued and unpaid interest due thereon) (the Prepayment Right). Additionally, upon the occurrence of certain Events of Default, as defined in the Notes, each Investor may elect to accelerate the repayment of all unpaid principal and accrued interest under each Note and the Notes provide for automatic redemption upon the occurrence of certain bankruptcy related Events of Default, as defined in the Notes.

Accounting for Convertible Notes and Embedded Derivatives

The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from allocation of proceeds to interest expense using the effective interest method over the expected term of the Notes

pursuant to ASC 835, Interest (ASC 835).

See Note 3 for discussion of the Company's policies for accounting for debt with detachable warrants. In connection with the issuance of the Notes and Warrants, the Company recorded a debt discount of approximately $18.1 million based on an allocation of proceeds to the Warrants of approximately $9.6 million, an allocation to bifurcated derivatives (which consist of a contingent put option upon a change of control or acceleration upon event of default (the Contingent Put Option) and a contingent call option upon a change of control (the Contingent Call Option) included in the Notes) of approximately $1.3 million, and a beneficial conversion feature of approximately $7.2 million, before issuance costs, based on the difference between the fair value of the underlying common stock at the commitment date of each Note transaction and the effective conversion price of the Notes, as limited by the proceeds allocated to the Notes. The debt discount and issuance costs are

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Note 5. Convertible Notes (continued)

amortized using the effective interest method over the expected term of the Notes.

Convertible promissory notes outstanding were:

($ in thousands)	September 30, 2016
Convertible promissory notes	$ 18,088
Debt discount - warrants	(9,643)
Debt discount - compound bifurcated derivatives	(1,273)
Debt discount - beneficial conversion feature	(7,172)
Convertible promissory notes, net	$ —

Amortization of the debt discounts included in interest expense in the Condensed Consolidated Statements of Operations for both the three and nine months ended September 30, 2016 was $0.

Assumptions Used in Determining Fair Value of Compound Bifurcated Derivative

The Company utilizes a binomial lattice model to value its bifurcated derivatives included in the Notes. ASC 815 does not permit an issuer to account separately for individual derivative terms and features embedded in hybrid financial instruments that require bifurcation and liability classification as derivative financial instruments. Rather, such terms and features must be combined together and fair valued as a single, compound embedded derivative. The Company selected a binomial lattice model to value the compound embedded derivative because it believes this technique is reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of the Notes. Such assumptions include, among other inputs, stock price volatility, risk-free rates, credit risk assumptions, early redemption and conversion assumptions, and the potential for future adjustment of the conversion price due to a future dilutive financing. Additionally, there are other embedded features of the Notes requiring bifurcation, other than the Contingent Put Option and the Contingent Call Option, which had no value at September 30, 2016 due to management’s estimates of the likelihood of certain events, but that may have value in the future should those estimates change.

The estimated fair value of the compound bifurcated derivative is determined using Level 2 and Level 3 inputs. Significant inputs and assumptions used in the binomial lattice model for the derivative liability are as follows:

($ in thousands except per share data)	September 30, 2016
Calculated aggregate value	$ 1,524
Closing price per share of common stock	$ 0.72
Contractual remaining term	9 years, 11 months
Contractual interest rate	4.0 %
Volume-weighted average conversion rate	$ 1.13662
Risk-free interest rate (term structure)	0.20% - 1.60%
Dividend yield	—
Credit Rating	CC

Credit Spread	32.28	%
Volatility	99.9	%

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Note 6. Warrants

The Company accounts for common stock warrants as equity instruments, derivative liabilities, or liabilities, depending on the specific terms of the warrant agreement. See Note 3 for further details on accounting policies related to the Company's stock warrants.

In connection with various financing transactions, the Company has issued warrants to purchase the Company's common stock. In September 2016, the Company issued warrants to purchase 18,087,500 shares of its common stock for an exercise price of $1.50 per share to investors in connection with a private placement offering of convertible debt securities as more fully discussed in Note 5. The warrants are exercisable at any time beginning six months after issuance through five years after issuance. The Company classified these warrants as liabilities based on the guidance in ASC 480, as the warrants contain a provision that could result in the Company's redemption of the warrants outside its control for cash equal to the value of the warrants calculated using a Black-Scholes pricing model. As of September 30, 2016 and December 31, 2015, all of the Company's outstanding common stock warrants were classified as either derivative liabilities or liabilities.

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

Liability-classified warrants	Number of Warrants		Exercise Price	Expiration Dates
	September 30, 2016	December 31, 2015		
Issued in March 2010 financing	—	319,789	$6.25	Mar 2016
Issued in June 2011 financing	—	6,113	$22.50	Jun 2016
Issued in August 2011 financing	—	565,759	$18.75	Aug 2016
Issued to placement agents in August 2011 financing	—	50,123	$13.635	Aug 2016
Issued in Series B and D Preferred Stock offerings	1,389,194	1,970,594	$6.25	Jul 2016 - Dec 2016
Issued in Series E Preferred Stock offering [1]	132,014	60,000	$1.13625	Dec 2017
Issued with June 2012 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
Issued with September 2016 Convertible Notes	18,087,500	—	$1.50	Sep 2021
Total	22,303,109	5,666,779		

(1) As a result of the issuance of the September 2016 Convertible Notes, the exercise price for warrants issued in connection with the Company's Series E Preferred Stock offering was decreased from $2.50 per warrant share to $1.13625 and the number of warrant shares was increased by 72,014, due to anti-dilution provisions contained in the warrants for certain investors who did not agree to modifications the Company offered in October 2012.

The table below is a summary of the Company's warrant activity during the nine months ended September 30, 2016:

	Number of warrants	Weighted-average exercise price
Outstanding at December 31, 2015	5,666,779	$ 7.14
Issued	18,087,500	1.50
Adjustments [1]	72,014	1.13625
Exercised	—	—
Expired	(1,523,184)	11.20
Outstanding at September 30, 2016	22,303,109	$ 2.27

(1) See footnote 1 in table above.

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Note 6. Warrants (continued)

Accounting for Liability-classified Warrants

The foregoing warrants were recorded as derivative liabilities or liabilities at their estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in other income (expense) in the Company's Condensed Consolidated Statements of Operations in each subsequent period. The change in the estimated fair value of the warrant liability for the three and nine months ended September 30, 2016 resulted in non-cash income of approximately $3.0 million and $10.5 million, respectively. The change in the estimated fair value of the warrant liability for the three and nine months ended September 30, 2015 resulted in non-cash income of approximately $5.3 million and $4.2 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 stock price volatility based on the Company's historical stock price performance over a period of time 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.

