Fibrocell Science, Inc.
Form 10-Q
November 14, 2018

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, 2018
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 every Interactive Data File required to be submitted 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 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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o
Non-accelerated filer ý	Smaller reporting company ý
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

As of November 7, 2018, there were 9,314,982 outstanding shares of the registrant's common stock, par value $0.001.

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Fibrocell Science, Inc.

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

Trademark Notice

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EXPLANATORY NOTE

The information contained in "Item 1 - Financial Statements" of this Form 10-Q gives retroactive effect to a one-for-five reverse stock split of our issued and outstanding shares of common stock effected on May 24, 2018. See Note 1 of the Notes to Condensed Consolidated Financial Statements for further information.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our review of strategic alternatives, including the possible sale or merger of the Company;
- our expectation that our existing cash resources will be sufficient to enable us to fund our operations into the fourth quarter of 2019;
- future expenses and capital expenditures;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our plans to address our future capital requirements and the consequences of failing to do so;
- our need to raise substantial additional capital to fund our operations;
- our plans to report interim data from patients from the Phase 2 portion of our Phase 1/2 clinical trial for FCX-007 and provide a trial update in the first quarter of 2019;
- our plans to use data from the Phase 1/2 clinical trial of FCX-007 to support a petition for Regenerative Medicine Advanced Therapy or Breakthrough Therapy Designation for FCX-007;
- our plans to submit a Phase 3 clinical trial protocol for FCX-007 to the United States Food and Drug Administration (FDA) in the fourth quarter of 2018 while continuing to collect additional data from the Phase 2 portion of the Phase 1/2 clinical trial of FCX-007;
- our plans to initiate a Phase 3 clinical trial for FCX-007 in the first half of 2019;
- our product development goals under our collaborations with Precigen, Inc., a wholly owned subsidiary of Intrexon Corporation, for our product candidates;
- the potential benefits of Fast Track, Orphan Drug and Rare Pediatric Disease designations;
- the potential advantages of our product candidates and technologies; and
- the effect of legal and regulatory developments;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-Q entitled "Item 1—Financial Statements," and "Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations." In some cases, you can identify forward-looking statements by words such as "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "c "scheduled" and similar expressions, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based upon current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-Q, our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the 2017 Form 10-K), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018 (the 2018 Q1 Form

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10Q), our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 (the 2018 Q2 Form 10Q), and in particular, the risks and uncertainties discussed under the caption "Item 1A—Risk Factors" of our 2017 Form 10-K, our 2018 Q1 Form 10Q and our 2018 Q2 Form 10Q. As a result, you should not place undue reliance on forward-looking statements.

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

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-Q. For all forward-looking statements, we claim protection of the safe harbor for the forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,111	$ 17,417
Prepaid expenses and other current assets	294	485
Total current assets	16,405	17,902
Property and equipment, net of accumulated depreciation of $2,221 and $1,919, respectively	1,295	1,470
Other assets	1	39
Total assets	$ 17,701	$ 19,411
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 782	$ 862
Related party payable	63	2,303
Accrued expenses	966	1,260
Total current liabilities	1,811	4,425
Convertible promissory notes, net of debt discount of $18,003 and $18,003, respectively (see Note 4)	—	—
Accrued interest payable	1,542	967
Warrant liability	482	1,073
Derivative liability	2,870	3,136
Deferred rent	812	803
Total liabilities	7,517	10,404
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized:		
Series A nonredeemable convertible preferred stock; 8,000 shares designated, 8,000 shares issued and outstanding as of September 30, 2018 and December 31, 2017 respectively; aggregate liquidation preference of $8,514 at September 30, 2018	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized, 9,314,982 and 5,189,755 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	9	5
Additional paid-in capital	197,632	187,805
Accumulated deficit	(187,457)	(178,803)
Total stockholders' equity	10,184	9,007
Total liabilities and stockholders' equity	$ 17,701	$ 19,411

