Fibrocell Science, Inc.
Form 10-Q
August 07, 2015

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

FORM 10-Q

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

For the quarterly period ended June 30, 2015

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

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

As of July 31, 2015, issuer had 43,887,201 shares issued and outstanding of 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.

owners.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this Form 10-Q regarding our future operations, financial performance and financial position, prospects, strategies and objectives and other future events (including assumptions relating to the foregoing) are forward-looking statements. 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,” “continue,” “ongoing,” “scheduled” and expressions, although not all forward-looking statements contain these identifying words. Forward-looking statements appear in this Form 10-Q primarily in Part I., Item 1. “Notes to Unaudited Financial Statements,” Part I., Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part II., Item 1. "Legal Proceedings" and include, among others, statements relating to:

- our focus on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs;
- our expectation to complete dosing in our Phase II clinical trial by year-end 2015 and announce efficacy results in the second quarter of 2016;
- our plan to seek orphan drug designation for FCX-013;
- the initiation, timing and scope of a Phase I/II clinical trial for FCX-007;
- our expectation to complete proof-of-concept studies for FCX-013 in the first half of 2016 and submit an IND application to the FDA in the second half of 2016;
- our ability to complete, or obtain modifications to, the postmarketing study that the FDA required as a condition for the approval of LAVIV;
- the potential for our collaboration with UCLA to expand our biologics platform;
- the use of proceeds from our July 2015 underwritten public offering; and
- the sufficiency of our cash and cash equivalents to fund our operations into the fourth quarter of 2016.

Forward-looking statements are based upon our current expectations, intentions and beliefs and are subject to a number of risks, uncertainties, assumptions 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, 2014 (our "Form 10-K for 2014") under the caption "Item 1A. Risk Factors." As a result, you should not place undue reliance on forward-looking statements. 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, whether as a result of new information, future developments or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in the periodic and current reports that we file with the SEC.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements.
Fibrocell Science, Inc.
Consolidated Balance Sheets
(unaudited)
($ in thousands, except share and per share data)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$26,850	$37,495
Accounts receivable, net of allowance for doubtful accounts of $16 and $17, respectively	3	4
Inventory	484	571
Prepaid expenses and other current assets	730	1,279
Total current assets	28,067	39,349
Property and equipment, net of accumulated depreciation of $1,121 and $1,051, respectively	1,639	1,598
Intangible assets, net of accumulated amortization of $1,929 and $1,653, respectively	4,411	4,687
Total assets	$34,117	$45,634
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,957	$1,124
Accrued expenses	2,113	1,675
Deferred revenue	500	416
Warrant liability, current	650	278
Total current liabilities	5,220	3,493
Warrant liability, long term	11,697	11,008
Other long term liabilities	773	724
Total liabilities	17,690	15,225
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 40,913,065 and 40,856,815 shares issued and outstanding, respectively	41	41
Additional paid-in capital	144,385	143,086
Accumulated deficit	(127,999)	(112,718)
Total stockholders' equity	16,427	30,409
Total liabilities and stockholders' equity	$34,117	$45,634

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

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

	Three months ended June 30, 2015	Three months ended June 30, 2014	Six months ended June 30, 2015	Six months ended June 30, 2014
Revenue from product sales	$55	$58	$168	$104
Collaboration revenue	82	—	163	—
Total revenue	137	58	331	104
Cost of product sales	77	547	221	1,340
Cost of collaboration revenue	85	—	88	—
Total cost of revenue	162	547	309	1,340
Gross (loss) profit	(25)	(489)	22	(1,236)
Research and development expense	3,694	2,925	7,681	10,840
Selling, general and administrative expense	3,640	3,182	6,564	5,520
Operating loss	(7,359)	(6,596)	(14,223)	(17,596)
Other income (expense):				
Warrant revaluation and other finance income (expense)	602	4,008	(1,061)	958
Other income	—	330	—	370
Interest income	1	1	3	2
Loss before income taxes	(6,756)	(2,257)	(15,281)	(16,266)
Deferred tax benefit	—	—	—	—
Net loss	$(6,756)	$(2,257)	$(15,281)	$(16,266)
Per Share Information:				
Net loss:				
Basic	$(0.17)	$(0.06)	$(0.37)	$(0.40)
Diluted	$(0.17)	$(0.09)	$(0.37)	$(0.43)
Weighted average number of common shares outstanding				
Basic	40,889,732	40,856,815	40,875,704	40,720,958
Diluted	40,889,732	41,250,886	40,875,704	40,917,993

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

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

	Common Stock Shares	Amount	Additional paid-in capital	Accumulated deficit	Total Equity
Balance, December 31, 2014	40,856,815	$41	$143,086	$(112,718)	$30,409
Stock-based compensation expense	—	—	1,044	—	1,044
Exercise of stock options	56,250	—	255	—	255
Net loss	—	—	—	(15,281)	(15,281)
Balance, June 30, 2015	40,913,065	$41	$144,385	$(127,999)	$16,427

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

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

	Six months ended June 30, 2015	Six months ended June 30, 2014
Cash flows from operating activities:		
Net loss	$(15,281)	$(16,266)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,044	739
Stock issued for supplemental stock issuance agreement	—	5,154
Warrant revaluation and other finance expense (income)	1,061	(958)
Depreciation and amortization	346	452
Provision for doubtful accounts	(1)	16
Change in operating assets and liabilities:		
Accounts receivable	2	(2)
Inventory	87	121
Prepaid expenses and other current assets	549	496
Other assets	—	214
Accounts payable	833	(1,590)
Accrued expenses and other long-term liabilities	489	1,206
Deferred revenue	84	132
Net cash used in operating activities	(10,787)	(10,286)
Cash flows from investing activities:		
Purchase of property and equipment	(111)	(211)
Net cash used in investing activities	(111)	(211)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	255	—
Principle payments on capital lease obligations	(2)	—
Net cash provided by financing activities	253	—
Net decrease in cash and cash equivalents	(10,645)	(10,497)
Cash and cash equivalents, beginning of period	37,495	60,033
Cash and cash equivalents, end of period	$26,850	$49,536