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)	September 30, 2016	December 31, 2015
Calculated aggregate value	$ 7,400	$ 8,275
Weighted average exercise price per share	$ 2.27	$ 7.14
Closing price per share of common stock	$ 0.72	$ 4.55
Volatility	85.3 %	85.2 %
Weighted average remaining expected life	4 years, 3 months	1 year, 8 months
Risk-free interest rate	1.04 %	0.98 %
Dividend yield	—	—

Note 7. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company follows the guidance in ASC 820, Fair Value Measurement, to account for financial assets and liabilities measured at fair value 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.

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Note 7. Fair Value Measurements (continued)

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 into within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the periods presented.

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:

	September 30, 2016			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$21,283	$ —	$ —	$21,283
Total Assets	$21,283	$ —	$ —	$21,283
Liabilities:				
Warrant liability	$—	$ —	$7,400	$7,400
Derivative liability	—	—	1,524	1,524
Total Liabilities	$—	$ —	$8,924	$8,924

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

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Note 7. Fair Value Measurements (continued)

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

Common Stock Warrants - Warrant Liability

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
Issuance of warrants [1]	9,643
Expiration of warrants [2]	(477)
Change in fair value of warrant liability	(10,041)
Balance at September 30, 2016	$7,400

(1) Represents fair value of warrants on the issuance date.
(2) Represents the fair value as of the beginning of the year for warrants expiring during the year and has been recorded to warrant revaluation income or expense in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2016.

Bifurcated Compound Derivative - Derivative Liability

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

($ in thousands)	Derivative Liability
Balance at December 31, 2015	$ —
Issuance of convertible notes [1]	1,273
Change in fair value of derivative	251
Balance at September 30, 2016	$ 1,524

(1) Represents fair value of embedded derivatives on the issuance date.

Effect of Fibrocell's Stock Price and Assumptions on the Calculation of Fair Value of Financial Instruments Measured on a Recurring Basis

Common Stock Warrants - Warrant Liability

The fair value of the warrant liability is based on Level 3 inputs. As discussed in Note 6, 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 6 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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Note 7. Fair Value Measurements (continued)

Bifurcated Compound Derivative - Derivative Liability

The fair value of the derivative liability is based on Level 3 inputs. As discussed in Note 5, the Company uses a binomial lattice model to value the compound embedded derivative bifurcated from the Notes. 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, changes in interest rates, assumptions regarding the adjusted conversion prices in the Notes, and early redemption or conversion of the Notes. 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.

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. The fair value of the long-term convertible promissory notes was approximately $14.8 million at September 30, 2016, compared to a carrying value of $0, as a result of unamortized debt discounts.

Note 8. 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 7,600,000 shares of the Company's common stock. In addition, as of September 30, 2016, there were 25,000 options outstanding that were issued outside the Plan to consultants in 2013.

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 at the time each award is granted, provided that the term of the option does not exceed ten years. Vesting schedules for stock options vary, but generally vest 25% per year over four years for employee options and on the one-year anniversary date for non-employee director options. The Plan had 3,179,527 shares available for future grants as of September 30, 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 nine months ended September 30, 2016 and 2015, the weighted average fair market value for options granted was $1.37 and $3.59, 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 for both

the three months ended September 30, 2016 and 2015, and approximately $1.6 million for both the nine months ended September 30, 2016 and 2015.

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 stock price volatility based on the Company’s historical stock price performance over a period of time that matches the expected term of the stock options.

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Note 8. Share-Based Compensation (continued)

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, 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.

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

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.

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 nine months ended:

	September 30, 2016		September 30, 2015	
Expected term	6 years, 2 months		6 years, 1 month	
Interest rate	1.37	%	1.56	%
Dividend yield	—		—	
Volatility [1]	92.5	%	103.2	%

(1) For the nine months ended September 30, 2016, the Company estimated expected volatility based on the historical volatility of its own common stock on a stand-alone basis. Prior to January 1, 2016, including the nine months ended September 30, 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 nine months ended September 30, 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	1,316,000	1.79		
Exercised	—	—		
Forfeited	(36,334)	4.39		
Expired	(32,534)	8.18		
Outstanding at September 30, 2016 [1]	4,381,226	$ 4.90	7 years, 11 months	$ —
Exercisable at September 30, 2016	2,078,808	$ 7.26	6 years, 10 months	$ —

(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 nine months ended September 30, 2016 was approximately $2.1 million. Additionally, as of September 30, 2016, there was approximately $4.4 million of unrecognized compensation expense related to non-vested stock options which is expected to be recognized over a weighted-average period of 2.6 years.

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Note 9. 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 September 30, 2016 and 2015, the Company incurred total expenses of $0.5 million and $1.8 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 $0.5 million incurred during the 2016 period, $0.2 million related to direct expenses for work performed by Intrexon and $0.3 million related to pass-through costs. Of the $1.8 million incurred during the 2015 period, $0.7 million related to direct expenses for work performed by Intrexon and $1.1 million related to pass-through costs.

For the nine months ended September 30, 2016 and 2015, the Company incurred total expenses of $2.8 million and $4.7 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 $2.8 million incurred during the 2016 period, $1.0 million related to direct expenses for work performed by Intrexon and $1.8 million related to pass-through costs. Of the $4.7 million incurred during the 2015 period, $2.4 million related to direct expenses for work performed by Intrexon and $2.3 million related to pass-through costs.

As of September 30, 2016 and December 31, 2015, the Company had outstanding payables to Intrexon of $0.3 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.

Affiliates of Randal J. Kirk (including Intrexon) participated in the Company’s private placement offering of convertible debt securities in September 2016, more fully described in Note 5, and were issued an aggregate of $6,762,500 in principal of Notes and accompanying Warrants to purchase an aggregate of 6,762,500 shares of common stock.

Note 10. Restructuring Costs

In June 2016, the Company determined to wind-down its azficel-T operations at the Company’s Exton, PA facility and to reduce the workforce that supports such operations. This decision enables the Company to focus its resources towards development of its gene-therapy product candidates.

Restructuring-related charges for the three months ended September 30, 2016 totaled less than $0.1 million and were related solely to employee severance and benefit-related charges. Restructuring-related charges for the nine months ended September 30, 2016 were comprised of approximately $0.3 million of employee severance and benefit-related

charges and less than $0.1 million of asset impairments.