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Total revenues	$—	$ —	$—	$—
Total cost of revenue	—	—	—	—
Gross profit (loss)	—	—	—	—
Research and development expense	1,541	1,657	4,601	4,800
Research and development expense - related party (see Note 8)	63	981	(134)	4,168
Selling, general and administrative expense	1,501	1,958	4,696	5,109
Operating loss	(3,105)	(4,596)	(9,163)	(14,077)
Other income (expense):				
Warrant revaluation income (expense)	265	4,981	591	(4,742)
Derivative revaluation income (expense)	87	(254)	266	287
Interest expense	(194)	(273)	(575)	(641)
Other income, net	88	27	227	33
Loss before income taxes	(2,859)	(115)	(8,654)	(19,140)
Income taxes	—	—	—	—
Net loss	(2,859)	(115)	(8,654)	(19,140)
Dividend paid in-kind to preferred stockholders	(85)	(82)	(250)	(182)
Deemed dividend on preferred stock (see Note 10)	(130)	(111)	(377)	(3,981)
Net loss attributable to common stockholders	$(3,074)	$ (308)	$(9,281)	$(23,303)
Per Share Information:				
Net loss:				
Basic	$(0.33)	$ (0.10)	$(1.31)	$(7.92)
Diluted	$(0.33)	$ (0.12)	$(1.31)	$(7.92)
Weighted average number of common shares outstanding:				
Basic	9,234,869	2,945,035	7,107,678	2,942,202
Diluted	9,234,869	2,948,290	7,107,678	2,942,202

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

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

	Series A Convertible Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Total Equity
	Shares	Amount	Shares	Amount			
Balance, December 31, 2017	8,000	$ —	5,189,755	5	$ 187,805	$ (178,803)	$ 9,007
Conversion of pre-funded warrants	—	—	483,221	1	23	—	24
Stock-based compensation expense	—	—	—	—	393	—	393
May 2018 Registered Direct Offering, net of offering costs of $676	—	—	2,038,224	2	5,322	—	5,324
July 2018 Registered Direct Offering, net of offering costs of $494	—	—	1,474,080	1	3,590	—	3,591
Exercise of warrants	—	—	129,702	—	499	—	499
Net loss	—	—	—	—	—	(8,654)	(8,654)
Balance, September 30, 2018	8,000	$ —	9,314,982	$ 9	$ 197,632	$ (187,457)	$ 10,184

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

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

	Nine months ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(8,654)	$(19,140)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	393	194
Warrant revaluation expense (income)	(591)	4,742
Derivative revaluation income	(266)	(287)
Depreciation and amortization of long lived assets	302	282
Amortization of debt discount	—	86
Loss on disposal or impairment of property and equipment	—	40
Decrease (increase) in operating assets:		
Prepaid expenses and other current assets	191	248
Other assets	38	4
Increase (decrease) in operating liabilities:		
Accounts payable	258	132
Related party payable	(2,240)	789
Accrued expenses and deferred rent	(223)	(524)
Accrued interest payable	575	555
Net cash used in operating activities	(10,217)	(12,879)
Cash flows from investing activities:		
Purchase of property and equipment	(155)	(348)
Net cash used in investing activities	(155)	(348)
Cash flows from financing activities:		
Proceeds from 2017 Series A Preferred Stock Offering, (net of offering costs of $377)	—	7,623
Payment of deferred offering costs	(444)	—
Proceeds from conversion of pre-funded warrants	24	—
Proceeds from conversion of common warrants	499	—
Proceeds from May 2018 Registered Direct Offering, (net of offering costs of $640)	5,360	—
Proceeds from July 2018 Registered Direct Offering, (net of offering costs of $458)	3,627	—
Net cash provided by financing activities	9,066	7,623
Effect of exchange rate changes on cash balances	—	—
Net increase (decrease) in cash and cash equivalents	(1,306)	(5,604)
Cash and cash equivalents, beginning of period	17,417	17,515
Cash and cash equivalents, end of period	$16,111	$11,911
Supplemental disclosures of cash flow information:		
Non-cash investing and financing activities:		
Property and equipment in accounts payable	$—	$29
Offering costs in accounts payable and accrued expenses	$72	$—
Reduction of warrant liability upon cashless exercise of warrants	$—	$41
Reduction in accrued interest payable upon cashless exercise of promissory notes	$—	$3
Reduction in derivative liability upon cashless exercise of promissory notes	$—	$6
Cashless exercise of promissory notes	$—	$85
Dividend paid in-kind to preferred stockholders	$250	$182

Deemed dividend on preferred stock	$377	$3,981

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

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Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1. Business and Organization

Organization

Fibrocell Science, Inc. (as used herein, "we," "us," "our," "Fibrocell" or the "Company") is the parent company of Fibrocell Technologies, Inc. (Fibrocell Tech). Fibrocell Tech is the parent company of Isolagen International, S.A., a company organized under the laws of Switzerland (Isolagen Switzerland). The Company's international activities are currently immaterial.