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

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

Note 1. Business and Organization

Fibrocell Science, Inc. (as used herein, “we,” “us,” “our,” “Fibrocell” or the “Company”) is the parent company of Fibrocell Technologies, Inc. (“Fibrocell Tech”) and Fibrocell Science Hong Kong Limited (“Fibrocell Hong Kong”), a company organized under the laws of Hong Kong. Fibrocell Tech is the parent company of Isolagen Europe Limited, a company organized under the laws of the United Kingdom (“Isolagen Europe”), Isolagen Australia Pty Limited, a company organized under the laws of Australia (“Isolagen Australia”), and Isolagen International, S.A., a company organized under the laws of Switzerland (“Isolagen Switzerland”). The Company’s international activities are currently immaterial.

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

Note 2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by GAAP for complete consolidated financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission (“SEC”). The results of the Company’s operations for any interim period are not necessarily indicative of the results of operations for any other interim period or full year.

There have been certain reclassifications made to the prior year’s results of operations to conform to the current year’s presentation. Compensation and related expenses for manufacturing and facilities personnel of $0.3 million and $0.8 million were reclassified from selling, general and administrative expense to research and development expense for the three and six months ended June 30, 2014, respectively.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

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

Revenue Recognition

Product Sales. In June 2011, the FDA approved the Company's Biologics License Application ("BLA") for LAVIV (azficel-T) for the treatment of nasolabial fold wrinkles. The Company recognizes revenue over the period LAVIV is shipped for injection in accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification ("ASC") 605, Revenue Recognition (“ASC 605”). In general, ASC 605 requires that four basic criteria

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

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Note 3. Summary of Significant Accounting Policies (continued)

Collaboration Revenue. The Company's collaboration agreements may contain multiple elements, such as fees to perform proof of concept studies, product development, aid in obtaining U.S. patents and trademarks, and royalties based upon future commercial sales. The deliverables under such an arrangement are evaluated under ASC 605-25, Revenue Recognition: Multiple-Element Arrangements. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has “stand-alone value” to the customer. The arrangement’s consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Collaboration revenue is recognized on a gross basis, in accordance with the criteria set forth in ASC 605-45, Revenue Recognition: Principal Agent Considerations. Collaboration revenue for the three and six months ended June 30, 2015 is related to a research and development agreement that the Company has with an unrelated third party to investigate potential new non-pharmaceutical applications for the Company's conditioned fibroblast media technology. Revenue recognized from this collaboration relates to an upfront license fee and a proof of concept study currently underway.

Cost of Revenue.

Cost of revenue includes expenses related to product sales and collaboration revenue.

Cost of Product Sales. Costs include the processing of cells for LAVIV, including direct and indirect costs. Cost of product sales is accounted for using a standard cost system which allocates the direct costs associated with the Company’s manufacturing, facility, quality control, and quality assurance operations as well as an allocation of overhead costs.

Cost of Collaboration Revenue. Costs directly related to deliverables in a revenue-generating collaboration are charged to cost of revenue as incurred.

Research and Development Expense.

Research and development costs are expensed as incurred and include salaries and benefits, costs paid to third party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices, and an allocation of overhead cost. Research and development costs also include costs to develop manufacturing, cell collection and logistical process improvements.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third party contractors. Invoicing from third party contractors for services performed can lag several months. The Company accrues the costs of services rendered in connection with third party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs.

Warrant Liability.

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with ASC 815, Derivatives and Hedging, (“ASC 815”) if the stock warrants contain “down-round protection” or other terms that could potentially require “net cash settlement” and therefore, do not meet the scope exception for treatment as a derivative. Since “down-round protection” is not an input into the calculation of the fair value of the warrants, the 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.

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 six months ended June 30, 2015 and 2014, the

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Note 3. Summary of Significant Accounting Policies (continued)

Income Taxes. (continued)
Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company had not recorded its net deferred tax asset as of either June 30, 2015 or December 31, 2014, 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 June 30, 2015 and December 31, 2014, the Company had no uncertain tax positions.
Intangible Assets.
Intangible assets are research and development assets related to the Company's primary study on azficel-T that was recognized upon emergence from bankruptcy. Azficel-T has three current or target indications: the Company's commercial product, LAVIV; a clinical development program for azficel-T for the treatment of chronic dysphonia resulting from vocal cord scarring; and a clinical development program for azficel-T for the treatment of restrictive burn scarring. Effective January 1, 2012, the Company launched LAVIV and as a result, the research and development intangible assets related to the Company's primary study were considered to be finite-lived intangible assets and are being amortized over 12 years.
Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis. In accordance with ASC 360-10-35, Impairment or Disposal of Long-Lived Assets, the Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There was no impairment expense recognized for either the three or six months ended June 30, 2015 or 2014.
Recently Issued Accounting Pronouncements
In April 2015, the FASB issued Accounting Standards Update ("ASU") 2015-05, Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, which provides additional guidance to customers about whether a cloud computing arrangement includes a software license. Under ASU 2015-05, if a software cloud computing arrangement contains a software license, customers should account for the license element of the arrangement in a manner consistent with the acquisition of other software licenses. If the arrangement does not contain a software license, customers should account for the arrangement as a service contract. ASU 2015-05 also removes the requirement to analogize to ASC 840-10, Leases, to determine the asset acquired in a software licensing arrangement. An entity can elect to adopt the amendments either prospectively to all arrangements entered into or materially modified after the effective date or retrospectively. This ASU will be effective beginning in the first quarter of 2017 and early adoption is permitted. The Company is currently evaluating the effects of the adoption of this ASU on its financial statements but does not believe the impact to be material.
Note 4. Inventory

Inventories consisted of the following as of:

($ in thousands)	June 30, 2015	December 31, 2014
Raw materials (LAVIV and product candidates)	$298	$357
Work in process (LAVIV)	186	214
Inventory (LAVIV)	$484	$571

Note 5. Warrants

The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants are accounted for as a derivative in accordance with ASC 815, Derivatives and Hedging, ("ASC 815") if the stock warrants contain "down-round protection" or other terms that

could potentially require “net cash settlement” and therefore, do not meet the scope exception for treatment as an equity instrument. Since “down-round protection” is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company’s own stock which is a requirement for the scope exception as outlined under ASC 815.