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Note 10. Restructuring Costs (continued)

The restructuring and asset impairment activity for the nine months ended September 30, 2016 was as follows:

($ in thousands)	Employee Severance and Benefits	Asset Impairments	Total
Accrued restructuring balance as of December 31, 2015	$ —	$ —	$—
Additional accruals	301	34	335
Cash payments	(282)	—	(282)
Non-cash settlements	—	(34)	(34)
Accrued restructuring balance as of September 30, 2016	$ 19	$ —	$19

The restructuring-related charges incurred during the nine months ended September 30, 2016 related to employee severance and benefits resulting from the reduction-in-workforce and the impairment of property and equipment. In connection with the reduction-in-workforce, approximately 50% of the Company's employees were terminated, primarily in the areas of manufacturing and quality operations. The accrued restructuring balance as of September 30, 2016 relates to employee severance and benefits which are expected to be paid in the fourth quarter of 2016 and is recorded as a current liability within accrued expenses in the Condensed Consolidated Balance Sheet. Additionally, the Company recognized inventory write-offs in cost of goods sold related to the wind-down of its azficel-T (including LAVIV) operations as described in Note 4.

The Company may incur additional charges in the future for contract termination and wind-down costs, asset impairments and costs to decommission the Company’s azficel-T manufacturing facility, but cannot estimate them at this time.

Note 11. 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, convertible notes and other potentially dilutive common stock equivalents outstanding during the period. Diluted loss per share is based on the if-converted method or the treasury stock method, as applicable, and includes the effect from the potential issuance of common stock, such as shares issuable pursuant to the conversion of convertible notes and the exercise of stock options and warrants, assuming the exercise of all "in-the-money" common stock equivalents 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 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
($ in thousands, except share and per share data)	2016	2015	2016	2015
Loss per share - basic:				
Numerator for basic loss per share	$(2,299)	$(1,521)	$(11,798)	$(16,802)
Denominator for basic loss per share	43,898,785	43,021,121	43,898,785	41,598,632
Basic loss per common share	$(0.05)	$(0.04)	$(0.27)	$(0.40)
Loss per share - diluted:				

Numerator for diluted loss per share	$(2,299)	$(1,521)	$(11,798)	$(16,802)
Adjust: Warrant revaluation income (expense) for dilutive warrants	—	1,529	1,958	1,529
Net loss attributable to common share	$(2,299)	$(3,050)	$(13,756)	$(18,331)
Denominator for basic loss per share	43,898,785	43,021,121	43,898,785	41,598,632
Plus: Incremental shares underlying dilutive warrants outstanding	—	691,797	24,023	230,599
Denominator for diluted loss per share	43,898,785	43,712,918	43,922,808	41,829,231
Diluted net loss per common share	$(0.05)	$(0.07)	$(0.31)	$(0.44)

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Note 11. 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 September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
“In the money” stock options	441,000	2,733,864	510,667	1,923,926
“Out of the money” stock options	3,940,226	457,480	3,684,407	1,113,960
“In the money” warrants	—	—	—	801,132
“Out of the money” warrants	22,303,109	4,741,725	10,601,799	4,801,476
Shares underlying convertible notes	15,913,612	—	15,913,612	—
Shares underlying accrued interest on convertible notes	40,657	—	40,657	—
Other securities excluded from the calculation of diluted loss per share:				
Stock options with performance condition	—	—	—	66,667

Note 12. Equity

Common Stock - Shares Authorized

In July 2016, the Company amended its Restated Certificate of Incorporation, as amended, to increase the number of shares of common stock that the Company is authorized to issue from 100,000,000 to 150,000,000.

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

In January 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 September 30, 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 for diseases affecting the skin and connective tissue. 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 delivery vehicle for proteins targeted to these areas. We target the underlying cause of disease by using fibroblast cells from a patient's skin to create localized therapies with 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 and connective tissue, 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 pipeline consists of the following product candidates which we are developing in collaboration with Intrexon Corporation (Intrexon):

Development Programs

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

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blistering, open wounds and scarring in response to 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 (which can cost a patient in excess of $10,000 per month), hydrogel dressings, antibiotics, feeding tubes and surgeries.

Our lead product candidate, FCX-007, is in clinical development for the treatment of RDEB. FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for 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. In addition, we believe the autologous nature of the cells, localized delivery, use of an integrative vector and the low turnover rate of the protein will contribute to long-term persistence of the COL7 produced by FCX-007.

FCX-007 has received orphan drug designation and pediatric rare disease designation from the U.S. Food and Drug Administration’s (FDA) Office of Orphan Products Development (OOPD) for the treatment of RDEB.

Phase I/II Trial of FCX-007 for RDEB

The primary objective of this open-label trial is to evaluate the safety of FCX-007 in RDEB subjects. Additionally, the trial will assess (i) the mechanism of action of FCX-007 through the evaluation of type VII collagen expression and the presence of anchoring fibrils and (ii) the efficacy of FCX-007 through intra-subject paired analysis of target wound area by comparing FCX-007 treated wounds to untreated wounds in Phase I and to wounds administered with sterile saline in Phase II. 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 enrolling 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.

We are actively recruiting adult subjects to complete enrollment in the Phase I portion of the trial and currently have four of the six adult subjects enrolled. The subjects in the Phase I portion of the trial are divided into two equal cohorts in order to evaluate the safety of FCX-007 in each population type. One cohort is comprised of subjects who have positive expression of the non-collagenous portion of COL7 protein (NC1+) and the other cohort is comprised of subjects who do not express the non-collagenous portion of the protein (NC1-). We have completed enrollment in the Phase I portion of the trial for the NC1+ cohort and require two more subjects to complete enrollment in the NC1- cohort .

The manufacture of FCX-007 for all four enrolled subjects is in process and we expect to dose our first subject at the end of 2016. Additional adult subjects will be dosed after a required 90-day waiting period is complete to ensure there are no safety concerns for the first dose of the new gene-therapy product. We expect to have three-month post-treatment data for safety, mechanism of action and efficacy for the Phase I portion of the trial in the third quarter of 2017 and expect to initiate the Phase II portion of trial in the fourth quarter of 2017.

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 that there are approximately 40,000 patients in the U.S. who have linear scleroderma over a major joint and exhibit severe joint pain.

Our second gene-therapy product candidate, FCX-013, is in pre-clinical development for the treatment of linear scleroderma, a form of localized scleroderma. FCX-013 incorporates Intrexon's proprietary RTS® switch, a biologic switch activated by an orally administered compound to control future 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.