Business Overview

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

On April 18, 2018, the Company announced that its Board of Directors (the Board) would begin conducting a comprehensive review of strategic alternatives focused on maximizing stockholder value and had engaged Canaccord Genuity LLC as its strategic financial advisor to assist with the review process. The Board has established a Special Committee to explore and evaluate potential strategic alternatives which may include a sale of the Company, a business combination, a merger or reverse merger with another company, a strategic investment into the Company, a sale, license or other disposition of corporate assets of the Company or continuing with the current business plan. The Company has not set a timetable for completion of the review process. No decision has been made as to whether the Company will engage in a transaction or transactions, and there can be no assurance that this process will result in any transaction, or the terms or timing of any potential transaction.

Liquidity and Financial Condition

The Company expects to continue to incur losses and will require additional capital to advance its product candidates through development to commercialization. For the nine month period ended September 30, 2018 the Company incurred a net loss of approximately $8.7 million and used approximately $10.2 million in cash for operations. As of September 30, 2018, the Company had cash and cash equivalents of approximately $16.1 million, working capital of approximately $14.6 million and an accumulated deficit of approximately $187.5 million. The Company believes that its cash and cash equivalents at September 30, 2018 will be sufficient to fund operations into the fourth quarter of 2019. The Company will require additional capital to fund operations beyond that point. To meet its capital needs, the Company intends to raise additional capital through debt or equity financings, collaborations, partnerships or other strategic transactions. However, there can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition. These conditions raise substantial doubt about its ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

On January 23, 2018, the Company received notice (the Notice) from the Nasdaq Stock Market LLC (Nasdaq) that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of the Company's common stock had been below $1.00 per share for 30 consecutive business days. On May 24, 2018, the Company implemented a one-for-five reverse split of its issued and outstanding shares of the Company's common stock (the Reverse Stock Split), as authorized at the annual meeting of stockholders on May 23, 2018. The Reverse Stock Split became effective on May 24, 2018 at 5:00 pm and the Company's common stock began trading on Nasdaq on a post-split basis at the open of business on May 25, 2018. As of a result of the Reverse Stock Split, every five shares of the Company's issued and outstanding common stock were combined into one share of its common stock, except to the extent that the Reverse Stock Split resulted in any of the Company's stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of $0.001. The Reverse Stock Split was

effectuated in order to increase the per share trading price of the Company's common stock to satisfy the $1.00 minimum bid price requirement for continued listing on Nasdaq. On June 11, 2018, the Company received written notice from Nasdaq notifying the Company that the closing bid price of the Company's common stock had been at $1.00 per share or greater for a minimum of ten consecutive business days and accordingly, the Company had regained compliance with Nasdaq Listing Rule 5550(a)(2). All share and per share amounts of common stock, options and warrants in the accompanying financial statements and related notes, have been restated for all periods to give retroactive effect to the Reverse Stock Split. Accordingly, the Condensed Consolidated Statement of Stockholders' Equity reflects the impact of the Reverse Stock Split by reclassifying from "Common Stock" to "Additional paid-in capital" an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

Nasdaq has the authority, pursuant to Nasdaq Listing Rule 5550(b)(1), to delist the Company's common stock if its stockholders' equity falls below $2.5 million. As of September 30, 2018, the Company's stockholders' equity was approximately $10.2 million. If the Company's stockholders' equity is hereafter reduced below $2.5 million as a result of operating losses or for other reasons, the Company will fail to meet Nasdaq's stockholders' equity requirement. If that occurs, or if the Company is unable to demonstrate to Nasdaq's satisfaction that it will be able to sustain compliance with this requirement, Nasdaq may delist the Company's common stock. In addition, even if the Company regains technical compliance with the stockholders' equity requirement, it will have to continue to meet other objective and subjective listing requirements to continue to be listed on Nasdaq, including the requirement that the Company's common stock continues to trade above $1.00.

The Company is actively monitoring its stockholders' equity and will consider any and all options available to it to maintain compliance. There can be no assurance, however, that the Company will be able to maintain compliance and meet Nasdaq's minimum stockholders' equity requirements.