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Note 5. Warrants (continued)

Warrant instruments that could potentially require "net cash settlement" in the absence of express language precluding such settlement or those which include "down-round provisions" are initially classified as derivative liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to classify the fair value of the warrants that contain "down-round protection" or "net cash settlement" as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability.

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

	Number of Warrants			
Liability-classified warrants	June 30, 2015	December 31, 2014	Exercise Price	Expiration Dates
Issued in Series A, B and D Preferred Stock offerings	2,247,118	2,247,118	$6.25	Oct 2015 - Dec 2016
Issued in March 2010 financing	393,416	393,416	$6.25	Mar 2016
Issued in June 2011 financing	6,113	6,113	$22.50	Jun 2016
Issued in August 2011 financing	565,759	565,759	$18.75	Aug 2016
Issued to placement agents in August 2011 financing	50,123	50,123	$13.635	Aug 2016
Issued in Series B, D and E Preferred Stock offerings	76,120	76,120	$2.50	Nov 2015 - Dec 2017
Issued with Convertible Notes	1,125,578	1,125,578	$2.50	Jun 2018
Issued in Series E Preferred Stock offering	1,568,823	1,568,823	$7.50	Dec 2018
Total	6,033,050	6,033,050		

There were no warrants exercised or canceled during the six months ended June 30, 2015.

Liability-classified Warrants

The foregoing warrants were recorded as derivative liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in other income (expense) in the Company's consolidated statement of operations in each subsequent period. The change in the estimated fair value of the warrant liability for the three and six months ended June 30, 2015 resulted in non-cash income of approximately $0.6 million and expense of $1.1 million, respectively. The change in the estimated fair value of the warrant liability for the three and six months ended June 30, 2014 resulted in non-cash income of approximately $4.0 million and $1.0 million, respectively. The Company utilizes a Monte Carlo simulation valuation method to value its liability-classified warrants.

The estimated fair value of these warrants is determined using Level 3 inputs. Inherent in the Monte Carlo valuation method are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility of a peer group that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.

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

($ in thousands)	June 30, 2015	December 31, 2014
Calculated aggregate value	$12,347	$11,286
Weighted average exercise price per share	$7.08	$7.08

Closing price per share of common stock	$5.27		$2.59	
Volatility	84.2	%	67.6	%
Weighted average remaining expected life	2 years, 1 month		2 years, 7 months	
Risk-free interest rate	0.67	%	0.86	%
Dividend yield	—		—	

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(unaudited)

Note 6. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis
The Company adopted the accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:
•Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
•Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.
•Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).
The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014:

	Fair value measurement using			
($ in thousands)	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Balance at June 30, 2015				
Assets:				
Cash and cash equivalents	$26,850	$—	$—	$26,850
Liabilities:				
Warrant liability	$—	$—	$12,347	$12,347

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

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

($ in thousands)	Warrant Liability
Balance at December 31, 2014	$11,286
Exercise of warrants	—
Change in fair value of warrant liability	1,061
Balance at June 30, 2015	$12,347

The fair value of the warrant liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 5 for

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

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Notes to Consolidated Financial Statements
(unaudited)

Note 7. Share-Based Compensation

The Company's board of directors (the "Board") adopted the 2009 Equity Incentive Plan (as amended to date, the "Plan") effective September 3, 2009. The Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisers by providing incentives for such persons to exert maximum efforts for the success of the Company. The Plan allows for the issuance of up to 5,600,000 shares of the Company's common stock. The Company issued 206,000 options outside of the Plan to consultants.

The types of awards that may be granted under the Plan include stock options (both non-qualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units and other stock-based awards. The term of each award is determined by the Compensation Committee of the Board of Directors at the time each award is granted, provided that the terms of options do not exceed ten years. Vesting schedules for the stock options vary, but generally vest 25% per year, over four years. The Plan had 2,323,939 shares available for future grants as of June 30, 2015.

Total share-based compensation expense, net of estimated forfeitures, recognized using the straight-line attribution method in the consolidated statements of operations is as follows:

	Three months ended June 30,		Six months ended June 30,	
($ in thousands)	2015	2014	2015	2014
Stock option compensation expense for employees and directors	$804	$436	$1,044	$736
Equity awards for non-employees issued for services	—	—	—	3
Total stock-based compensation expense	$804	$436	$1,044	$739

($ in thousands except share and per share data)	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value ($ in thousands)
Outstanding at December 31, 2014	2,086,450	$7.43	8 years	$—
Granted	1,333,614	4.45		
Exercised	(56,250)	4.53		
Forfeited	(115,000)	3.91		
Expired	(12,000)	10.50		
Outstanding at June 30, 2015	3,236,814	$6.37	8 years, 5 months	$2,910
Exercisable at June 30, 2015	1,353,075	$9.39	7 years, 4 months	$810

The total fair value of options vested during the six months ended June 30, 2015 was approximately $1.0 million. As of June 30, 2015, there was approximately $4.9 million of total forfeiture adjusted unrecognized compensation cost, related to time-based and performance-based non-vested stock options. That cost is expected to be recognized over a weighted-average period of 3.0 years. As of June 30, 2015, there was no unrecognized compensation expense related to non-vested non-employee options.

