Fibrocell Science, Inc.
Form 10-Q
November 14, 2013
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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, 2013

OR

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

Fibrocell Science, Inc.

(Exact name of registrant as specified in its Charter.)

Delaware	**001-31564**	**87-0458888**
(State or other jurisdiction	**(Commission**	**(I.R.S. Employer**

of incorporation) **File Number)** **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 x No ¨

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

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

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes x No ¨

As of November 11, 2013, issuer had 39,832,225 shares issued and outstanding of common stock, par value $0.001.

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FIBROCELL SCIENCE, INC.

Form 10-Q for the Quarter Ended September 30, 2013

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial statements.

FIBROCELL SCIENCE, INC.

Consolidated Balance Sheets

(in thousands, except per share and share data)

	Unaudited September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 16,875	$ 31,346
Accounts receivable, net of allowance for doubtful accounts of $18 and $25, respectively	45	62
Inventory	574	477
Deferred equity costs	274	
Prepaid expenses	1,404	1,271
Total current assets	19,172	33,156
Property and equipment, net of accumulated depreciation of $714 and $434, respectively	1,540	1,658
Other assets	215	
Intangible assets, net	5,376	5,789
Total assets	$ 26,303	$ 40,603
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	$ 1,170	$ 921
Accrued expenses	1,317	494
Deferred revenue	132	139
Total current liabilities	2,619	1,554
Warrant liability	205	374
Other long-term liabilities	493	344
Total liabilities	3,317	2,272
Commitments		
Shareholders equity:		

Common stock, $0.001 par value; 100,000,000 and 1,100,000,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 27,520,527 and 26,229,909 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	28	26
Common stock-subscription receivable		(2,004)
Additional paid-in capital	120,014	112,384
Accumulated deficit	(97,056)	(72,075)
Total shareholders equity	22,986	38,331
Total liabilities and shareholders equity	$ 26,303	$ 40,603

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

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FIBROCELL SCIENCE, INC.

Consolidated Statements of Operations

(in thousands, except per share and share data)

(unaudited)

	For the three months ended September 30, 2013	For the three months ended September 30, 2012 Restated	For the nine months ended September 30, 2013	For the nine months ended September 30, 2012 Restated
Revenue from product sales	$ 68	$ 69	$ 156	$ 113
Cost of sales	1,930	2,321	6,523	5,968
Gross loss	(1,862)	(2,252)	(6,367)	(5,855)
Selling, general and administrative expenses	2,902	2,632	7,719	9,594
Research and development expenses	8,357	426	10,753	1,294
Operating loss	(13,121)	(5,310)	(24,839)	(16,743)
Other income (expense)				
Warrant income (expense)	188	14,545	(129)	17,192
Derivative revaluation income (expense)		1,894		(23)
Interest expense		(140)		(586)
Extinguishment of debt				(4,421)
(Loss) income from continuing operations before income taxes	(12,933)	10,989	(24,968)	(4,581)
Deferred tax benefit				2,500
(Loss) income from continuing operations	(12,933)	10,989	(24,968)	(2,081)
(Loss) income from discontinued operations, net of tax	(4)	5	(13)	(1)
Gain on sale of discontinued operations, net of tax		443		443
Net (loss) income	(12,937)	11,437	(24,981)	(1,639)
Net loss attributable to noncontrolling interest		(4)		(24)
	$ (12,937)	$ 11,433	$ (24,981)	$ (1,663)

Net (loss) income attributable to Fibrocell Science, Inc. common shareholders				
Per share information:				
Income (loss) from discontinued operations				
basic	$	$	$	$
diluted	$	$	$	$
Income from deferred tax benefit-basic and diluted	$	$	$	$ 0.64
Gain on sale of discontinued operations, net of tax-basic and diluted	$	$ 0.11	$	$ 0.11
Net (loss) income attributable to common shareholders per common share				
basic	$ (0.48)	$ 2.89	$ (0.94)	$ (0.43)
diluted	$ (0.48)	$ (1.27)	$ (0.94)	$ (0.43)
Weighted average number of basic common shares outstanding	27,158,394	3,957,231	26,543,099	3,887,530
Weighted average number of diluted common shares outstanding	27,158,394	3,957,231	26,543,099	3,887,530

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

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FIBROCELL SCIENCE, INC.

Consolidated Statements of Shareholders Equity

(in thousands, except share data)

(unaudited)

	Common stock					
	Shares	Amount	Subscription receivable	Additional paid-in capital	Accumulated deficit	Total shareholders equity
Balance, January 1, 2013	26,229,909	$ 26	$ (2,004)	$ 112,384	$ (72,075)	$ 38,331
Stock-based compensation expense				928		928
Warrants exercised	46,837			298		298
Subscription received			2,004			2,004
Issuance of common stock for exclusive collaboration channel agreement	1,243,781	2		6,404		6,406
Net loss					(24,981)	(24,981)
Balance, September 30, 2013	27,520,527	$ 28	$	$ 120,014	$ (97,056)	$ 22,986

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

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FIBROCELL SCIENCE, INC.

Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	For the nine months ended September 30, 2013	For the nine months ended September 30, 2012 Restated
Cash flows from operating activities:		
Net loss	$ (24,981)	$ (1,639)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt		4,421
Gain on sale of Agera		(443)
Expense related to stock-based compensation	928	857
Stock issued for supplemental stock issuance agreement	6,406	
Warrant expense (income)	129	(17,192)
Derivative revaluation expense		23
Deferred tax benefit		(2,500)
Depreciation and amortization	693	604
Provision for doubtful accounts	(7)	
Amortization of debt issue costs		112
Change in operating assets and liabilities:		
Accounts receivable	23	(82)
Inventory	(97)	(306)
Prepaid expenses	(133)	574
Other assets	(214)	
Accounts payable	248	(186)
Accrued expenses and other	973	420
Deferred revenue	(7)	80
Net cash used in operating activities	(16,039)	(15,257)
Cash flows from investing activities:		
Purchase of property and equipment	(162)	(473)
Proceeds from the sale of Agera, net		1,002
Net cash (used in) provided by investing activities	(162)	529
Cash flows from financing activities:		
Offering costs associated with the issuance of convertible debt		(46)

Proceeds from the issuance of redeemable preferred stock, net		7,864
Subscription received	2,004	
Deferred equity costs	(274)	
Payments on insurance loan		(97)
Principal payments on 12.5% note payable		(3,517)
Cash dividends paid on redeemable preferred stock		(157)
Net cash provided by financing activities	1,730	4,047
Net decrease in cash and cash equivalents	(14,471)	(10,681)
Cash and cash equivalents, beginning of period	31,346	10,799
Cash and cash equivalents, end of period	$ 16,875	$ 118

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

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FIBROCELL SCIENCE, INC.

Notes to Consolidated Financial Statements

(in thousands, except per share and share data)

(unaudited)

Note 1 Business and Organization

Fibrocell Science, Inc. (Fibrocell or the Company) is the parent company of Fibrocell Technologies (Fibrocell Tech) and Fibrocell Science Hong Kong Limited, 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 (NYSE MKT: FCSC) is an autologous cell therapy company primarily focused on developing first-in-class treatments for skin diseases and conditions, particularly those with high unmet medical needs. Based on its proprietary autologous fibroblast technology, the Company is pursuing breakthrough medical applications of azficel-T for restrictive burn scarring and vocal cord scarring. The Company s collaboration with Intrexon Corporation (NYSE: XON), a leader in synthetic biology, includes using genetically-modified fibroblasts for treating orphan skin diseases for which there are no currently approved products and exploring the localized treatment of the most common autoimmune skin disease, moderate-to-severe psoriasis. The Company s collaboration with UCLA and MIT focusing on skin-derived stem cells and more efficient ways to convert skin cells to other cell types holds potential for future discovery and development of autologous cellular therapeutics.