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Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 2. Basis of Presentation

General

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by GAAP for complete consolidated financial statements and certain information and footnote disclosures included in the Company’s annual consolidated financial statements and accompanying notes included in the 2017 Form 10-K, filed with the SEC, have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary to a fair statement of the results for the interim periods have been included. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP.

These financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and accompanying notes included in the 2017 Form 10-K. The Company’s significant accounting policies are described in the Notes to the Consolidated Financial Statements in the 2017 Form 10-K and updated, as necessary, in Note 3 in this Form 10-Q. The results of the Company’s operations for any interim period are not necessarily indicative of the results of operations for any other interim period or full year.

All intercompany accounts and transactions have been eliminated in consolidation. The Company's international operations are immaterial, it has no unrealized gains or losses from the sale of investments and its minimal assets and liabilities are highly liquid and approximate fair value.

Note 3. Summary of Significant Accounting Policies

Convertible Instruments

The Company has utilized various types of financing to fund its business needs, including convertible debt and convertible preferred stock with detachable warrants. The Company considers guidance within the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 470-20, Debt with Conversion and Other Options (ASC 470-20), ASC 480, Distinguishing Liabilities from Equity (ASC 480), and ASC 815, Derivatives and Hedging (ASC 815) when accounting for the issuance of its convertible securities. Additionally, the Company reviews the instruments to determine whether they are freestanding or contain an embedded derivative and, if so, whether they should be classified in permanent equity, mezzanine equity or as a liability at each reporting period until the amount is settled and reclassified into equity.

When multiple instruments are issued in a single transaction, the Company allocates total proceeds from the transaction among the individual freestanding instruments identified. The allocation is made after identifying (1) all the freestanding instruments and (2) the subsequent measurement basis for those instruments. The subsequent measurement basis determines how the proceeds are allocated. Generally, proceeds are allocated based on one of the following methods:

- Fair value method - The instrument being analyzed is allocated a portion of the proceeds equal to its fair value, with the remaining proceeds allocated to the other instruments as appropriate.
- Relative fair value method - The instrument being analyzed is allocated a portion of the proceeds based on the proportion of its fair value to the sum of the fair values of all the instruments covered in the allocation.
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Residual value method - The instrument being analyzed is allocated the remaining proceeds after an allocation is made to all other instruments covered in the allocation.

Generally, when there are multiple instruments issued in a single transaction that have different subsequent measurement bases, the proceeds from the transaction are first allocated to the instrument that is subsequently measured at fair value (i.e. - instruments accounted for as a derivative liability) at its issuance date fair value, with the residual proceeds allocated to the instrument not subsequently measured at fair value. In the event both instruments in the transaction are not subsequently measured at fair value (i.e. equity-classified instruments), the proceeds from the transaction are allocated to the freestanding instruments based on their respective fair values, using the relative fair value method.

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Note 3. Summary of Significant Accounting Policies (continued)

After the proceeds are allocated to the freestanding instruments, resulting in an initial discount on the host contract, those instruments are further evaluated for embedded features (i.e. conversion options) that require bifurcation and separate accounting as a derivative financial instrument pursuant to ASC 815. Embedded derivatives are initially and subsequently measured at fair value. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract is allocated to the fair value of the derivative. See Note 4 for additional discussion on the identified embedded derivatives associated with the Company's convertible notes.

The Company accounts for convertible instruments in which it is determined that the embedded conversion options should not be bifurcated from their host instruments, in accordance with ASC 470-20. Under ASC 470-20, the Company records, when necessary, discounts to convertible notes or convertible preferred stock for the intrinsic value of conversion options embedded in the convertible instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the transaction and the effective conversion price embedded in the convertible instrument, unless limited by the proceeds allocated to such instrument. See Note 4 and Note 10 for additional discussion on the identified embedded features (conversion options) associated with the Company's convertible notes and convertible preferred stock and resulting beneficial conversion features recorded.

The Company allocates issuance costs between the individual freestanding instruments identified on the same basis as proceeds were allocated. Issuance costs associated with the issuance of stock or equity contracts (i.e. equity-classified warrants and convertible preferred stock) are recorded as a charge against the gross proceeds of the offering. Issuance costs associated with the issuance of debt (i.e. convertible debt) is recorded as a direct reduction of the carrying amount of the debt liability, however, if debt issuance costs exceed the carrying amount of the debt, issuance costs are recorded to additional paid-in capital as a reduction of the beneficial conversion feature. Any issuance costs associated with the issuance of liability-classified warrants are expensed as incurred.