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Notes to Consolidated Financial Statements
(unaudited)
Note 7. Share-Based Compensation (continued)

During the six months ended June 30, 2015 and 2014, the weighted average fair market value of the options granted was $3.57 and $2.74, respectively. The fair market value of these options was computed using the Black-Scholes option-pricing model with the following key weighted average assumptions for the six months ended as of the dates indicated:

	June 30, 2015		June 30, 2014	
Expected life	6 years, 1 month		6 years, 3 months	
Interest rate	1.56	%	1.97	%
Dividend yield	—		—	
Volatility	103.3	%	70.4	%

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

Note 8. Collaboration Agreement with Related Party

The Company and Intrexon are parties to an exclusive channel collaboration agreement, as amended. 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 also collectively own more than 35% of our common stock. Our directors, Marcus Smith and Julian Kirk (who is the son of Randal J. Kirk), are employees of Third Security, LLC, which is an affiliate of Randal J. Kirk.

For the three months ended June 30, 2015 and 2014, the Company incurred expenses of $1.1 million and $0.7 million, respectively, for work performed under the Company's exclusive channel collaboration agreement, as amended, with Intrexon.

For the six months ended June 30, 2015 and 2014, the Company incurred expenses of $2.9 million and $1.8 million, respectively, for work performed under the Company's exclusive channel collaboration agreement, as amended, with Intrexon. As of June 30, 2015 and December 31, 2014, the Company had outstanding payables to Intrexon of $0.7 million and $1.0 million, respectively.

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Fibrocell Science, Inc.
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Note 9. Loss Per Share

Basic loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during a period. The diluted loss per share calculation gives effect to dilutive options, warrants, convertible notes, convertible preferred stock, and other potentially dilutive common stock including selected restricted shares of common stock outstanding during the period. Diluted loss per share is based on the treasury stock method and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and warrants, assuming the exercise of all in-the-money stock options based on the average market price during the period. Common share equivalents have been excluded where their inclusion would be anti-dilutive.

	For the three months ended June 30,		For the six months ended June 30,	
($ in thousands except share and per share data)	2015	2014	2015	2014
Loss per share - basic:				
Numerator for basic loss per share	$(6,756)	$(2,257)	$(15,281)	$(16,266)
Denominator for basic loss per share	40,889,732	40,856,815	40,875,704	40,720,958
Basic loss per common share	$(0.17)	$(0.06)	$(0.37)	$(0.40)
Loss per share - diluted:				
Numerator for diluted loss per share	$(6,756)	$(2,257)	$(15,281)	$(16,266)
Add back: Fair value of “in the money” warrants outstanding	—	1,284	—	1,284
Net loss attributable to common share	$(6,756)	$(3,541)	$(15,281)	$(17,550)
Denominator for basic loss per share	40,889,732	40,856,815	40,875,704	40,720,958
Plus: Incremental shares underlying “in the money” warrants outstanding	—	394,071	—	197,035
Denominator for diluted loss per share	40,889,732	41,250,886	40,875,704	40,917,993
Diluted net loss per common share	$(0.17)	$(0.09)	$(0.37)	$(0.43)

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 June 30,		Six months ended June 30,	
	2015	2014	2015	2014
“In the money” stock options	1,482,614	844,000	1,518,957	1,094,000
“Out of the money” stock options	1,654,200	1,553,717	1,442,200	1,241,719
“In the money” warrants	1,201,698	—	1,201,698	600,849
“Out of the money” warrants	4,831,352	4,831,352	4,831,352	4,831,352
Other securities excluded from the calculation of diluted loss per share:				
Stock options with performance condition	100,000	—	100,000	—

Note 10. Subsequent Events

On July 27, 2015, Fibrocell sold 2,974,136 shares of its common stock, par value $0.001 per share, in an underwritten public offering at a price per share of $5.80 (the "Offering"). The net proceeds to Fibrocell from the Offering, after deducting underwriting commissions and other estimated offering expenses payable by Fibrocell, was approximately $15.7 million.

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

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

- our unaudited 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 Form 10-K for 2014, as well as the information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K for 2014.

Overview

We are an autologous cell and gene therapy company focused on developing first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs. All of our product candidates use our proprietary autologous fibroblast technology. Fibroblasts are the most common cells located in skin and connective tissue and are responsible for synthesizing extracellular matrix proteins that provide cellular structure and support. Our autologous fibroblast technology uses our patented manufacturing process, which involves collecting small skin samples from patients, separating the tissue into its component cells, then expanding the fibroblast cells using classical tissue culture techniques until the numbers are adequate for repeated injection. In this manner, each patient is treated with cells that were grown from his or her own dermal tissue (i.e., autologous).

Our most advanced development program is azficel-T for the treatment of chronic dysphonia resulting from vocal cord scarring. We are currently in a Phase II clinical trial for this indication. We expect to complete dosing in our Phase II clinical trial by year-end 2015 and announce efficacy results in the second quarter of 2016. In collaboration with Intrexon, a leader in synthetic biology, we are also in the preclinical development stage with two gene-therapy product candidates. Our lead orphan gene-therapy product candidate, FCX-007, has received an orphan drug designation from the FDA and is in late stage preclinical development for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"), a devastating, rare, congenital, painful, progressive blistering skin disease that typically leads to premature death. We are also in preclinical development of our second gene-therapy product candidate, FCX-013, for the treatment of linear scleroderma, an excess production of extracellular matrix characterized by skin fibrosis and linear scars. We plan to seek orphan drug designation for FCX-013.