The Company previously marketed a skin care line with broad application in core target markets through its consolidated subsidiary, Agera Laboratories, Inc. (Agera), which was sold on August 31, 2012. The Company had owned 57% of the outstanding shares of Agera. As a result of the sale of Agera, the Company operates in one segment and Agera is classified as discontinued operations. Please refer to Note 6 for more details.

The Company transitioned from its development stage to operational activities as of July 1, 2012. As such, the financial statements have been updated to reflect that the Company is no longer a development stage company.

Note 2 Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by GAAP for complete consolidated financial statements. In the opinion of management, all adjustments (consisting only 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, 2012, 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.

The prior year financial statements contain certain reclassifications and restatements to present discontinued operations and also to present deferred taxation in the first quarter of 2012 in this Form 10-Q. Please refer to Notes 5 and 6 respectively for more details.

On April 29, 2013, the Company announced a reverse stock split on the basis of one share of common stock for each currently outstanding 25 shares of pre-split common stock that became effective on April 30, 2013. All common share and per-share data included in these financial statements reflect such reverse stock split.

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.

Intangible assets

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 are considered finite-lived intangible assets and are being amortized over 12 years. For the three months ended September 30, 2013 and 2012, the Company amortized $138, respectively, for the intangible assets. For the nine months ended September 30, 2013 and 2012, the Company amortized $414, respectively, for the intangible assets.

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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. We review our 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 during the three and nine months ended September 30, 2013 and 2012.

Loss per share data

Basic income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during a period. The diluted earnings per share calculation gives effect to dilutive options, warrants, convertible notes, convertible preferred stock, and other potential dilutive common stock including selected restricted shares of common stock outstanding during the period. Diluted income (loss) per share is based on the treasury stock method and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options, assuming the exercise of all in-the-money stock options. Common share equivalents have been excluded where their inclusion would be anti-dilutive. The warrants related to the stock warrant liability were first evaluated on an as if converted basis; the change in the fair value of the stock warrants recognized in the first quarter was subtracted from earnings to calculate net income (loss) applicable to dilutive common stock. Then, the incremental shares for dilution were determined utilizing the treasury method. Since the average stock price for the quarter was below the exercise price of the warrants, the calculation under the treasury method resulted in repurchasing more shares than would have been exercised and therefore, the inclusion of these shares were deemed to be anti-dilutive and excluded from the dilutive share calculation.

The following table presents computations of net income (loss) per share.

	For the three months ended September 30,		For the nine months ended September 30,	
	2013	2012	2013	2012
Net income (loss) per share-Basic:				
Numerator for basic net (loss) income per share	$ (12,937)	$ 11,433	$ (24,981)	$ (1,663)
Denominator for basic net (loss) income per share	27,158,394	3,957,231	26,543,099	3,887,530
Basic net (loss) income per common share	$ (0.48)	$ 2.89	$ (0.94)	$ (0.43)
Net income (loss) per share-Diluted:				
Numerator for diluted net income (loss) per share	$ (12,937)	$ 11,433	$ (24,981)	$ (1,663)
Less: Fair value of stock warrants		(14,545)		
Less: Fair value of derivatives		(1,894)		

Net loss attributable to common share	$ (12,937)	$ (5,006)	$ (24,981)	$ (1,663)
Denominator for diluted net loss per share	27,158,394	3,957,231	26,543,099	3,887,530
Diluted net loss per common share	$ (0.48)	$ (1.27)	$ (0.94)	$ (0.43)

The following potentially dilutive securities have been excluded from the calculations of diluted net loss per share as their effect would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Shares of convertible preferred stock		1,917,120		1,917,120
Shares underlying options outstanding	1,269,320	546,490	1,269,320	546,490
Shares underlying warrants outstanding	6,033,050	5,466,470	6,033,050	5,466,470

Note 4 Collaboration

On October 5, 2012, the Company entered into an Exclusive Channel Collaboration Agreement (the Channel Agreement) with Intrexon Corporation (Intrexon) that governs a channel collaboration arrangement. The Channel Agreement grants the Company an exclusive license to use proprietary technologies and other intellectual property of Intrexon to develop and

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commercialize certain products in the United States. Through the original collaboration with Intrexon, the Company is exploring the use of genetically modified fibroblast cells to treat patients with collagen deficient diseases. The Company is working to genetically modify fibroblasts with the gene to produce collagen VII to treat patients with recessive dystrophic epidermolysis bullosa (RDEB). This development concept utilizes genetically modified fibroblasts to up-regulate and produce collagen VII in a controlled manner for localized or systematic treatment of RDEB.

On June 28, 2013, the Company and Intrexon entered into a First Amendment (Amendment) to the parties Channel Agreement. The Amendment broadens the existing collaboration to include potential treatments based on engineered autologous fibroblast cells for the localized treatment of autoimmune and inflammatory disorders including morphea (localized scleroderma), cutaneous eosinophilias and moderate to severe psoriasis.

Pursuant to the Channel Agreement and Amendment, the Company engaged Intrexon for support services for the development of new products covered under the Channel Agreement and Amendment, and will reimburse Intrexon for its fully-loaded cost for time and materials for transgenes, cell processing, or other work performed by Intrexon for such research and manufacturing. For the three and nine months ended September 30, 2013, the Company incurred expenses of $1.4 million and $2.4 million, respectively, for work performed. The Company will pay quarterly cash royalties on improved products equal to one-third of cost of goods sold savings less any such savings developed by the Company outside of the Channel Agreement or Amendment. On all other developed products, the Company will pay Intrexon quarterly cash royalties of 7% on aggregate annualized net sales up to $100 million, and 14% on aggregate annualized net sales greater than $100 million. Sales from the Company s currently marketed products (including new indications) are not subject to royalty payments unless they are improved upon through the Channel Agreement.

As consideration for the Channel Agreement, the Company issued 1,317,520 shares of its common stock. This resulted in a non-cash expense of approximately $6.9 million that was included in research and development expense in the fourth quarter of 2012, due to the recording of the fair value of the issued shares of common stock valued at $5.25 per share, issued to Intrexon as consideration for the Channel Agreement.

In connection with the execution of the Amendment, on June 28, 2013, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon see Note 11.

Note 5 Deferred Tax Adjustment

During the quarter ended December 31, 2012, the Company discovered that the deferred tax liability reported in its quarters ended March 31, June 30, and September 30, 2012 consolidated financial statements was recorded incorrectly. In the first quarter ended March 31, 2012, the Company commenced amortizing the deferred tax liability over a twelve-year period to match the amortization of the related intangible. However, the full amount of the deferred tax liability should have been recorded as a deferred tax benefit in the first quarter of 2012 in the Consolidated Statement of Operations. This error was identified and recorded as an out-of-period adjustment in the quarter ended December 31, 2012. If the transaction was recorded in the first quarter of 2012, the deferred tax benefit would have been $0.0 and $2.5 million for the three and nine months ended September 30, 2012 and the deferred tax liability would have been $0.0 as of September 30, 2012. The Consolidated Statements of Cash Flows have been restated to reflect a net loss of $1.6 million and a deferred tax benefit of $2.5 million for the nine months ended September 30, 2012. The Company has restated the three and nine months of 2012 in this Form 10-Q to reflect this adjustment.