Income Taxes

In accordance with ASC 270, Interim Reporting, and ASC 740, Income Taxes, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2018 and 2017, the Company did not record a tax expense or benefit due to the expected current year loss and its historical losses. The Company does not have a net deferred tax asset as of either September 30, 2018 or December 31, 2017 because it maintained a full valuation allowance against all deferred tax assets as management has determined that it is more likely than not, that the Company will be unable to realize these future tax benefits. As of September 30, 2018 and December 31, 2017, the Company had no uncertain tax positions.

On December 22, 2017, the United States enacted tax reform legislation "known as H.R. 1", commonly referred to as the "Tax Cuts and Jobs Act" (TCJA or the Act), resulting in significant modifications to existing law. In response to the enactment of the TCJA, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118), which provides guidance on accounting for the tax effects of the Act. SAB 118 provides a measurement period that should not extend beyond one year from the Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, the Company has recorded a provisional estimate in these financial statements for the effect of the corporate tax rate change. There has been no change to the provisional amounts recorded by the Company since December 31, 2017.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that we adopt as of the specified date. Unless otherwise noted, management does not believe that any recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, or is expected to have, a material impact on the Company's present or future consolidated financial statements.
In June 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation (Topic 718)."
ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions. This ASU is effective for public

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Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 3. Summary of Significant Accounting Policies (continued)

entities for interim and annual reporting periods beginning after December 15, 2018. The Company has evaluated the potential impact of this guidance and does not believe that it will have a material impact on the Company's financial statements.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): Part 1 - Accounting for Certain Financial Instruments with Down Round Features and Part 2 - Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with Scope Exception." Part 1 of ASU No. 2017-11 addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of ASU No. 2017-11 addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification®. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. For public business entities, the amendments in Part I of this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The amendments in Part II of this update do not require any transition guidance because those amendments do not have an accounting effect. The Company currently does not have any outstanding financial instruments with down round provisions, and therefore the impact of the adoption of this standard on its Consolidated Financial Statements, will not be material.
In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under the new guidance, lessees (including lessees under both leases classified as finance leases, which are to be classified based on criteria similar to that applicable to capital leases under current guidance, and leases classified as operating leases) will recognize a right-to-use asset and a lease liability on the balance sheet, initially measured as the present value of lease payments under the lease. Under current guidance, operating leases are not recognized on the balance sheet. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The new standard must be adopted using a modified retrospective transition approach for leases with an option to elect a package of practical expedients. Further, companies can elect to apply the transition approach either for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements or those existing at, or entered into after, the adoption date. While the Company is currently assessing the full impact this ASU will have on its Consolidated Financial Statements, the Company believes the primary impact upon adoption will be the recognition, on a discounted basis, of its minimum commitments under the current noncancelable operating lease, as amended, for its Exton, PA facility, resulting in the recording of right of use assets and lease obligations. The Company does not anticipate any other material impacts to its Consolidated Financial Statements.

Note 4. Convertible Notes

2016 Private Placement

In September 2016, the Company issued an aggregate of $18,087,500 in principal of convertible promissory notes (each, a Note and collectively, the Notes) and accompanying warrants to purchase an aggregate of 1,205,840 shares of

the Company's common stock (each a Warrant and collectively, the Warrants) in a private placement to institutional and accredited investors (each an Investor and collectively, the Investors).

The Notes bear interest at four percent (4%) per annum. Interest is earned daily and compounded quarterly and, at the election of the Company at the beginning of each quarter, shall accrue or be paid in cash. If the Company elects to have interest accrue, such interest will not be added to the principal amount of the Notes but such interest shall be subject to additional interest at the rate of four percent (4%) per annum, compounded quarterly, and shall be due and payable upon the earliest of the conversion of the Notes, exercise of the Put Right, exercise of the Prepayment Right or the Maturity Date (in each case, as defined below). Additionally, if the Company elects for interest to accrue, then (i) the Company may elect to repay any such accrued and unpaid interest in cash at any time and from time to time and (ii) each Investor may elect to have the Company

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Note 4. Convertible Notes (continued)

repay any such accrued and unpaid interest by delivering such number of shares of the Company's common stock equal to (x) the amount of the accrued and unpaid interest to be repaid, divided by (y) the greater of (i) the last closing bid price of a share of the Company's common stock as reported on Nasdaq on the date of such election plus $0.12625, and (ii) the Conversion Price (as defined below). As of September 30, 2018 and for each prior quarterly period since issuance, the Company has elected to accrue interest.