Azficel-T for Chronic Dysphonia

Dysphonia is a reduction in vocal capacity and is caused by damage to the fibroblast layer of the vocal cords, which limits airflow and results in severe and significant limitations in voice quality. Depending on the severity of dysphonia, a patient's resulting voice is hoarse or raspy and is perceived by sufferers as a communication disorder. Severe cases can lead to a total loss of voice. The number of U.S. patients suffering from chronic dysphonia caused by vocal fold scarring is approximately 125,000. No long-term effective therapy is presently available, and rehabilitation of subjects (for example, with voice therapy) is difficult. In our Phase I clinical trial of azficel-T for chronic dysphonia, which involved a feasibility study to determine the safety and efficacy of injections for the treatment of chronic dysphonia in patients who had failed to improve following currently available treatments, a positive trend of sustained improvement was noted in a majority of clinical trial subjects. Our Phase II clinical trial for chronic dysphonia currently in progress is a double-blind, randomized, placebo-controlled trial that is designed to test the safety and efficacy of azficel-T in subjects with chronic dysphonia caused by idiopathic vocal cord scarring or age-related dysphonia. Efficacy endpoints will be assessed four months after administration of final treatment.

FCX-007 for RDEB

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

FCX-007, our lead gene-therapy product candidate, is an autologous fibroblast cell genetically modified to express COL7. We are developing FCX-007 in collaboration with Intrexon. We submitted our investigational new drug ("IND") application for FCX-007 to the FDA on July 17, 2015 and expect to initiate a Phase I/II clinical trial for FCX-007 by the end of

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2015. We expect that the primary objective of our Phase I/II trial will be to evaluate the safety of FCX-007. We also expect that the secondary objectives will be to (i) assess the mechanism of action at weeks 4, 12, 25, 52 and unscheduled visits through the evaluation of skin biopsies for COL7 expression and the presence of anchoring fibrils and (ii) assess the efficacy of FCX-007 through an intra-subject paired analysis of target wound area at weeks 4, 8, 12, 25, 52 and unscheduled visits. We expect to access efficacy by comparing FCX-007 treated wounds to untreated wounds in Phase I and to wounds administered sterile saline in Phase II through the evaluation of digital imaging of wounds. We aim to enroll nine subjects in this Phase I/II clinical trial (three adults in Phase I followed by six pediatric subjects in Phase II).

FCX-013 for Linear Scleroderma

Linear scleroderma is a localized autoimmune skin disorder that manifests as excess production of extracellular matrix characterized by fibrosis and linear scars. The linear areas of skin thickening may extend to underlying tissue and muscle in children which may impair growth and development. Lesions appearing across joints can be painful, impair motion and may be permanent. Current treatments only address symptoms, including systemic or topical corticosteroids, UVA light therapy and physical therapy. Our second gene-therapy product candidate, FCX-013, is also being developed in collaboration with Intrexon and is currently in preclinical development for the treatment of linear scleroderma. Our product development efforts to date have included gene selection and design, transduction efficiency and protein expression analysis, ligand development for use in connection with Intrexon's proprietary RheoSwitch Therapeutic System® ("RTS®") expression technology and analytical assay design. Research is ongoing to select the optimal gene configuration, optimize RTS® control, develop animal models to establish proof of concept and progress the regulatory path for FCX-013. We expect to complete the proof-of-concept studies in the first half of 2016 and plan to submit our IND application to the FDA in the second half of 2016.

LAVIV (azficel-T) for Nasolabial Fold Wrinkles

We currently market LAVIV® (azficel-T), an FDA-approved biological product that uses our proprietary autologous fibroblast technology, for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults. In 2013, we changed our business strategy to focus on rare skin and connective tissue diseases, resulting in our product candidates mentioned above. As a result, we devote minimal sales and marketing efforts towards our LAVIV aesthetic product line, and we intend to support only a nominal amount of LAVIV aesthetic procedures in 2015 and beyond. Given the limited use of LAVIV we are experiencing difficulties in recruiting a sufficient number of subjects for the postmarketing study that the FDA required as a condition for the approval of LAVIV. We are actively engaged in discussions with the FDA about how to fulfill the requirement in light of the limited patient population given our shift in focus to rare skin and connective tissue diseases.

Research Collaboration with UCLA

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

Results of Operations

Comparison of Three Months Ended June 30, 2015 and 2014

Revenue and Cost of Revenue.

Revenue and cost of revenue was comprised of the following:

	Three months ended June 30,		Increase (Decrease)	
($ in thousands)	2015	2014	$	%
Revenue from product sales	$55	$58	$(3)	(5.2)%
Collaboration revenue	82	—	82	100.0 %
Total revenue	137	58	79	136.2 %
Cost of product sales	77	547	(470)	(85.9)%
Cost of collaboration revenue	85	—	85	100.0 %
Total cost of revenue	162	547	(385)	(70.4)%

Gross loss	$(25)	$(489)	$464	(94.9)%

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Total revenue was approximately $0.1 million for each of the three months ended June 30, 2015 and 2014, respectively. Revenue from product sales is recognized based on the shipment of LAVIV injections to patients and was relatively constant in the second quarter of 2015 as compared to the second quarter of 2014. Collaboration revenue is related to a research and development agreement that we have with an unrelated third party to investigate potential new non-pharmaceutical applications for our conditioned fibroblast media technology. Revenue recognized from our collaboration relates to an upfront license fee and a proof of concept study currently underway.

Cost of product sales was approximately $0.1 million and $0.5 million for the three months ended June 30, 2015 and 2014, respectively. Cost of product sales includes the costs related to the processing of cells for LAVIV, including direct and indirect costs. The decrease of $0.5 million is primarily due to our continued de-emphasis on commercial sales in the aesthetic market (LAVIV) as well as the increase in clinical manufacturing which reduces the allocation of fixed overhead costs to commercial sales. We believe that cost of product sales will remain at or above product sales for the foreseeable future and, thus, we anticipate that we will continue to report gross losses from product sales of LAVIV for the foreseeable future. Cost of collaboration revenue was $0.1 million for the three months ended June 30, 2015, and consists primarily of manufacturing costs related to a proof of concept study which began in 2015.

Research and Development Expense.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, preclinical and clinical development costs. Indirect expenses include regulatory, laboratory, personnel, facility, stock compensation and other overhead costs that we do not allocate to any specific program. We expect research and development costs to continue to be significant for the foreseeable future as we continue in our efforts to develop first-in-class treatments for rare and serious skin and connective tissue diseases.