Note 6 Discontinued Operations

On August 31, 2012, the Company sold all of the shares of common stock of Agera held by the Company, which represented 57% of the outstanding common stock of Agera to Rohto Pharmaceutical Co., Ltd. for approximately $1.0 million. Accordingly, all operating results from continuing operations exclude the results for Agera which are presented as discontinued operations for all prior year numbers.

The financial results of Agera are classified as discontinued operations in the accompanying Consolidated Statement of Operations. Summary financial information related to discontinued operations is as follows:

	For the three months ended September 30, 2012	For the nine months ended September 30, 2012
Product sales	$ 142	$ 516
Cost of sales	65	275
Gross profit	77	241
Operating income	$ 20	$ 27
Net income (loss)	$ 11	$ (2)

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In addition, there are other minimal costs from the Company s Switzerland subsidiary which are classified as discontinued operations.

Note 7 Supplemental Cash Flow Information

The following table contains additional cash flow information for the periods reported.

	For the nine months ended September 30, 2013	For the nine months ended September 30, 2012
Supplemental disclosures of cash flow information:		
Cash paid for interest	$	$ 1,161
Cash paid for dividends		157
Non-cash investing and financing activities:		
Accrued preferred stock dividend		391
Accrued warrant liability		11,078
Accrued derivative liability		815
Subscription receivable		550
Conversion of preferred stock derivative balance into common stock		79
Cashless exercise of warrants recorded as a liability	(298)	
Common stock issued in connection with conversion of debt		229

Note 8 Inventory

Inventories consist of the following:

	September 30, 2013	December 31, 2012
Raw materials	$ 474	$ 326
Work in process	100	151
Total	$ 574	$ 477

Note 9 Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company adopted the accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following fair value hierarchy table presents information about each major category of the Company s financial assets and liability measured at fair value on a recurring basis as of September 30, 2013 and December 31, 2012:

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
Balance at September 30, 2013				
Liabilities				
Warrant liability	$	$	$ 205	$ 205

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	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Balance at December 31, 2012				
Liabilities				
Warrant liability	$	$	$ 374	$ 374

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

	Warrant Liability
Balance at December 31, 2012	$ 374
Exercise of warrants	(298)
Change in fair value of warrant liability	129
Balance at September 30, 2013	$ 205

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 12 for further discussion of the warrant liability.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

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

Note 10 Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2013	December 31, 2012
Accrued professional fees	$ 296	$ 58
Accrued compensation	125	48
Accrued exclusive channel collaboration costs	496	
Accrued severance	170	
Accrued other	230	388
Total accrued expenses	$ 1,317	$ 494

Note 11 Equity

Preferred stock

The Company is authorized to issue 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of the Company s preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of the Company or other corporate action. There are no preferred shares issued or outstanding as of September 30, 2013. The Company recorded accrued dividends at a rate of 6% per annum on previously issued shares of Series D preferred stock and 8% per annum on previously issued shares of Series E preferred stock. The Company accrued dividends payable of $0.3 million, and paid cash of $0.2 million in dividends during the nine months ended September 30, 2012.

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Common stock

In connection with the execution of the Amendment on June 28, 2013 between the Company and Intrexon, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon. The Company agreed to issue to Intrexon, who is an affiliate of NRM VII Holdings I, LLC, the Company s largest shareholder, a number of shares of Company common stock valued at $7.5 million based on a per share value of $6.03 per share, the closing price of the Company s common stock on the NYSE MKT on the day prior to execution of the Supplemental Stock Issuance Agreement (the Supplemental Access Fee Shares). The Supplemental Access Fee Shares were issued upon the satisfaction of customary closing conditions, including the approval for the listing of the Supplemental Access Fee Shares on the NYSE MKT. The closing took place on July 26, 2013. We recorded a fair value of $6.4 million for 1,243,781 shares issued to Intrexon for the closing of the Supplemental Stock Issuance Agreement as a research and development expense in the third quarter 2013.

Note 12 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 Financial Accounting Standards Board Accounting Standard Codification (ASC) 815, Derivatives and Hedging (ASC 815) if the stock warrants contain down-round protection 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. The Company will continue to classify the fair value of the warrants that contain down-round protection 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. From January 1, 2012 through September 30, 2012, the Company utilized the Monte Carlo simulation valuation method to value the liability classified warrants. Beginning October 1, 2012, the Company concluded that the Black-Scholes option pricing model was an appropriate valuation method due to the assumption that no future financing would be expected at a price lower than the current exercise price and the majority of the warrants were converted to equity-classified warrants on October 9, 2012.

The following table summarizes outstanding warrants to purchase common stock as of September 30, 2013 and December 31, 2012:

	Number of Warrants			
Liability-classified warrants	**As of September 30, 2013**	**As of December 31, 2012**	**Exercise Price**	**Expiration Dates**
Issued in Series B Preferred Stock offering	1,320	1,320	$ 2.50	Jul. Nov. 2015
Issued in Series D Preferred Stock offering	14,800	39,800	$ 2.50	Dec. 2015 Mar. 2016
Issued in Series E Preferred Stock offering	60,000	120,000	$ 2.50	May June 2017
Subtotal	76,120	161,120		

Equity-classified warrants						
Issued in June 2011 equity financing	6,113	6,113	$	22.50		June 2016
Issued in March 2010 and Preferred Stock offerings	4,209,357	4,209,357	$	6.25 7.50	Oct. 2015	June 2018
Issued with Convertible Notes	1,125,578	1,125,578	$	2.50		June 2018
Issued to placement agents in August 2011 equity financing	50,123	50,123	$	13.75		August 2016
Issued in August 2011 equity financing	565,759	579,759	$	18.75		August 2016
Subtotal	5,956,930	5,970,930				
Total	6,033,050	6,132,050				

There were 75,000 and 85,000 warrants exercised for the three and nine months ended September 30, 2013, respectively.

Liability-classified Warrants

The following table summarizes the calculated aggregate fair values as of the dates indicated along with the assumptions utilized in the Black-Scholes option pricing model for each calculation.

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	September 30, 2013	December 31, 2012
Calculated aggregate value (in thousands)	$ 205	$ 374
Exercise price per share of warrant	$ 2.50	$ 2.50
Closing price per share of common stock	$ 4.38	$ 3.75
Volatility	68%	70%
Expected term (years)	3.4	4.0
Risk-free interest rate	0.8%	0.6%
Dividend yield	%	%

Note 13 Equity-based Compensation

Our board of directors adopted the 2009 Equity Incentive Plan (the Plan) effective September 3, 2009. The Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisors by providing incentives for such persons to exert maximum efforts for the success of the Company. The Plan allowed for the issuance of up to 1,200,000 shares of the Company s common stock as of June 30, 2013. Effective July 19, 2013, at the Annual Shareholders Meeting, the holders of common stock approved an amendment to the Company s 2009 Equity Incentive Plan to increase the number of shares of common stock reserved for issuance under the plan from 1,200,000 to 2,600,000 shares.