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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 severe combined immunodeficiency (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 a pre-clinical dose-ranging study in November 2016 to be followed by a toxicology/biodistribution study. We expect to submit an IND application for FCX-013 to the FDA in the fourth quarter of 2017.

FCX-013 has received orphan drug designation from the OOPD for the treatment of localized scleroderma.

Gene Therapy Research Program for Arthritis and Related Conditions

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 in the research phase and is focused on the treatment of arthritis and related conditions. 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.

Intrexon Collaborations

We collaborate with Intrexon Corporation, a related party, through two distinct exclusive channel collaboration agreements consisting of 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 reimburse 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 a gene-therapy treatment for arthritis and related conditions under the 2015 ECC. For additional details, see Note 9 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.

Wind-down of azficel-T Operations

In June 2016, we reported that the primary efficacy endpoints were not met in our Phase II clinical trial of azficel-T for the treatment of vocal cord scarring resulting in chronic or severe dysphonia. As a result, we determined to wind-down azficel-T (including LAVIV) operations at our Exton, PA facility in order to focus our efforts and resources on our gene-therapy portfolio of product candidates. In connection with this wind-down, we terminated approximately 50% of our workforce, primarily in the areas of manufacturing and quality operations in the second quarter of 2016. With the focus now on our gene-therapy portfolio, we are seeking an acquiror for azficel-T.

Through September 30, 2016, we incurred one-time termination costs in connection with the reduction in workforce, which include severance, benefits and related costs, of approximately $0.3 million. We also incurred approximately $0.4 million and less than $0.1 million, respectively, for inventory write-offs and asset impairment charges for equipment used in our azficel-T operations through September 30, 2016. We may incur additional charges in the future for contract termination and wind-down costs, asset impairments and costs to decommission the Company's azficel-T manufacturing facility, but cannot estimate them at this time. Please refer to Note 10 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q for further details including

the financial statement impact this restructuring has had, and is expected to have, on our results of operations.

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Financial Condition, Liquidity and Capital Resources

Financial Condition

We have experienced losses since our inception. As of September 30, 2016, we had an accumulated deficit of $159.1 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. Additionally, to fund our operations, we issued convertible promissory notes in an aggregate amount of approximately $18.1 million, which bear interest at 4% per annum, in connection with our September 2016 private placement offering as more fully described under the heading "Contractual Obligations" in Item 2 of this Form 10-Q and in Note 5 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q.

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

($ in thousands)	September 30, 2016	December 31, 2015	Change $	Change %
Cash and cash equivalents	$21,283	$29,268	$(7,985)	(27.3)%
Working capital:				
Total current assets	$21,657	$30,994	$(9,337)	(30.1)%
Total current liabilities	(2,463)	(15,365)	12,902	(84.0)%
Net working capital	$19,194	$15,629	$3,565	22.8 %
Convertible notes (principal)	$18,088	$—	$18,088	100.0 %

Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents of $21.3 million as of September 30, 2016. As of September 30, 2016, we had net working capital of $19.2 million. Net working capital increased approximately $3.6 million, or 22.8%, from December 31, 2015 to September 30, 2016. This increase is primarily the result of a decrease in our short-term warrant liability of approximately $1.9 million and the net impact of our reduction in expenditures during 2016 (related to both a reduction in research and development expenses incurred with Intrexon and the wind-down of our azficel-T operations) and the increase in cash provided by financing activities (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 2017; 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 costs of pre-clinical activities and outcomes related to FCX-013, for which we expect to file an IND with the FDA in the fourth quarter of 2017;
- the costs to complete the wind-down of our azficel-T (including LAVIV) operations including, without limitation, the costs to decommission our azficel-T manufacturing facility and to terminate and wind-down our contractual and other obligations relating to our azficel-T operations;
- 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; and

- the cost of filing, surveillance around, prosecuting, defending and enforcing patent claims.

To meet our capital needs, we consider multiple alternatives, including but not limited to equity financings, debt financings, corporate collaborations, partnerships and other strategic transactions and funding opportunities. However, there is no assurance that we will be able to complete any such transaction or obtain the additional required capital on acceptable terms or otherwise. Furthermore, the covenants under our convertible notes limit our ability to obtain additional debt financing. If

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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.

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; or
- sell or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Additionally, failure to obtain the necessary capital in a timely manner could require us to seek bankruptcy protection or result in our breach or default under agreements on which our business relies or pursuant to which we obtain valuable rights which could result in, among other things, the potential acceleration of payments thereunder or the termination of such agreements.

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 in our 2015 Form 10-K related to our ability to continue as a going concern.

NASDAQ Deficiency Notice

On October 5, 2016, we received notice (the Notice) from The Nasdaq Stock Market LLC (NASDAQ) that we are not currently in compliance with the $1.00 minimum bid price requirement of NASDAQ Listing Rule 5550(a)(2). The Notice has no immediate effect on the listing of our common stock, and our common stock will continue to trade on The Nasdaq Capital Market under the symbol “FCSC” during the 180-day cure period. The Notice indicated that, consistent with NASDAQ Listing Rule 5810(c)(3)(A), we have until April 3, 2017 to regain compliance with the minimum bid price requirement by having the closing bid price of our common stock meet or exceed $1.00 per share for at least ten consecutive business days.

In the event we do not regain compliance by April 3, 2017, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares ($1 million) and all other initial listing standards for The Nasdaq Capital Market which require, among other things, that we have at least $5 million of stockholders’ equity or at least $4 million of stockholders’ equity and $50 million market value of listed shares. If we fail to regain compliance during the applicable period, NASDAQ will provide written notice that our securities will be delisted. In that event, we may appeal such delisting determination to a hearings panel. The delisting of our common stock from The Nasdaq Capital Market could result in an event of default under our convertible promissory notes.

We intend to monitor the closing bid price of our common stock and consider options available to us to resolve our noncompliance with the minimum bid price requirement before April 3, 2017 including, among other things, seeking

stockholder approval to effect a reverse stock split.

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Cash Flows

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

	Nine months ended September 30,	
($ in thousands)	2016	2015
Net cash flows (used in) provided by:		
Operating activities	$(25,596)	$(16,480)
Investing activities	$(186)	$(208)
Financing activities	$17,797	$16,124

Operating Activities. Cash used in operating activities during the nine months ended September 30, 2016 was approximately $25.6 million, an increase of $9.1 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, offset by a decrease in spending as a result of the completion of certain pre-clinical development activities for our FCX-007 product candidate, as more fully described under the heading “Results of Operations” in Item 2 of this Form 10-Q.

Investing Activities. Cash used in investing activities during both the nine months ended September 30, 2016 and 2015 was related primarily to equipment purchases.