Research and development expense was comprised of the following:

	Three months ended June 30,		Increase (Decrease)	
($ in thousands)	2015	2014	$	%
Direct costs:				
azficel-T for chronic dysphonia	$436	$110	$326	296.4 %
FCX-007	905	917	(12)	(1.3)%
FCX-013	254	78	176	225.6 %
Other	43	204	(161)	(78.9)%
Total direct costs	1,638	1,309	329	25.1 %
Indirect costs:				
Regulatory costs	239	227	12	5.3 %
Intangible amortization	138	138	—	—
Compensation and related expense	888	811	77	9.5 %
Process development	71	(5)	76	1,520.0 %
Other indirect R&D costs	720	445	275	61.8 %
Total indirect costs	2,056	1,616	440	27.2 %
Total research and development expense	$3,694	$2,925	$769	26.3 %

Total research and development expense increased $0.8 million, or 26.3%, to approximately $3.7 million for the three months ended June 30, 2015 as compared to $2.9 million for the three months ended June 30, 2014. The overall increase is due primarily to increased costs during the 2015 period of $0.3 million for our azficel-T for chronic dysphonia Phase II clinical trial, $0.2 million for preclinical development of FCX-013 and increased costs of $0.3 million for other indirect R&D costs.

Direct research and development expense by major clinical and preclinical development program was as follows:

- azficel-T for chronic dysphonia — Our Phase II clinical trial began enrollment in the second quarter of 2014. Costs increased approximately $0.3 million for the three months ended June 30, 2015 as compared to the same period last year due to costs for additional patient enrollment, clinical site fees and clinical manufacturing costs.

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- FCX-007 — Costs were relatively constant for the three months ended June 30, 2015 as compared to the same period last year.
- FCX-013 — Costs increased approximately $0.2 million for the three months ended June 30, 2015 as compared to the same period last year due to the advancement of our preclinical work related to linear scleroderma, specifically for gene screening and selection, construct build and optimization, vector optimization, assay development, RheoSwitch® and ligand optimization and early animal model work. RheoSwitch® refers to Intrexon's proprietary RheoSwitch Therapeutic System® technology which is a biologic switch activated by a small molecule ligand that provides the ability to control level and timing of protein expression in those diseases where such control is critical.
- Other - Other direct research and development expenses decreased approximately $0.2 million due to the reduction of efforts on our azficel-T for the treatment of restrictive burn scarring program. While enrollment for the Phase II clinical trial for this indication was closed in the fourth quarter of 2014, the trial is continuing with the subjects currently enrolled.

Total indirect research and development expense increased by $0.4 million for the three months ended June 30, 2015 as compared to the same period last year. This increase is primarily due to an increase in other miscellaneous indirect research and development costs of $0.3 million due to increased allocation of fixed overhead costs for our manufacturing facility due to lower commercial volume of LAVIV.

Selling, General and Administrative Expense.

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

	Three months ended June 30,		Increase (Decrease)		
($ in thousands)	2015	2014	$	%	
Compensation and related expense	$1,638	$1,311	$327	24.9	%
Professional fees	1,277	1,014	263	25.9	%
Facilities and related expense and other	725	857	(132)	(15.4)	%
Total selling, general and administrative expense	$3,640	$3,182	$458	14.4	%

Selling, general and administrative expense increased by approximately $0.5 million, or 14.4%, to $3.6 million for the three months ended June 30, 2015 as compared to $3.2 million for the same period last year. This increase is attributable to a $0.3 million increase in compensation and related expense due to an increase in stock based compensation and a $0.3 million increase in professional fees offset by a $0.1 million reduction in facilities and related expense and other. The total increase in professional fees was driven by increased legal expense of $0.7 million and was offset by a decrease of $0.4 million in accounting fees due to the warrant restatement project which drove costs higher in the second quarter of 2014.

Other Income.

During the three months ended June 30, 2014, we recorded approximately $0.3 million of other income related to a settlement agreement with one of our suppliers. There was no such income during the three months ended June 30, 2015.

Warrant Revaluation and Other Finance Expense.

During the three months ended June 30, 2015 and 2014, we recorded non-cash warrant income of approximately $0.6 million and $4.0 million in our consolidated statements of operations, respectively, related to the change in the fair value of our warrants.

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Comparison of Six Months Ended June 30, 2015 and 2014

Revenue and Cost of Revenue.

Revenue and cost of revenue was comprised of the following:

	Six months ended June 30,		Increase (Decrease)		
($ in thousands)	2015	2014	$	%	
Revenue from product sales	$168	$104	$64	61.5	%
Collaboration revenue	163	—	163	100.0	%
Total revenue	331	104	227	218.3	%
Cost of product sales	221	1,340	(1,119)	(83.5)	%
Cost of collaboration revenue	88	—	88	100.0	%
Total cost of revenue	309	1,340	(1,031)	(76.9)	%
Gross profit (loss)	$22	$(1,236)	$1,258	(101.8)	%

Total revenue was $0.3 million and $0.1 million for each of the six months ended June 30, 2015 and 2014, respectively. Revenue from product sales is recognized based on the shipment of LAVIV injections to patients. The increase in total revenue was primarily due to collaboration revenue received in 2015 related to a research and development agreement that we have with an unrelated third party to investigate potential new non-pharmaceutical applications for our conditioned fibroblast media technology. This revenue relates to an upfront license fee and a proof of concept study currently underway. No collaboration revenue was recognized in the 2014 period.

Cost of product sales was approximately $0.2 million and $1.3 million for the six months ended June 30, 2015 and 2014, respectively. Cost of product sales includes the costs related to the processing of cells for LAVIV, including direct and indirect costs. The decrease of $1.1 million is primarily due to our continued de-emphasis on commercial sales in the aesthetic market (LAVIV) as well as the increase in clinical manufacturing which reduces the allocation of fixed overhead costs to commercial sales. We believe that cost of product sales will remain at or above product sales for the foreseeable future and, thus, we anticipate that we will continue to report gross losses from product sales of LAVIV for the foreseeable future. Cost of collaboration revenue was $0.1 million for the six months ended June 30, 2015, and consists primarily of manufacturing costs related to a proof of concept study which began in 2015.