The types of awards that may be granted under the Plan include options (both nonqualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units, and other stock-based awards. The term of each award is determined by the Board at the time each award is granted, provided that the terms of options may not exceed ten years. The Plan had 1,512,680 options available for grant as of September 30, 2013.

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

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Stock option compensation expense for employees and directors	$ 620	$ 277	$ 826	$ 833
Equity awards for nonemployees issued for services	99	(3)	102	24
Total stock-based compensation expense	$ 719	$ 274	$ 928	$ 857

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2012	562,025	$ 18.50	7.0	$

Granted	732,000	$ 4.96			
Exercised					
Forfeited	(24,705)	$ 14.82			
Outstanding at September 30, 2013	1,269,320	$ 10.78	7.7	$	89
Exercisable at September 30, 2013	696,037	$ 15.48	7.2	$	23

The total fair value of shares vested during the nine months ended September 30, 2013 was $1.2 million. As of September 30, 2013, there was $1.3 million of total unrecognized compensation cost, related to non-vested stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 2.7 years. As of September 30, 2013, there was $0.6 million of total unrecognized compensation expense related to performance-based, non-vested consultant options.

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During the nine months ended September 30, 2013 and 2012, the weighted average fair market value using the Black-Scholes option-pricing model of the options granted was $3.47 and $5.75, respectively. The fair market value of the options was computed using the Black-Scholes option-pricing model with the following key weighted average assumptions for the nine months ended as of the dates indicated:

	September 30, 2013	September 30, 2012
Expected life (years)	5.6 years	6.0 years
Interest rate	1.4%	2.3%
Dividend yield		
Volatility	71%	60%

Note 14 Subsequent Events

On October 1, 2013, the Company completed an underwritten public offering of 11,000,000 shares of common stock at a public offering price of $4.10 per share. The net proceeds to the Company, after underwriting discounts and commissions and estimated offering expenses, were approximately $42.4 million.

On October 9, 2013, the underwriters for the public offering of common stock partially exercised their over-allotment option to purchase an additional 1,311,698 shares of common stock at a public offering price of $4.10 per share. The partial exercise of the over-allotment option increases the aggregate net proceeds to the company, after underwriting discounts and commissions and estimated offering expenses, from approximately $42.4 million to approximately $47.4 million.

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

This report contains certain forward-looking statements relating to Fibrocell that are based on management s exercise of business judgment and assumptions made by and information currently available to management. When used in this document, the words anticipate, believe, estimate, expect, intend, the facts suggest and words of similar impo intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements. Several of these factors include, without limitation:

whether our clinical human trials relating to the use of autologous cellular therapy applications, in particular, for burn scars and vocal cord scars, and such other indications as we may identify and pursue can be conducted within the timeframe that we expect, whether such trials will yield positive results, or whether additional applications for the commercialization of autologous cellular therapy can be identified by us and advanced into human clinical trials;

our ability to meet requisite regulations or receive regulatory approvals in the United States, and our ability to retain any regulatory approvals that we may obtain; and the absence of adverse regulatory developments in the United States;

whether our collaboration with Intrexon Corporation can be advanced with positive results within the timeframe and budget that we expect;

our ability to increase our manufacturing capacity and reduce our manufacturing costs through the improvement of our manufacturing process, our ability to validate any such improvements with the relevant regulatory agencies and our ability to accomplish the foregoing on a timely basis, if at all;

the effect on us from adverse publicity related to our products or the company itself;

new entrance of competitive products or further penetration of existing products in our markets;

any adverse claims relating to our intellectual property; and

our dependence on physicians to correctly follow our established protocols for the safe administration of our product.

These factors are not necessarily all of the important factors that could cause actual results of operations to differ materially from those expressed in these forward-looking statements. Other unknown or unpredictable factors also could have material adverse effects on our future results. We cannot assure you that projected results will be achieved.

General

We are an autologous cell therapy company primarily focused on developing first-in-class treatments for skin diseases and conditions, particularly those with high unmet medical needs. Based on our proprietary autologous fibroblast technology, we are pursuing breakthrough medical applications of azficel-T for restrictive burn scarring and vocal cord scarring. Our collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology, includes using genetically-modified fibroblasts for treating orphan skin diseases for which there are no currently approved products and exploring the localized treatment of the most common autoimmune skin disease, moderate-to-severe psoriasis. Our collaboration with UCLA and MIT focusing on skin-derived stem cells and more efficient ways to convert skin cells to other cell types holds potential for future discovery and development of autologous cellular therapeutics.

Critical Accounting Policies and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make significant judgments and estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management bases these significant judgments and estimates on historical experience and other assumptions it believes to be reasonable based upon information presently available. Actual results could differ from those estimates under different assumptions, judgments or conditions. There were no material changes to our critical accounting policies and use of estimates previously disclosed in our 2012 Annual Report on Form 10-K.

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Results of Operations

Three Months Ended September 30, 2013 compared to the Three Months Ended September 30, 2012

Revenue and Cost of Sales. Revenue and cost of sales for the three months ended September 30, 2013 and 2012 were comprised of the following:

	Three months ended September 30,		Increase (Decrease)	
	2013	2012	$000s	%
	(in thousands)			
Total revenue	$ 68	$ 69	$ (1)	(1)%
Cost of sales	1,930	2,321	(391)	(17)%
Gross loss	$ (1,862)	$ (2,252)	$ 390	(17)%

Revenue of less than $0.1 million was recognized for the three months ended September 30, 2013 for LAVIV. Revenue is booked based on the shipment of cells to the patients for injection of LAVIV. We booked cost of sales of $1.9 million for the three months ended September 30, 2013. Cost of sales primarily includes the costs related to the processing of cells for LAVIV, including direct and indirect costs. The cost of sales for the three months ended September 30, 2013 comprised $0.7 million of compensation related expenses, $0.8 million of laboratory supplies and other related expenses and $0.4 million of rent, utilities, amortization and depreciation. The cost of sales for the three months ended September 30, 2012 comprised $1.0 million of compensation related expenses, $0.9 million of laboratory supplies and other related expenses and $0.4 million of rent, utilities, amortization and depreciation. The principal reasons for the relatively small level of revenue as compared to the large cost of sales in this quarter are as follows: (1) Charging for biopsies and injections we are offering complimentary and reduced price biopsies and injections, and (2) Manufacturing complexity and quality control and assurance manufacturing for our cell therapy products is characterized by significant manual processing, autologous raw materials inconsistencies, logistical challenges, and significant quality control and assurance requirements. We significantly increased the selling price of LAVIV on May 1, 2013 in order to more closely align product pricing with our cost structure and our limited manufacturing capacity in 2013. We will have limited manufacturing capacity for the foreseeable future, with our available capacity addressing both commercial sales of LAVIV and our clinical research programs. As a result, we will not be generating significant revenue from the sales of LAVIV. We also believe that cost of sales will remain significantly higher than revenue for the foreseeable future and, thus, we anticipate the company will continue to report gross losses from sales of LAVIV for the aesthetic indication for the foreseeable future.