Financing Activities. Cash provided by financing activities during the nine months ended September 30, 2016 was approximately $17.8 million, an increase of $1.7 million as compared to the same period last year, primarily due to net proceeds from our September 2016 private placement offering of approximately $17.9 million compared to net proceeds received from our July 2015 common stock offering of approximately $15.9 million. See additional information regarding our September 2016 private placement offering included under the heading “Contractual Obligations” in Item 2 of this Form 10-Q and in Note 5 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2016 and 2015

Revenue and Cost of Revenue

Revenue and cost of revenue were comprised of the following:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
($ in thousands)	2016	2015	% Change	2016	2015	% Change	
Revenue from product sales	$215	$49	338.8 %	$300	$217	38.2 %	(1)
Collaboration revenue	—	30	(100.0)%	18	193	(90.7)%	(2)
Total revenue	215	79	172.2 %	318	410	(22.4)%	
Cost of product sales	287	62	362.9 %	696	283	145.9 %	(3)
Cost of collaboration revenue	—	142	(100.0)%	1	230	(99.6)%	(4)
Total cost of revenue	287	204	40.7 %	697	513	35.9 %	
Gross loss	$(72)	$(125)	(42.4)%	$(379)	$(103)	268.0 %	

(1) Revenue from product sales solely relates to, and is recognized based on, the shipment of LAVIV injections to 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. In connection with the wind-down of azficel-T

operations, the Company is no longer accepting new prescriptions.

(2) 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 less than $0.1 million that was being amortized 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 and nine months ended September 30, 2016 solely relates

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to amortization of the upfront license fee while collaboration revenue for the three and nine months ended September 30, 2015 includes amortization of both the upfront license fee and the proof-of-concept study.

(3) Cost of product sales includes direct and indirect costs related to the processing of cells for LAVIV. Cost of product sales increased approximately $0.2 million, or 362.9%, for the three months ended September 30, 2016 and $0.4 million, or 145.9%, for the nine months ended September 30, 2016 as compared to the same periods in 2015. The increases for both the three- and nine-month periods are primarily due to increases in sales volume during the 2016 periods as well as charges for inventory write-offs recorded as a result of the wind-down of our azficel-T operations.

(4) Cost of collaboration revenue during the three and nine months ended September 30, 2015 relates to a proof-of-concept study which was completed during 2015. As such, no such expenses were incurred during the three and nine months ended September 30, 2016.

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 development costs and clinical trial and manufacturing 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 resources 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:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
($ in thousands)	2016	2015	% Change	2016	2015	% Change	
Direct costs:							
FCX-007	$827	$1,298	(36.3)%	$2,745	$3,527	(22.2)%	(1)
FCX-013	125	512	(75.6)%	544	1,216	(55.3)%	(2)
azficel-T for vocal cord scarring	25	218	(88.5)%	195	942	(79.3)%	(3)
Other	26	23	13.0 %	82	122	(32.8)%	
Total direct costs	1,003	2,051	(51.1)%	3,566	5,807	(38.6)%	
Indirect costs:							
Regulatory costs	247	236	4.7 %	697	716	(2.7)%	
Intangible amortization	—	138	(100.0)%	231	414	(44.2)%	(4)
Compensation and related expense	638	1,165	(45.2)%	2,693	2,981	(9.7)%	(5)
Process development	8	481	(98.3)%	1,007	552	82.4 %	(6)
Other indirect R&D costs	283	150	88.7 %	1,188	1,432	(17.0)%	(7)
Total indirect costs	1,176	2,170	(45.8)%	5,816	6,095	(4.6)%	
Total research and development expense	$2,179	$4,221	(48.4)%	$9,382	$11,902	(21.2)%	

(1) Costs for our FCX-007 program decreased approximately $0.5 million, or 36.3%, for the three months ended September 30, 2016 and $0.8 million, or 22.2%, for the nine months ended September 30, 2016 as compared to the same periods in 2015. The decreases for both the three- and nine-month periods are primarily due to the completion of pre-clinical development activities in the first quarter of 2016 that were ongoing during the nine

months ended September 30, 2015, offset partially by costs associated with the initiation of the Phase I portion of our Phase I/II clinical trial for FCX-007 in adults in the second quarter of 2016.

Through September 30, 2016, we have incurred approximately $20.0 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, the design of the Phase I/II clinical trial protocol and recruiting subjects. 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.

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(2) Costs for our FCX-013 program decreased approximately $0.4 million, or 75.6%, for the three months ended September 30, 2016 and $0.7 million, or 55.3%, for the nine months ended September 30, 2016 as compared to the same periods in 2015. The decreases for both the three- and nine-month periods are primarily due to the completion of our proof-of-concept study in the first quarter of 2016, as compared to early product development expenses incurred during the nine months ended September 30, 2015, which included gene screening and selection, construct build and optimization, vector optimization, assay development, RTS® switch and ligand optimization and some early animal model work.

Through September 30, 2016, we have incurred approximately $9.7 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.

(3) Costs for our azficel-T for vocal cord scarring program decreased approximately $0.2 million, or 88.5%, for the three months ended September 30, 2016 and $0.7 million, or 79.3%, for the nine months ended September 30, 2016 as compared to the same periods in 2015 as dosing in the Phase II trial was complete as of December 31, 2015. No subject enrollment or clinical manufacturing costs were incurred in the 2016 periods.

Through September 30, 2016, we have incurred approximately $2.6 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 subjects, executing our Phase I and II clinical trials and statistical analyses. Going forward, no significant research and development investments for this program are anticipated as the Phase II trial did not meet primary efficacy endpoints and the trial will be terminated upon assessment of the final 12-month endpoint.

(4) Intangible asset amortization decreased approximately $0.1 million, or 100.0%, for the three months ended September 30, 2016 and $0.2 million, or 44.2%, for the nine months ended September 30, 2016 as compared to the same periods in 2015 due to the impairment of the Company's intangible assets during the second quarter of 2016 which resulted in no amortization expense during the three months ended September 30, 2016. See Note 3 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q for further details.

(5) Compensation and related expense decreased approximately $0.5 million, or 45.2%, for the three months ended September 30, 2016 and $0.3 million, or 9.7%, for the nine months ended September 30, 2016 as compared to the same periods in 2015. The decreases for both the three- and nine-month periods are primarily due to decreases in salaries and bonus expense resulting from the reduction in workforce associated with the wind-down of azficel-T operations which occurred in June 2016.