Research and Development Expense.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, preclinical and clinical development costs. Indirect expenses include regulatory, laboratory, personnel, facility, stock compensation and other overhead costs that we do not allocate to any specific program. We expect research and development costs to continue to be significant for the foreseeable future as we continue in our efforts to develop first-in-class treatments for rare and serious skin and connective tissue diseases with high unmet medical needs.

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Research and development expense was comprised of the following:

	Six months ended June 30,		Increase (Decrease)		
($ in thousands)	2015	2014	$	%	
Direct costs:					
azficel-T for chronic dysphonia	$724	$198	$526	265.7	%
FCX-007	2,227	1,622	605	37.3	%
FCX-013	704	262	442	168.7	%
Ehlers-Danlos Syndrome (hypermobility type)	—	5,156	(5,156)	(100.0)	%
Other	102	311	(209)	(67.2)	%
Total direct costs	3,757	7,549	(3,792)	(50.2)	%
Indirect costs:					
Regulatory costs	480	392	88	22.4	%
Intangible amortization	276	276	—	—	
Compensation and related expense	1,816	1,433	383	26.7	%
Process development	71	37	34	91.9	%
Other indirect R&D costs	1,281	1,153	128	11.1	%
Total indirect costs	3,924	3,291	633	19.2	%
Total research and development expense	$7,681	$10,840	$(3,159)	(29.1)	%

Total research and development expense decreased $3.2 million to approximately $7.7 million for the six months ended June 30, 2015 as compared to $10.8 million for the six months ended June 30, 2014. The overall decrease is due primarily to $5.2 million of supplemental stock issuance costs incurred in the 2014 period related to our Ehlers-Danlos Syndrome (hypermobility type) program in connection with the second amendment to the exclusive channel collaboration agreement with Intrexon. This up-front licensing cost did not recur in the 2015 period. That decrease was partially offset by increased costs during the 2015 period of $0.5 million for our azficel-T for chronic dysphonia Phase II clinical trial, $0.6 million for preclinical development of FCX-007, $0.4 million for preclinical development of FCX-013 and $0.4 million of compensation and related expenses related to salaries, bonus and stock based compensation.

Direct research and development expense by major clinical and preclinical development program was as follows:

- azficel-T for chronic dysphonia — Our Phase II clinical trial began enrollment in the second quarter of 2014. Costs increased approximately $0.5 million for the six months ended June 30, 2015 as compared to the same period last year due to costs for additional patient enrollment, clinical site fees and clinical manufacturing costs.
- FCX-007 — Costs increased approximately $0.6 million for the six months ended June 30, 2015 as compared to the same period last year due to the progression of our preclinical development program, specifically our animal studies and preclinical product manufacturing costs.
- FCX-013 — Costs increased approximately $0.4 million for the six months ended June 30, 2015 as compared to the same period last year due to the advancement of our preclinical work related to linear scleroderma, specifically for gene screening and selection, construct build and optimization, vector optimization, assay development, RheoSwitch® and ligand optimization and some early animal model work.
- Ehlers-Danlos Syndrome (hypermobility type) — Costs decreased approximately $5.2 million for the six months ended June 30, 2015 as compared to the same period last year due to the 2014 supplemental stock issuance costs incurred in connection with the second amendment to the exclusive channel collaboration agreement with Intrexon. No substantive work has yet begun on this program.
- Other — Other direct research and development expenses decreased approximately $0.2 million due to the reduction of efforts on our azficel-T for the treatment of restrictive burn scarring program. While enrollment for the Phase II clinical trial for this indication was closed in the fourth quarter of 2014, the trial is continuing with the subjects currently enrolled.

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Total indirect research and development expense increased by $0.6 million for the six months ended June 30, 2015 as compared to the same period last year. This increase is primarily due to increases in compensation and related expenses including stock based compensation.

Selling, General and Administrative Expense.

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

	Six months ended June 30,		Increase (Decrease)		
($ in thousands)	2015	2014	$	%	
Compensation and related expense	$2,525	$2,277	$248	10.9	%
Professional fees	2,569	1,739	830	47.7	%
Facilities and related expense and other	1,470	1,504	(34)	(2.3)	%
Total selling, general and administrative expense	$6,564	$5,520	$1,044	18.9	%

Selling, general and administrative expense increased by approximately $1.0 million, or 18.9%, to $6.6 million for the six months ended June 30, 2015 as compared to $5.5 million for the same period last year. The primary driver of increased expense was a $0.8 million increase in professional fees. The total increase in professional fees was driven by increased legal expense of $1.3 million and was offset by a decrease of $0.4 million in accounting fees due to costs incurred related to the warrant restatement project in the second quarter of 2014 and of $0.1 million in investor relations services. Compensation and related expense increased $0.2 million mostly due to an increase in stock based compensation.

Other Income.

During the six months ended June 30, 2014, we recorded approximately $0.4 million of other income mostly related to a settlement agreement with one of our suppliers. There was no such income during the six months ended June 30, 2015.

Warrant Revaluation and Other Finance Expense.

During the six months ended June 30, 2015 and 2014, we recorded non-cash warrant expense of approximately $1.1 million and warrant income of $1.0 million in our consolidated statements of operations, respectively, related to the change in the fair value of our warrants.

Liquidity and Capital Resources

Overview

As of June 30, 2015, we had cash and cash equivalents of approximately $26.9 million and working capital of approximately $22.8 million. On July 27, 2015, we sold 2,974,136 shares of our common stock in an underwritten public offering at a price per share of $5.80 (the "July 2015 Offering"). The net proceeds to us from the sale of stock in the Offering, after deducting underwriting commissions and other estimated offering expenses payable by us, was approximately $15.7 million.