Selling, General and Administrative Expense. Selling, general and administrative expense for the three months ended September 30, 2013 and 2012 were comprised of the following:

	Three months ended September 30,		Increase (Decrease)	
	2013	2012	$000s	%
	(in thousands)			

Compensation and related expense	$ 1,277	$ 1,061	$ 216	20%
Severance	170		170	
External services consulting	58	33	25	76%
Legal expense	114	159	(45)	(28)%
Marketing expense	2	224	(222)	(99)%
Travel	65	105	(40)	(38)%
License fees	173	166	7	4%
Facilities and related expense and other	1,043	884	159	18%
Total selling, general and administrative expense	$ 2,902	$ 2,632	$ 270	10%

Selling, general and administrative expense increased $0.3 million to $2.9 million for the three months ended September 30, 2013 as compared to $2.6 million for the three months ended September 30, 2012. There was an increase in compensation expense of $0.2 million due primarily to stock options granted in the third quarter of 2013, offset by the reduction of sales and marketing personnel. There was an increase in severance of $0.2 million. There was a decrease in marketing and travel expenses of $0.3 million as there was increased spending for the initial launch for the three months ended September 30, 2012 as compared to the three months ended September 30, 2013. License fees remained constant at $0.2 million for the three months ended September 30, 2013 and 2012. Facilities and other expenses increased $0.2 million.

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Research and Development Expense. Research and development expense for the three months ended September 30, 2013 and 2012 were comprised of the following:

	Three months ended September 30,		Increase (Decrease)	
	2013	2012	$000s	%
	(in thousands)			
Compensation and related expense	$ 70	$ 77	$ (7)	(9)%
External services consulting	8,280	291	7,989	2,745%
Lab costs and related expense	3	58	(55)	(95)%
Facilities and related expense and other	4		4	
Total research and development expense	$ 8,357	$ 426	$ 7,931	1,862%

Research and development expense increased $7.9 million to $8.4 million for the three months ended September 30, 2013 from $0.4 million for the three months ended September 30, 2012. The increase is due primarily to the increase in consulting fees related to research and development costs incurred in the three months ended September 30, 2013 in connection with our collaboration with Intrexon Corporation. We recorded a fair value of $6.4 million for the shares issued for the Supplemental Stock Issuance Agreement with Intrexon and $1.4 million for reimbursement of work performed by Intrexon for the three months ended September 30, 2013. We expect research and development costs to continue to be significant for the foreseeable future as a result of our clinical trials and our collaboration with Intrexon Corporation.

Change in Revaluation of Warrant Liability. During the three months ended September 30, 2013 and 2012, we recorded non-cash warrant income of $0.2 million and $14.5 million in our statements of operations, respectively. In the fourth quarter of 2012, more than 98% of the warrants were reclassified to the equity section due to the modification of the warrants as a result of the October 2012 financing.

Change in Revaluation of Derivative Liability. During the three months ended September 30, 2013, there was no revaluation of the derivative liability as our previously outstanding preferred stock was converted to common stock in the fourth quarter of 2012 and the related derivative liability was reclassified to shareholders deficit as it no longer required the liability classification. During the three months ended September 30, 2012, we recorded non-cash derivative revaluation income of $1.9 million in our statements of operations.

Interest Expense. There was no interest expense for the three months ended September 30, 2013, compared to $0.1 million for the three months ended September 30, 2012. The 12.5% notes were either paid or converted into common stock with the close of the October 2012 financing.

Loss from Discontinued Operations. The net loss from discontinued operations for the three months ended September 30, 2013 remained relatively constant to the net income from discontinued operations for the three months ended September 30, 2012.

Net Loss. Net loss for the three months ended September 30, 2013 of $12.9 million, as compared to net income for the comparable three-month period in the prior year of $11.4 million, represented a change of approximately $24.3 million. The change is primarily due to the changes in warrant and derivative revaluation as more fully described

above, as well as the extinguishment of debt in the three months ended September 30, 2012, offset by the increase in selling, general and administrative expenses and research and development expenses.

Nine Months Ended September 30, 2013 compared to the Nine Months Ended September 30, 2012

Revenue and Cost of Sales. Revenue and cost of sales for the nine months ended September 30, 2013 and 2012 were comprised of the following:

	Nine months ended September 30,		Increase (Decrease)	
	2013	2012	$000s	%
	(in thousands)			
Total revenue	$ 156	$ 113	$ 43	38%
Cost of sales	6,523	5,968	555	9%
Gross loss	$ (6,367)	$ (5,855)	$ (512)	9%

Revenue of less than $0.2 million was recognized for the nine months ended September 30, 2013 for LAVIV. Revenue is booked based on the shipment of cells to the patients for injection of LAVIV. We booked cost of sales of $6.5 million for the nine

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months ended September 30, 2013. Cost of sales includes the costs related to the processing of cells for LAVIV, including direct and indirect costs. The cost of sales for the nine months ended September 30, 2013 comprised $2.8 million of compensation related expenses, $2.5 million of laboratory supplies and other related expenses and $1.2 million of rent, utilities, amortization and depreciation. The cost of sales for the nine months ended September 30, 2012 comprised $2.8 million of compensation related expenses, $2.1 million of laboratory supplies and other related expenses and $1.1 million of rent, utilities, amortization and depreciation. The principal reasons for the relatively small level of revenue as compared to the large cost of sales in these quarters are as follows: (1) Charging for biopsies and injections we are offering complimentary and reduced price biopsies and injections, and (2) Manufacturing complexity and quality control and assurance manufacturing for our cell therapy products is characterized by significant manual processing, autologous raw materials inconsistencies, logistical challenges, and significant quality control and assurance requirements. We significantly increased the selling price of LAVIV on May 1, 2013 in order to more closely align product pricing with our cost structure and our limited manufacturing capacity in 2013. We will have limited manufacturing capacity for the foreseeable future, with our available capacity addressing both commercial sales of LAVIV and our clinical research programs. As a result, we will not be generating significant revenue from the sales of LAVIV. We also believe that cost of sales will remain significantly higher than revenue for the foreseeable future and, thus, we anticipate the company will continue to report gross losses from sales of LAVIV for the aesthetic indication for the foreseeable future.

Selling, General and Administrative Expense. Selling, general and administrative expense for the nine months ended September 30, 2013 and 2012 were comprised of the following:

	Nine months ended September 30,		Increase (Decrease)	
	2013	2012	$000s	%
	(in thousands)			
Compensation and related expense	$ 2,893	$ 3,229	$ (336)	(10)%
Severance	170		170	
External services consulting	113	351	(238)	(68)%
Legal expense	517	381	136	36%
Marketing expense	290	2,078	(1,788)	(86)%
Travel	240	443	(203)	(46)%
License fees	516	499	17	3%
Facilities and related expense and other	2,980	2,613	367	14%
Total selling, general and administrative expense	$ 7,719	$ 9,594	$ (1,875)	(20)%

Selling, general and administrative expense decreased $1.9 million to $7.7 million for the nine months ended September 30, 2013 as compared to $9.6 million for the nine months ended September 30, 2012. There was a decrease in compensation expense of $0.3 million due primarily to the reduction of sales and marketing personnel employed for the nine months ended September 30, 2013, offset by the grant of stock options. There was a decrease in marketing expenses of $1.8 million as there was increased spending for the initial launch for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2013. License fees remained constant at $0.5 million for the nine months ended September 30, 2013 and 2012. Facilities and other expenses increased $0.3 million.