All unpaid principal of each Investor's Note is convertible, at any time and from time to time, at the option of such Investor into shares of the Company's common stock at each such Investors' applicable conversion price (as subject to adjustment, the Conversion Price) which range from $17.04375 to $18.39375 per share.

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

During the three and nine months ending September 30, 2018, there were no conversions of the Notes into shares of the Company's common stock.

Accounting for Convertible Notes and Embedded Derivatives

The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from allocation of proceeds to interest expense using the effective interest method over the expected term of the Notes pursuant to ASC 835, Interest (ASC 835).

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

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Note 4. Convertible Notes (continued)

Convertible promissory notes outstanding were as follows:

($ in thousands)	September 30, 2018	December 31, 2017
Convertible promissory notes	$ 18,003	$ 18,003
Debt discount - warrants	(9,598)	(9,598)
Debt discount - compound bifurcated derivatives	(1,267)	(1,267)
Debt discount - beneficial conversion feature	(7,138)	(7,138)
Convertible promissory notes, net	$—	$—

The debt discount and issuance costs are amortized using the effective interest method over five years, the expected term of the Notes, and is included in interest expense in the Condensed Consolidated Statements of Operations. Amortization for the three and nine months ended September 30, 2018 and September 30, 2017, including the amortization of the issuance costs, was $0 for the 2018 periods and approximately $36,000 for the three months ended September 30, 2017 and $86,000 for the nine months ended September 30, 2017, due to the conversion of $85,000 in principal value notes. Based on an effective yield of approximately 1,157% resulting from the Notes being initially recorded at a full discount, the Company will not recognize any material amounts of amortization until years 2020 and 2021.

Assumptions Used in Determining Fair Value of Compound Bifurcated Derivative

The Company utilizes a binomial lattice model to value its bifurcated derivatives included in the Notes. ASC 815 does not permit an issuer to account separately for individual derivative terms and features embedded in hybrid financial instruments that require bifurcation and liability classification as derivative financial instruments. Rather, such terms and features must be combined together and fair valued as a single, compound embedded derivative. The Company selected a binomial lattice model to value the compound embedded derivative because it believes this technique is reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of the Notes. Such assumptions include, among other inputs:

Volatility. The Company estimates stock price volatility based on the Company’s historical stock price performance over a period of time that matches the volume-weighted average expected remaining life of the Notes.

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

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

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

Scenarios. The probability of complex features of the compound bifurcated derivative being triggered is subjective (no observable inputs or available market data) and based on internal and external information known to management at the valuation date. Such assumptions include, among other inputs, probabilities related to a change of control and

when it might occur as well as probabilities related to a default under the provisions of the Notes and when it might occur.

Changes to the key assumptions or to the scenarios used in the valuation model, including the probability of key events, such as a change of control transaction, could have a material impact to the overall valuation of the compound bifurcated derivative liability. Additionally, there are other embedded features of the Notes requiring bifurcation, other than the Contingent Put Option and the Contingent Call Option, which had no value at September 30, 2018 or December 31, 2017, due to management’s estimates of the likelihood of certain events, but that may have value in the future should those estimates change.

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Note 4. Convertible Notes (continued)

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

($ in thousands except per share data)	September 30, 2018	December 31, 2017
Calculated aggregate value	$2,870	$3,136
Closing price per share of common stock	$2.36	$3.20
Contractual remaining term	7 years, 11 months	8 years, 8 months
Contractual interest rate	4.0 %	4.0 %
Volume-weighted average conversion rate	$17.04667	$17.04667
Risk-free interest rate (term structure)	2.12% - 3.05%	1.28% - 2.40%
Dividend yield	—	—
Credit Rating	CC	CC
Credit Spread	27.11 %	36.98 %
Volatility	91.5 %	99.0 %

The foregoing compound bifurcated derivative was recorded at its estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in derivative revaluation income in the Company’s Condensed Consolidated Statements of Operations. The change in estimated fair value of the Company's derivative liability for the three months ended September 30, 2018 and September 30, 2017 resulted in non-cash income of approximately $0.1 million and non-cash expense of approximately $0.3 million, respectively, and for the nine months ended September 30, 2018 and September 30, 2017 the change in estimated fair value of the Company’s derivative liability resulted in non-cash income of approximately $0.3 million and $0.3 million, respectively.