(6) Process development costs decreased approximately $0.5 million, or 98.3%, for the three months ended September 30, 2016 compared to the same period in 2015 as a result of internal process development work being halted in June 2016 in connection with the wind-down of azficel-T operations and related restructuring initiatives.

Process development costs increased approximately $0.5 million, or 82.4%, for the nine months ended September 30, 2016 as compared to the same period in 2015. The increase, which can be attributed to costs incurred during the first and second quarters of 2016, was primarily due to an increase in internal process development work as additional

resources were directed towards optimizing our azficel-T manufacturing processes which also benefits our ongoing development programs.

(7) Other indirect R&D costs increased approximately $0.1 million, or 88.7%, for the three months ended September 30, 2016 as compared to the same period in 2015 primarily due to a greater allocation of fixed overhead costs for our manufacturing facility to indirect research and development expense. No process development for the azficel-T manufacturing process occurred in the third quarter of 2016 due to the wind-down of azficel-T.

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Other indirect R&D costs decreased approximately and $0.2 million, or 17.0%, for the nine months ended September 30, 2016 as compared to the same period in 2015 primarily due to a research agreement with an unrelated third party that was ongoing during the 2015 periods but terminated in the second half of 2015.

Selling, General and Administrative Expense

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

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
($ in thousands)	2016	2015	% Change	2016	2015	% Change	
Compensation and related expense	$1,194	$1,304	(8.4)%	$3,944	$3,829	3.0 %	
Professional fees	744	461	61.4 %	1,762	3,030	(41.8)%	(1)
Facilities and related expense and other	785	712	10.3 %	2,297	2,182	5.3 %	
Total selling, general and administrative expense	$2,723	$2,477	9.9 %	$8,003	$9,041	(11.5)%	

(1) Professional fees increased approximately $0.3 million, or 61.4%, for the three months ended September 30, 2016 as compared to the same period in 2015 primarily due to financing-related costs incurred during the 2016 period that were not incurred during the 2015 period.

Professional fees decreased approximately $1.3 million, or 41.8%, for the nine months ended September 30, 2016 as compared to the same period in 2015 primarily due to legal fees related to litigation and contract matters that were incurred in the prior year period and did not recur in 2016, offset partially by financing-related costs incurred in 2016. Additionally, in the second quarter of 2015, we hired in-house general counsel which further reduced legal costs incurred with outside vendors.

Intangible Asset Impairment Expense

During the nine months ended September 30, 2016 we recorded a non-cash impairment charge of approximately $3.9 million to write off the Company’s intangible assets. No such charges were incurred in the other periods presented. See Note 3 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q for further details.

Restructuring Costs

During the three and nine months ended September 30, 2016 we recorded restructuring costs totaling less than $0.1 million and approximately $0.3 million, respectively. Restructuring costs were comprised of employee severance and benefit-related charges associated with our reduction in workforce and non-cash impairment charges against the carrying values of equipment. No such costs were incurred in the prior periods. See additional information included under the heading “Wind-down of azficel-T Operations” in Item 2 of this Form 10-Q and in Note 10 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q.

Warrant Revaluation Income

During the three months ended September 30, 2016 and 2015, we recorded non-cash income of approximately $3.0 million and $5.3 million for warrant revaluation charges in our Condensed Consolidated Statements of Operations, respectively. During the nine months ended September 30, 2016 and 2015, we recorded non-cash income of approximately $10.5 million and $4.2 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 normal 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. Warrant revaluation income for both the three months ended September 30, 2016 and 2015 was primarily driven by decreases in both our stock price and the remaining contractual life of the warrants. In addition to the impact of a decrease in remaining contractual life of the warrants, warrant revaluation income during the nine months ended September 2016 was primarily driven by the decrease in our stock price during the period, while warrant revaluation income during the nine months ended September 2015 was primarily driven by the decrease in management's estimated probability of certain events occurring that would impact the warrants.

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Derivative Revaluation Expense

During the three months ended September 30, 2016, we recorded non-cash derivative revaluation expense of approximately $0.3 million for derivative liability revaluation charges in our Condensed Consolidated Statements of Operations related to a compound bifurcated derivative initially recorded in September 2016 in connection with our convertible notes issued in a private placement offering. No such revaluation charges were incurred in prior periods. See Note 5 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q for further details.

Interest Expense

During the three months ended September 30, 2016, we recorded interest expense of less than $0.1 million in our Condensed Consolidated Statements of Operations related to the convertible notes that we issued in September 2016 in a private placement offering which bear interest at 4% per annum. No such expenses were incurred in prior periods. See additional information regarding our September 2016 private placement offering in Note 5 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Contractual Obligations

During the nine months ended September 30, 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, except as described below.

September 2016 Private Placement Offering

In September 2016, the Company issued an aggregate of $18,087,500 in principal of convertible promissory notes (each, a Note and collectively, the Notes) and accompanying warrants to purchase an aggregate of 18,087,500 shares of common stock (each a Warrant and collectively, the Warrants) in a private placement to institutional and accredited investors (each an Investor and collectively, the Investors).

The Notes bear interest at four percent (4%) per annum. Interest is earned daily and compounded quarterly and, at the election of the Company at the beginning of each quarter, shall accrue or be paid in cash. If the Company elects to have interest accrue, such interest will not be added to the principal amount of the Notes but such interest shall be subject to additional interest at the rate of four percent (4%) per annum, compounded quarterly, and shall be due and payable upon the earliest of the conversion of the Notes, exercise of the Put Right, exercise of the Prepayment Right or the Maturity Date (in each case, as defined below). Additionally, if the Company elects for interest to accrue, then (i) the Company may elect to repay any such accrued and unpaid interest in cash at any time and from time to time and (ii) each Investor may elect to have the Company repay any such accrued and unpaid interest by delivering such number of shares of Common Stock equal to (x) the amount of the accrued and unpaid interest to be repaid, divided by (y) the greater of (i) the last closing bid price of a share of Common Stock as reported on The Nasdaq Capital Market (NASDAQ) on the date of such election and (ii) the Conversion Price (as defined below).

All unpaid principal of each Investor’s Note is convertible, at any time and from time to time, at the option of such Investor into shares of Common Stock at the greater of (x) $1.13625 and (y) the last closing bid price of a share of Common Stock as reported on NASDAQ at the time of such Investor’s execution of the Purchase Agreement, plus $0.12625 (as subject to adjustment, the “Conversion Price”) which range from $1.13625 to $1.22625 per share.