Research and Development Expense. Research and development expense for the nine months ended September 30, 2013 and 2012 were comprised of the following:

	Nine months ended September 30,			
	2013	2012	$000s	%
	(in thousands)			
Compensation and related expense	$ 198	$ 247	$ (49)	(20)%
External services consulting	10,305	946	9,359	989%
Lab costs and related expense	239	92	147	160%
Facilities and related expense and other	11	9	2	22%
Total research and development expense	$ 10,753	$ 1,294	$ 9,459	731%

Research and development expense increased $9.5 million to $10.8 million for the nine months ended September 30, 2013 from $1.3 million for the nine months ended September 30, 2012. The increase is due primarily to the increase in consulting fees related to research and development costs incurred in the nine months ended September 30, 2013 in connection with our collaboration with Intrexon Corporation. We recorded a fair value of $6.4 million for the shares issued for the Supplemental Stock Issuance Agreement with Intrexon and $2.4 million for reimbursement of work performed by Intrexon for the nine months ended September 30, 2013. We expect research and development costs to continue to be significant for the foreseeable future as a result of our clinical trials and our collaboration with Intrexon Corporation.

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Change in Revaluation of Warrant Liability. During the nine months ended September 30, 2013 and 2012, we recorded non-cash warrant expense of $0.1 million and non-cash warrant income of $17.2 million in our statements of operations. In the fourth quarter of 2012, more than 98% of the warrants were reclassified to the equity section due to the modification of the warrants as a result of the October 2012 financing.

Change in Revaluation of Derivative Liability. During the nine months ended September 30, 2013, there was no revaluation of the derivative liability as our previously outstanding preferred stock was converted to common stock in the fourth quarter of 2012 and the related derivative liability was reclassified to shareholders deficit as it no longer required the liability classification. During the nine months ended September 30, 2012, we recorded non-cash derivative revaluation expense of less than $0.1 million in our statements of operations.

Interest Expense. There was no interest expense for the nine months ended September 30, 2013, compared to $0.6 million for the nine months ended September 30, 2012. The 12.5% notes were either paid or converted into common stock with the close of the October 2012 financing.

Loss on Extinguishment of debt. During the nine months ended September 30, 2012, the Company recorded a loss on extinguishment of the 12.5% Promissory Notes of $4.4 million in the consolidated statement of operations due to a significant modification of the original debt. The details of the loss included recording the fair value of the embedded conversion option of $1.2 million and the fair value of liability-classified warrants of $3.2 million.

Deferred tax benefit. During the nine months ended September 30, 2012, we recorded a deferred tax benefit of $2.5 million due to the favorable impact to the computation of the valuation allowance recorded against our net deferred tax asset as a result of the reclassification of the intangible assets recognized upon emergence from bankruptcy as a finite-lived intangible asset. The restatement freed-up the related deferred tax liability by allowing it to offset our net deferred tax asset before applying the valuation allowance.

Loss from Discontinued Operations. The net loss from discontinued operations for the nine months ended September 30, 2013 remained relatively constant to the net loss for the nine months ended September 30, 2012.

Net Loss. Net loss for the nine months ended September 30, 2013 of $25.0 million, as compared to a net loss for the comparable nine-month period in the prior year of $1.7 million represented a change of approximately $23.3 million. The change is primarily due to the changes in the warrant and derivative revaluations as more fully described above, as well as the extinguishment of debt in the nine months ended September 30, 2012. In addition, the deferred tax benefit was realized in the nine months ending September 30, 2012, offset by an increase in cost of goods sold and an increase in research and development expenses for the nine months ending September 30, 2013.

Liquidity and Capital Resources

The following table summarizes our cash flows from operating, investing and financing activities for the nine months ended September 30, 2013 and 2012:

Statement of Cash Flows Data:	**Nine months Ended September 30,**	
	2013	**2012**
	(in thousands)	
Cash used in operating activities	$ (16,039)	$ (15,257)
Cash (used) provided in investing activities	$ (162)	$ 529

Cash provided in financing activities	$ 1,730	$ 4,047

Operating Activities. Cash used in operating activities during the nine months ended September 30, 2013 amounted to $16.0 million, an increase of $1.0 million over the nine months ended September 30, 2012. The increase in our cash used in operating activities over the prior year is primarily due to an increase in net losses (adjusted for non-cash items) of approximately $1.0 million.

Investing Activities. Cash used in investing activities amounted to $0.2 million for the nine months ended September 30, 2013, due to the purchase of equipment for the lab facility in Exton, Pennsylvania. Cash provided in investing activities amounted to $0.5 million for the nine months ended September 30, 2012 due to the purchase of equipment for the lab facility in Exton, Pennsylvania, offset by funds received for the sale of Agera.

Financing Activities. Cash provided in financing activities amounted to $1.7 million due to a subscription receivable of $2.0 million received during the nine months ended September 30, 2013, offset by deferred equity costs of $0.3 million related to the financing that closed in October 2013. There was $4.0 million net cash received from financing activities during the nine months ended September 30, 2012 mainly due to the issuance of Series E Preferred Stock of $7.9 million, net of fees, offset by a debt repayment of $3.6 million and $0.3 for dividend payments and fees.

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Working Capital

As of September 30, 2013, we had cash and cash equivalents of $16.9 million and working capital of $16.6 million. In October 2013, we raised net proceeds of $47.4 million from an equity financing transaction. This, in addition to the September 30, 2013 cash position, is estimated to be sufficient capital to fund our operations into 2015. We expect we will require additional financing prior to our business achieving significant net cash from operations. We would likely raise such additional capital through the issuance of our equity securities, which may result in dilution to our investors, or by entering into strategic partnerships. Our ability to raise additional capital is dependent on, among other things, the state of the financial markets at the time of any proposed offering. To secure funding through strategic partnerships, it may be necessary to partner one or more of our technologies at an earlier stage of development, which could cause us to share a greater portion of the potential future economic value of those programs with our partners. There is no assurance that additional funding, through any of the aforementioned means, will be available on acceptable terms, or at all. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our operations could be materially negatively impacted.

Contractual Obligations

During the nine month period ended September 30, 2013, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our Annual Report on Form 10-K for the year ended December 31, 2012.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange rates or interest rates.

Foreign Exchange Rate Risk

We do not believe that we have significant foreign exchange rate risk at September 30, 2013.

We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures and Changes in Internal Control over Financial Reporting

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this report. Based on our evaluation under the framework in *Internal Control Integrated Framework*, management concluded that our internal control over financial reporting was ineffective as of September 30, 2013 due to the accounting for the deferred tax liability in 2012 as discussed in more detail below.

Except as described in Item 9A in our Annual Report on Form 10-K for the year ended December 31, 2012, and discussed below, there was no change in our internal control over financial reporting that occurred during 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Material Weakness

When we emerged from bankruptcy in September 2009, an intangible asset was recorded in respect of our primary clinical study on LAVIV, and the related deferred tax liability was also recorded. In the first quarter of 2012, we commercially launched LAVIV and commenced generating revenue. As a result, the intangible asset was considered a finite-lived intangible asset and we commenced amortizing it over 12 years, and also initiated the amortization of the related deferred tax liability over the same period. In connection with the finalization of our audit for the year ended December 31, 2012, it came to our attention that the accounting treatment adopted for the deferred tax liability related to the intangible asset in the first quarter of 2012 and for the subsequent second and third quarters of 2012 was incorrect. Rather than the deferred tax liability being a permanent timing difference for the calculation of deferred tax, we concluded that it would have been more appropriately treated as a temporary timing difference. The impact of this adjustment is that the full deferred tax liability of $2.5 million should have been released to the Consolidated Statement of Operations in the first quarter of 2012.