We believe that our cash and cash equivalents at June 30, 2015 and the net proceeds from the July 2015 Offering will be sufficient to fund our operations into the fourth quarter of 2016. The additional capital that will be required to fund our operations beyond that point will depend largely on the timing and outcomes of our current clinical and preclinical product development programs, the number of other product candidates we choose to develop and the amount of capital investment we choose to make in our manufacturing facility.

To address our future capital needs, we will consider a range of possibilities, including raising additional capital through the issuance of equity or equity-linked securities, through debt financing or by entering into corporate collaborations, partnerships or other strategic transactions. Our ability to raise additional capital will be dependent on, among other things, the the status of our development programs and the state of the financial markets at the time of any proposed capital-raising transaction. There is no assurance that additional capital, through any of the aforementioned means, will be available on acceptable terms, or at all. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations could be materially harmed.

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

Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities for the six months ended June 30, 2015 and 2014:

Statement of Cash Flows Data:	Six months ended June 30,	
($ in thousands)	2015	2014
Cash used in operating activities	$(10,787)	$(10,286)
Cash used in investing activities	$(111)	$(211)
Cash provided by financing activities	$253	$—

Operating Activities.

Cash used in operating activities during the six months ended June 30, 2015 was approximately $10.8 million, an increase of $0.5 million as compared to the same period last year, due largely to the increase in selling, general and administrative expense related to professional fees.

Investing Activities.

Cash used in investing activities during the six months ended June 30, 2015 was approximately $0.1 million, a decrease of $0.1 million as compared to the same period last year, due to fewer equipment purchases.

Financing Activities.

Cash provided by financing activities during the six months ended June 30, 2015 was approximately $0.3 million, an increase of $0.3 million as compared to the same period last year, due to cash received for the exercise of stock options.

Contractual Obligations

During the six months ended June 30, 2015, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our Form 10-K for 2014.

Recently Issued Accounting Pronouncements

Please refer to Note 3 in the accompanying notes to the consolidated financial statements for additional information 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, 2014.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, pursuant to Rule 13a-15 promulgated under the Exchange Act, as of June 30, 2015. Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the SEC. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal

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executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, management is required to apply its judgment in evaluating the benefits of possible disclosure controls and procedures relative to their costs to implement and maintain.

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

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2015, the Company devoted significant effort and resources to the remediation and improvement of our internal control over financial reporting and completed its corrective actions to respond to a material weakness with respect to internal control over management's review of the assumptions used in the valuation modeling of our liability-classified warrants identified in our 2014 Annual Report on Form 10-K. We require additional communication between management and any third parties who perform advisory services. We have also supplemented procedures for both compiling inputs to the warrant valuation model and for reviewing the outputs of such model provided by any third parties with whom we contract to verify that management's assumptions were used as expected during the valuation process. We believe that these controls and procedures have remediated this material weakness in our internal control over financial reporting. As we continue to evaluate and work to improve our internal control over financial reporting, we may determine to take additional measures to address the material weakness or determine to supplement or modify certain of the remediation efforts described above.

There have been no other changes in internal control over financial reporting that have occurred during the quarterly period ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

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

On or about December 19, 2014, Shandong Fabosaier Bio-Tech Co., Ltd. of China ("Shandong") and Ran Liu of Vancouver, Canada, who is allegedly a director of Shandong, commenced a lawsuit against us in the United States District Court for the Eastern District of Pennsylvania, Case No. 2:14-cv-07180-CMR. The Complaint asserts claims for breach of contract, promissory estoppel, and unjust enrichment against us relating to the marketing of our LAVIV product in China and Vancouver. We vigorously deny and dispute the factual allegations contained in the Complaint and, on February 12, 2015, we filed an amended answer, additional defenses and counterclaims against Shandong and Ms. Liu. Our counterclaims include counts for trademark infringement, violations of the Lanham Act and the Anti-cybersquatting Consumer Protection Act, unfair competition, and tortious interference with contractual relations resulting from Shandong's repeated, unauthorized use of our marks on Shandong's website and in other marketing materials. At this time, we are unable to state whether an outcome unfavorable to us is either probable or remote nor are we able to estimate the amount or range of loss in the event of an unfavorable outcome.

Item 1A. Risk Factors.

You should carefully consider each of the risk factors set forth under the heading "Risk Factors" in our Form 10-K for 2014. The risk factor 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.

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The results seen in preclinical studies of our product candidates may not be replicated in humans.

Although we have seen positive results in preclinical studies of FCX-007 and FCX-013, we may not see positive results when these and any other product candidates undergo future clinical trials in humans. Preclinical studies are not designed to test the efficacy of a product candidate in humans, but rather to:

• test short-term safety;
• establish biological plausibility;
• identify biologically active dose levels;
• establish feasibility and reasonable safety of the investigational product's proposed clinical route of administration;
• identify physiologic parameters that can guide clinical monitoring; and/or
• establish proof of concept, or the feasibility and rationale for use of an investigational product in the targeted patient population.

Success in preclinical studies does not ensure that later studies or any clinical trials will be successful nor does it predict future results. The rate of failure in drug development is quite high, and many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in preclinical studies and earlier clinical trials. Product candidates may fail to show desired safety and efficacy when used with human subjects. Negative or inconclusive results from any of our ongoing preclinical studies could result in delays, modifications, or abandonment of clinical trials and the termination of our development of a product candidate.

Item 6. Exhibits.

(a) Exhibits

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
10.1*	Employment Agreement, dated June 1, 2015, by and between Fibrocell Science, Inc. and Michael F. Marino, Esq.
31.1*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed or furnished, as applicable herewith.

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SIGNATURE

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

FIBROCELL SCIENCE, INC.

By: /s/ Keith A. Goldan
Keith A. Goldan
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 7, 2015

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