The Notes have a maturity date of the earlier of (i) September 7, 2026 and (ii) one-hundred and eighty (180) days after the date on which the Company's product candidate, FCX-007, is approved by the FDA for the treatment of RDEB. Each individual Note holder has the right to require the Company to repay all or any portion of the unpaid principal and accrued and unpaid interest from time to time on or after September 7, 2021 (such right, a Put Right). Such Put Right must be exercised by such Note holder by delivering written notice to the Company no later than one-hundred and eighty (180) days prior to such exercise date of such Put Right. In addition, upon consummation of a specified change of control transaction or the occurrence of certain Events of Default, as defined in the Notes, each Note holder may elect to accelerate the repayment of all unpaid principal and accrued interest under such holder's Note. If an Investor does not elect to have the Company prepay its Note upon such change of control transaction, then the Company may prepay the Notes, in an amount equal to one hundred one

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percent (101%) of the outstanding principal due under the Notes (together with accrued and unpaid interest due thereon) (the Prepayment Right). Additionally, upon the occurrence of certain Events of Default, as defined in the Notes, each Investor may elect to accelerate the repayment of all unpaid principal and accrued interest under each Note and the Notes provide for automatic redemption upon the occurrence of certain bankruptcy related Events of Default, as defined in the Notes.

Critical Accounting Policies

Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon our unaudited 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.

A summary of our 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.

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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 September 30, 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 September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider each of the risk factors set forth under the heading "Risk Factors" in our Form 10-K for 2015. The risk factors set forth below supplements those risk factors. The occurrence of any one or more of these risks could materially harm our business, operating results, financial condition and prospects. These risks and uncertainties could also cause actual results to differ materially and adversely from those expressed or implied by forward-looking statements that we make from time to time. Please see "Note Regarding Forward-Looking Statements" appearing at the beginning of this Form 10-Q.

Our failure to comply with the restrictive covenants or other terms of our outstanding convertible notes, including as a result of events beyond our control, could result in a default under the notes that could materially and adversely affect our financial condition.

In connection with our September 2016 Private Placement, we issued an aggregate of $18,087,500 in principal of convertible promissory notes (the Notes), which bear interest at 4% per annum. The Notes have a stated maturity date of the earlier of (i) September 7, 2026 and (ii) one-hundred and eighty (180) days after the date on which the Company's product candidate, FCX-007, is approved by the FDA for the treatment of RDEB. Each individual Note

holder has the right to require the Company to repay all or any portion of the unpaid principal and accrued and unpaid interest from time to time on or after September 7, 2021. In addition, each Note holder may elect to accelerate the repayment of all unpaid principal and accrued

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interest under such holder's Note upon consummation of a specified change of control transaction or occurrence of certain Events of Default (as specified in the Notes), including, among other things:

- Our default in a payment obligation under the Notes;
- Our default in a payment obligation under other Company debt in excess of $5 million;
- Our breach of the restrictive covenants or other terms of the Notes;
- Certain specified insolvency and bankruptcy-related events; and
- Our common stock ceasing to be listed or quoted on NASDAQ or other national securities exchange.

In addition, upon an Event of Default, the base interest rate (excluding any additional interest) for the Notes automatically increases to twelve percent (12%) per annum. Subject to any applicable cure period set forth in the Notes, all amounts outstanding with respect to the Notes (principal and accrued interest) would become due and payable immediately upon an Event of Default. We cannot assure you that our assets or cash flow would be sufficient to fully repay our obligations under the Notes if the obligations thereunder are accelerated upon any Events of Default. Further, if we are unable to repay, refinance or restructure our obligations under the Notes, the holders of such Notes could proceed to protect and enforce their rights under the Notes by exercising such remedies as are available to the holders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Notes or in aid of the exercise of any power granted in the Notes. The foregoing would materially and adversely affect our financial condition.

Restrictive covenants in the Notes may restrict our ability to pursue business strategies that are in our long-term best interests.

The Notes contain a number of restrictive covenants that impose significant restrictions on us and may limit our ability to engage in acts that may be in our long-term best interests. Subject to certain limited exceptions, the Notes include covenants restricting, among other things, our ability to:

- pay dividends or make distributions on our capital stock or redeem or repurchase our capital stock;
- create, assume or suffer to exist at any time any lien upon any of our properties or assets;
- assign any accounts or other right to receive income;
- incur any senior and pari passu debt;
- enter into transactions with affiliates other than on terms and conditions approved by a majority of the disinterested members of our board of directors; and
- use the proceeds of the 2016 Private Placement for any purpose other than solely for the continued pre-clinical and clinical development of our product candidates and for other general corporate purposes.

In addition, a breach of any of these restrictive covenants could result in a default under the Notes, entitling the holders to declare the Notes, together with accrued and unpaid interest and other amounts payable thereunder, to be immediately due and payable.

Provisions of the Notes and warrants issued in the 2016 Private Placement provide for certain potential payments to the holders of such Notes and warrants that could impede a sale of the Company.

The warrants we issued in the 2016 Private Placement give each holder the option to receive a cash payment based on a Black-Scholes valuation upon our change of control. We are required, at the warrant holder's option, exercisable at any time concurrently with, or within 30 days after, the announcement of a change of control, to repurchase the warrants from the applicable holder by paying to the holder an amount of cash equal to the value of the warrant as determined in accordance with the Black-Scholes option pricing model and the terms of the warrants. In addition, upon consummation of a specified change of control transaction, each holder of a Note may elect to accelerate the repayment of all unpaid principal and accrued interest under such holder's Note. If a holder does not elect to have us prepay its Note upon such change of control transaction, then we may prepay the Notes, in an amount equal to one

hundred one percent (101%) of the outstanding principal due under the Notes (together with accrued and unpaid interest due thereon). These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

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We may be subject to payment of liquidated damages if we fail to file and maintain an effective registration statement with respect to the securities covered under the registration rights agreements that we entered into in connection with the 2016 Private Placement.

In connection with the 2016 Private Placement, we entered into a registration rights agreement (the Registration Rights Agreement) with the investors that participated in the offering. The Registration Rights Agreement contains demand and piggyback registration rights requiring us to register shares of Common Stock issuable upon the conversion of the Notes or the exercise of the warrants and any other shares held by the investors for resale under the Securities Act of 1933, as amended. If we fail, under certain circumstances as described in the Registration Rights Agreement, to file and maintain an effective a registration statement with respect to the securities covered under the Registration Rights Agreement, we have agreed to pay liquidated damages to each investor in an amount equal to one percent (1.0%) of the aggregate amount invested by such investor pursuant to the Notes then owned thereby for each 30-day period or pro rata for any portion thereof during which the failure to file or keep a registration statement effective continues.