As a result of this adjustment, it was determined that a control deficiency that constitutes a material deficiency in the design and operation of our internal control over financial reporting in connection with deferred tax liability relating to the intangible asset was present.

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We are taking the steps necessary to fully remediate this material weakness condition, including having retained the services of an independent public accounting firm with the appropriate experience and technical accounting skills required to assure that we are receiving the support necessary to avoid any future weaknesses in our internal controls over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 1A. Risk Factors

On September 25, 2013, the Company filed with the Securities and Exchange Commission a preliminary prospectus supplement to its effective shelf registration statement on Form S-3 (the Preliminary Prospectus Supplement) pursuant to Rule 424 under the Securities Act of 1933, as amended, relating to a public offering of shares of the Company s common stock, which was completed in October 2013. The Preliminary Prospectus Supplement contained certain revised risk disclosures from the risk factors previously disclosed in the Annual Report on Form 10-K filed on April 1, 2013, which are set forth below.

In order to potentially increase our revenue from the sale of LAVIV or commercialize any future product candidates, we will need to increase our manufacturing capacity and improve our manufacturing capabilities, which will require significant expenditures and regulatory approval.

We currently have limited manufacturing capacity and we have had limited manufacturing experience with LAVIV, our Autologous Crème product and our other product candidates. In addition, our current manufacturing process is primarily a manual process. To potentially increase our revenue from the sale of LAVIV and our Autologous Crème product, and to commercialize any future product candidates, we will need to add manufacturing capacity. We also are developing enhancements and alternatives to our current manual manufacturing process. If we have difficulties in increasing our manufacturing capacity and improving our capabilities, we will be limited in our ability to potentially increase our revenue from LAVIV, our Autologous Crème product, as well as any new product candidates, if they are approved for marketing; and we may not be able to decrease our manufacturing costs. These difficulties could adversely affect our financial performance and damage our reputation. Even if we are successful in developing such enhancements or finding alternatives to our current process, such manufacturing changes will require additional expenditures, for which we may be required to seek external financing. In addition, our ability to increase our manufacturing capacity or modify our manufacturing processes will be subject to additional FDA review and approval.

Our research, development and manufacturing operations depend on one facility. If such facility is destroyed or is out of operation for a substantial period of time, our business will be adversely impacted.

We currently conduct all our research, development and manufacturing operations in one facility located in Exton, Pennsylvania. As a result, all of the commercial manufacturing of LAVIV and our Autologous Crème product for the U.S. market takes place at a single U.S. facility. In addition, the clinical trials for our product candidates depend upon the manufacturing of such product candidates in the same facility. If regulatory, manufacturing or other problems require us to discontinue production at that facility, we will not be able to supply our product to our customers or have

supplies for our clinical trials, which would adversely impact our business. If this facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before any products manufactured at that facility could be sold or used.

Obtaining FDA and other regulatory approvals is complex, time consuming and expensive, and the outcomes are uncertain.

The process of obtaining FDA and other regulatory approvals is time consuming, expensive and difficult. Clinical trials are required to establish the safety and efficacy of product candidates. Applications to market product candidates must be submitted to the FDA which must be reviewed for approval and approved by the FDA before product candidates may be marketed and clinical trials, manufacturing, and the marketing of products, if approved, are subject to strict regulatory compliance.

The commencement and completion of clinical trials for any of our product candidates could be delayed or prevented by a variety of factors, including:

- delays in obtaining regulatory approvals to commence a study;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

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delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;

delays in the enrollment of subjects;

manufacturing difficulties;

failure of our clinical trials and clinical investigators to be in compliance with the FDA s Good Clinical Practices, or GCP;

failure of our third-party contract research organizations, clinical site organizations or other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines;

lack of efficacy during clinical trials; or

unforeseen safety issues.

We do not know whether our clinical trials will need to be restructured or will be completed on schedule, if at all, or whether they will provide data necessary to support necessary regulatory approval. Significant delays in clinical trials will impede our ability to commercialize our product candidates and generate revenue, and could significantly increase our development costs.

We utilize bovine-sourced materials to manufacture LAVIV, our Autologous Crème product and our product candidates. It is possible that future FDA regulations may require us to change the source of the bovine-sourced materials we use in our products or to cease using bovine-sourced materials. If we are required to use alternative materials in our products, and in the event that such alternative materials are available to us, or if we choose to change the materials used in our products in the future, we would need to validate the new manufacturing process and run comparability trials with the reformulated product, which could delay our submission for regulatory approval of our product candidates and negatively impact the commercialization of LAVIV, our Autologous Crème product and any of our product candidates, if approved.

With respect to LAVIV and any of our product candidates, if marketing approval is received from the FDA, the FDA may impose post-marketing requirements, such as:

labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contraindications or use limitations that could have a material impact on the future profitability of our product candidates;

testing and surveillance to further evaluate or monitor our future products and their continued compliance with regulatory standards and requirements;

submitting products for inspection; or

imposing a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the drug outweigh the risks.

With respect to our LAVIV product, which was approved in June 2011, as part of our label the FDA required us, based on clinical study data, to conduct a post-marketing study of approximately 2,700 patients, which has not yet commenced and must be completed by 2016. This study will assess the risk of skin cancer such as basal cell cancer in the area of LAVIV injections and the risk of immune-mediated hypersensitivity reactions such as leukocytoclasticvasculitis in 2,700 patients who receive LAVIV. We have been in discussions with the FDA on the design of the post-marketing study, as we believe the original study design requested by the FDA will be time-consuming, expensive and difficult to complete. Although we believe we will be able to reach an agreement with the FDA on this post-marketing study, to the extent we are unable to complete an acceptable post-marketing study the FDA may determine to take action against us, including the withdrawal of its approval of LAVIV.

The FDA may determine that our Autologous Crème product is a therapeutic product, which would require us to file a biologics license application with the FDA.

We have developed the Fibrocell Science Autologous Crème, an autologous skin care cream containing personalized growth factors and proteins derived from a person s own fibroblast cells. Our autologous cream leverages the LAVIV manufacturing process to provide a personalized topical cosmetic product consisting of a cream vehicle blended with the conditioned media extract from the cell culture of a customer s own fibroblasts. We intend to market our Autologous Crème product as a cosmetic product and we believe

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the product meets the definition of a cosmetic product. However, due to the uniqueness of our Autologous Crème product, the FDA may determine that the product is a therapeutic product, which would require us to file a biologics license application with the FDA. To the extent the FDA determines that our Autologous Crème is a therapeutic product and requires us to file a biologics license application, we would be unable to sell our Autologous Crème unless and until we receive approval of our application from the FDA, which would be complex, time-consuming and expensive.

Our business may be harmed and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

A third party may assert that we, one of our subsidiaries or one of our strategic collaborators has infringed his, her or its patents and proprietary rights or challenge the validity or enforceability of our patents and proprietary rights. Likewise, we may need to resort to litigation to enforce our patent rights or to determine the scope and validity of a third party s proprietary rights.