The exercise of the warrants or conversion of the Notes issued in connection with the 2016 Private Placement may cause substantial dilution to our existing stockholders.

We issued an aggregate of $18,087,500 of Notes and warrants to purchase a total of 18,087,500 shares of our common stock in connection with the 2016 Private Placement. Each warrant has a five year term ending on September 7, 2021 and is initially exercisable at $1.50 per share beginning March 8, 2017. Holder of the Notes have the right to convert unpaid principal of the Notes into shares of Company common stock at any time at conversion prices ranging from $1.13625 to $1.22625 per share. The Notes bear interest at four percent (4%) per annum which we may elect to pay in cash or accrue. If we elect for interest to accrue, then (i) we may elect to repay any such accrued and unpaid interest in cash at any time and from time to time and (ii) each holder of a Note may elect to have us repay any such accrued and unpaid interest by delivering such number of shares of Company common stock equal to (x) the amount of the accrued and unpaid interest to be repaid, divided by (y) the greater of (i) the last closing bid price of a share of Company common stock as reported on The Nasdaq Capital Market on the date of such election and (ii) the Conversion Price. As of September 30, 2016, we have elected to accrue interest.

Subject to adjustment upon certain corporate events, including stock dividends, stock splits and distributions of cash or other assets to stockholders:

- up to 15,913,612 shares of Company common stock could be issuable by us in connection with the conversion of principal under the Notes, plus
- up to 7,779,584 shares of Company common stock could be issuable by us in satisfaction of our interest payment obligations under the Notes; plus
- up to 18,087,500 shares of Company common stock could be issuable by us in connection with the exercise of the warrants.

The exercise of these warrants or the conversion of the Notes may cause substantial dilution to our existing stockholders.

We recently announced the wind-down of our azficel-T (including LAVIV) operations at our Exton, PA facility and a related workforce reduction that are expected to result in significant cost savings as we focus our efforts and resources on our gene-therapy portfolio of product candidates. If we are unable to realize the anticipated cost-saving benefits of these measures or we incur additional costs as we progress through the wind-down process, our operating results and financial condition could be adversely affected.

In June 2016, we announced that we are focusing our efforts and resources on our gene-therapy portfolio of product candidates and, as a result, determined to wind-down azficel-T (including LAVIV) operations at our Exton, PA facility and reduce the workforce that supports such operations. In connection with this reduction in workforce, approximately 50% of our employees were eliminated, primarily in the areas of manufacturing and quality operations. We have incurred one-time termination costs in connection with the reduction in workforce, which include severance, benefits and related costs, totaling approximately $0.3 million through September 30, 2016. Additionally, we have incurred approximately $0.3 million and $0.1 million, respectively, for inventory write-offs and asset impairment charges for equipment used in our azficel-T operations during the second quarter of 2016. We may incur other cash expenditures to decommission our azficel-T manufacturing facility and to terminate and wind-down our contractual and other obligations relating to our azficel-T operations, as well as potential non-cash charges related to future impairments of the carrying values of equipment used in our azficel-T operations, but cannot estimate them at this time.

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If we are unable to realize the expected cost savings from the workforce reduction and wind-down activities, our operating results and financial condition would be adversely affected. In addition, as we progress through the wind-down activities, we may incur additional costs and expenses, including costs to decommission our azficel-T manufacturing facility and to terminate and wind-down our contractual and other obligations relating to our azficel-T operations. The wind-down process may also be difficult to manage and may increase the likelihood of turnover of other key employees, all of which may have an adverse impact on our business, as well as on our operating results and financial condition.

If we are unable to regain compliance with the listing requirements of The Nasdaq Capital Market, our common stock may be delisted from The Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on The Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly-held shares, market value of listed shares, minimum bid price per share, and minimum stockholder's equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from The Nasdaq Capital Market.

On October 5, 2016, we received notice (the Notice) from NASDAQ that we are not currently in compliance with the $1.00 minimum closing bid price requirement of NASDAQ Listing Rule 5550(a)(2). The Notice indicated that, consistent with NASDAQ Listing Rule 5810(c)(3)(A), we have until April 3, 2017 to regain compliance with the minimum bid price requirement by having the closing bid price of our common stock meet or exceed $1.00 per share for at least ten consecutive business days. The notification had no immediate effect on the listing of the Company’s common stock and our common stock will continue to trade on The Nasdaq Capital Market under the symbol “FCSC” at this time.

If we do not regain compliance by April 3, 2017, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares ($1 million) and all other initial listing standards for The Nasdaq Capital Market which require, among other things, that we have at least $5 million of stockholders’ equity or at least $4 million of stockholders’ equity and $50 million market value of listed shares. If the Company fails to regain compliance during the applicable period, we will receive notification from NASDAQ that our common stock is subject to delisting. At that time we may then appeal the delisting determination to a Hearings Panel. Such notification will have no immediate effect on our listing on The Nasdaq Capital Market, nor will it have an immediate effect on the trading of our common stock pending such hearing. There can be no assurance, however, that we will be able to regain compliance with NASDAQ's minimum bid price requirement. If we regain compliance with the NASDAQ's minimum bid price requirement, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for The Nasdaq Capital Market, or that our common stock will not be delisted from The Nasdaq Capital Market in the future. In addition, we may be unable to meet other applicable listing requirements of The Nasdaq Capital Market, including maintaining minimum levels of stockholders’ equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the minimum bid price requirement.

Delisting from The Nasdaq Capital Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. Moreover, a delisting of our common stock could result in an Event of Default under the Notes issued in the 2016 Private Placement.

If we are delisted from The Nasdaq Capital Market and we are not able to list our common stock on another exchange, our common stock could be quoted on the OTC Bulletin Board or in the "pink sheets." As a result, we could face significant adverse consequences including, among others:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and little or no analyst coverage for us;
- we would no longer qualify for exemptions from state securities registration requirements, which may require us to comply with applicable state securities laws; and

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- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

If our common stock becomes subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on The Nasdaq Capital Market and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

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: November 3, 2016

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EXHIBIT INDEX

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
4.1	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to Fibrocell's Form 8-K filed on September 8, 2016)
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to Fibrocell's Form 8-K filed on September 8, 2016)
10.1*	Agreement for the Purchase and Sale of Convertible Debt and Common Stock Warrants dated August 9, 2016
10.2	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.1 to Fibrocell's Form 8-K filed on September 8, 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 herewith.