We cannot be sure that other parties have not filed for or obtained relevant patents that could affect our ability to obtain patents or operate our business. Even if we have previously filed patent applications or obtain issued patents, others may file their own patent applications for our inventions and technology, or improvements to our inventions and technology. We have become aware of published patents and patent applications, filed after the issuance of our earliest patents that, should the owners seek to enforce one or more claims in such patents against the Company could require us to challenge the validity and enforceability of the asserted claims. In connection with some of those patents, we are aware of a settlement agreement entered into by a predecessor company inventor in 2000 that purports to grant certain rights in those patents, if any, to a third party. We are not aware of any subsequent attempts by such third party to enforce such rights or any other rights relating to inventorship. We are not aware of any patents related to these rights that relate to the Company s current or currently proposed activities, and that we believe are valid and enforceable. There is no assurance that this party will not attempt in the future to enforce rights purportedly granted in 2000. Others may challenge our patent or other intellectual property rights or sue us for infringement. In all such cases, we may commence legal proceedings to resolve our patent or other intellectual property disputes or defend against charges of infringement or misappropriation. An adverse determination in any litigation or administrative proceeding to which we may become a party could subject us to significant liabilities, result in our patents being deemed invalid, unenforceable or revoked, or drawn into an interference, require us to license disputed rights from others, if available, or to cease using the disputed technology. In addition, our involvement in any of these proceedings may cause us to incur substantial costs and result in diversion of management and technical personnel. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us.

The outcome of these proceedings is uncertain and could significantly harm our business. If we do not prevail in this type of litigation, we or our strategic collaborators may be required to:

- pay monetary damages;
- expend time and funding to redesign our product and/or product candidates so that it does not infringe others patents while still allowing us to compete in the market with a substantially similar product;

obtain a license, if possible, in order to continue manufacturing or marketing the affected products or services, and pay license fees and royalties, which may be non-exclusive. This license may be non-exclusive, giving our competitors access to the same intellectual property, or the patent owner may require that we grant a cross-license to our patented technology; or

stop research and commercial activities relating to the affected products or services if a license is not available on acceptable terms, if at all.

Any of these events could materially adversely affect our business strategy and the value of our business.

In addition, the defense and prosecution of intellectual property suits, interferences, oppositions and related legal and administrative proceedings in the United States and elsewhere, even if resolved in our favor, could be expensive and time consuming and could divert financial and managerial resources. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater financial resources.

If we are unable to adequately protect our intellectual property and proprietary technology, the value of our technology and future products will be adversely affected, and if we are unable to enforce our intellectual property against unauthorized use by third parties our business may be materially harmed.

Our long-term success largely depends on our future ability to market technologically competitive products. Our ability to achieve commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technology and future products, as well as successfully defending these patents against third party challenges. In order to do so we must:

obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;

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operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

As of September 10, 2013, we had 12 issued U.S. patents, 7 pending U.S. patent applications, 2 pending international patents, 28 granted foreign patents and 14 pending foreign patent applications. However, we may not be able to obtain additional patents relating to our technology or otherwise protect our proprietary rights. If we fail to obtain or maintain patents from our pending and future applications, we may not be able to prevent third parties from using our proprietary technology. We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents that we control or are effectively maintained by us as trade secrets. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage.

The patent situation of companies in the markets in which we compete is highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies patents has emerged to date in the United States. The laws of other countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of our patents in foreign countries in which we hold patents. Proceedings to enforce our patent rights in the United States or in foreign jurisdictions would likely result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

Other risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

the inventors of the inventions covered by each of our patents and pending patent applications might not have been the first to make such inventions;

we might not have been the first to file patent applications for these inventions or similar technology;

the future and pending applications we will file or have filed, or to which we will or do have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection;

our issued patents may not provide a basis for commercially viable products or may not be valid or enforceable;

we might not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us may not provide a competitive advantage;

patents issued to other individuals, companies, universities or research institutions may harm our ability to do business;

other individuals, companies, universities or research institutions may independently develop or have developed similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;

other individuals, companies, universities or research institutions may design around technologies we have licensed, patented or developed; and

many of our patent claims are method, rather than composition of matter, claims; generally composition of matter claims are easier to enforce and are more difficult to circumvent.

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The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock began trading on NYSE MKT on May 17, 2013. Between that date and September 20, 2013, our common stock has traded between $4.50 and $7.20. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether our clinical human trials relating to the use of autologous cellular therapy applications, in particular, for burn scars and vocal cord scars, and such other indications as we may identify and pursue can be conducted within the timeframe that we expect, whether such trials will yield positive results, or whether additional applications for the commercialization of autologous cellular therapy can be identified by us and advanced into human clinical trials;

- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;

- unanticipated serious safety concerns related to the use of our products or product candidates;

- a decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

- our ability to increase our manufacturing capacity and reduce our manufacturing costs through the improvement of our manufacturing process, our ability to validate any such improvements with the relevant regulatory agencies and our ability to accomplish the foregoing on a timely basis, if at all;

- whether our collaboration with Intrexon Corporation can be advanced with positive results within the timeframe and budget that we expect;

- adverse regulatory decisions;

- the introduction of new products or technologies offered by us or our competitors;

- the inability to effectively manage our growth;

- actual or anticipated variations in quarterly operating results;

the failure to meet or exceed the estimates and projections of the investment community;

the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

the overall performance of the U.S. equity markets and general political and economic conditions;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

additions or departures of key personnel;

the trading volume of our common stock; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On June 28, 2013, the Company and Intrexon Corporation (Intrexon) entered into a First Amendment (Amendment) to the parties Exclusive Channel Collaboration Agreement (the Channel Agreement) dated October 5, 2012. In connection with the execution of the Amendment, on June 28, 2013, the Company entered into a Supplemental Stock Issuance Agreement with Intrexon pursuant to which the Company agreed to issue to Intrexon a number of shares of Company common stock valued at $7.5 million based on a per share value of $6.03 per share, which was the closing price of the Company s common stock on the NYSE MKT on the day prior to execution of the Supplemental Stock Issuance Agreement. The closing occurred on July 26, 2013, with the issuance of

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1,243,781 shares to Intrexon. The shares were issued in a transaction exempt from registration under the Securities Act of 1933, as amended (the Securities Act), in reliance on Section 4(2) thereof. Intrexon represented that it was an accredited investor as defined in Regulation D of the Securities Act.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosure

Not Applicable

Item 5. Other Information

None

Item 6. Exhibits

(a) Exhibits

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
3.1	Restated Certificate of Incorporation filed December 12, 2012 (incorporated by reference to exhibit 3.1 of the Form 8-K filed on December 13, 2012)
3.2	Certificate of Amendment of the Restated Certificate of Incorporation filed April 26, 2013 (incorporated by reference to exhibit 3.1 of the Form 8-K filed on April 29, 2013)
3.3	Certificate of Amendment to the Company s Restated Certificate of Incorporation, as amended, filed July 19, 2013 (incorporated by reference to exhibit 3.1 of the Form 8-K filed on July 22, 2013)
10.1	Massachusetts Institute of Technology Office of Sponsored Programs Research Agreement (1)
10.2	The Regents of the University of California Research Agreement
10.3	Employment Agreement between the Company and Gregory Weaver dated August 26, 2013 (incorporated by reference to exhibit 10.1 of the Form 8-K filed on August 26, 2013)
10.4	Stock Option Agreement between the Company and Gregory Weaver issued pursuant to Employment Agreement between the Company and Gregory Weaver dated August 26, 2013 *
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.

* Indicates management contract or compensatory plan or arrangement.

(1) Confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

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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/ Gregory Weaver
Gregory Weaver
Chief Financial Officer

Date: November 14, 2013