Note 5. Warrants

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

In connection with various financing transactions, the Company has issued warrants to purchase the Company’s common stock. In July 2018, in connection with a private placement (the July 2018 Private Placement), the Company issued unregistered warrants to purchase 958,152 shares of its common stock. Each common stock purchase warrant has an exercise price of $2.70 per share, was exercisable upon the date of issuance and expires five and one-half years from the date of the issuance. In addition, the Company also issued unregistered warrants to purchase up to an aggregate of 103,186 shares of its common stock to the designees of H.C. Wainwright & Co., LLC (Wainwright), as partial compensation for placement agent services by Wainwright in connection with the Company’s registered direct public offering in July 2018 (the July 2018 Registered Direct Public Offering), and the July 2018 Private Placement. Such unregistered warrants have an initial exercise price of $3.464 per share are immediately exercisable and expire on July 3, 2023.

In May 2018 in connection with a private placement (the May 2018 Private Placement), the Company issued unregistered warrants to purchase 1,528,668 shares of its common stock. Each common stock purchase warrant has an

exercise price of $2.86 per share, was exercisable upon the date of the issuance and expires five and one-half years from the date of the issuance. The Company also issued unregistered warrants to purchase up to an aggregate of 142,676 shares of its common stock to the designees of Wainwright, as partial compensation for placement agent services by Wainwright in connection with the Company's registered direct public offering in May 2018 (the May 2018 Registered Direct Public Offering), and the May 2018 Private Placement. Such unregistered warrants have an initial exercise price of $3.679 per share are immediately exercisable and expire on May 30, 2023.

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Note 5. Warrants (continued)

On July 27, 2018, the Company filed a registration statement on Form S-1 (the Resale Registration Statement) registering the resale of shares of the Company's common stock underlying warrants issued in the May 2018 Private Placement and the July 2018 Private Placement. The Resale Registration Statement was declared effective by the SEC on August 8, 2018.

In December 2017, the Company issued (i) pre-funded warrants to purchase an aggregate of 1,184,442 shares of the Company's common stock and (ii) common stock purchase warrants to purchase up to an aggregate of 2,809,404 shares of the Company's common stock including warrants to purchase up to 82,118 shares, issued pursuant to the partial exercise of the underwriters option to purchase additional common stock purchase warrants (the December 2017 Offering). Each pre-funded warrant was sold together with a common stock purchase warrant to purchase one share of the Company's common stock at a combined effective price of $3.85 per share and accompanying warrant. Each common stock purchase warrant has an exercise price of $3.85 per share, was exercisable upon the date of issuance and expires five years from the date of issuance. As additional compensation, the Company issued warrants to the underwriter to purchase 87,274 shares of the Company's common stock. Each such warrant has an exercise price of $4.8125 per share, and was exercisable as of the date of the underwriting agreement, and will expire five years after the date of the underwriting agreement.

In March 2017, the Company issued warrants to purchase 687,468 shares of its common stock in connection with the Company's public offering of convertible preferred stock and warrants (each a Series A Warrant and collectively, the Series A Warrants), more fully described in Note 10. Each Series A Warrant has an exercise price of $12.69, is exercisable six months after the date of issuance and will expire five years from the date of issuance.

The Company's outstanding warrants consist of both liability-classified warrants and equity-classified warrants. The following table summarizes outstanding warrants to purchase the Company's common stock:

	Number of warrants			
	September 30, 2018	December 31, 2017	Exercise Price	Expiration Dates
Liability-classified Warrants				
Issued with June 2012 Convertible Notes	—	75,040	$37.50	Jun 2018
Issued in Series E Preferred Stock offering	104,676	104,676	$112.50	Dec 2018
Issued with September 2016 Convertible Notes	1,205,840	1,205,840	$22.50	Sept 2021
Total liability-classified warrants	1,310,516	1,385,556		
Equity-classified Warrants				
Issued in 2017 Series A Preferred Stock Offering	687,468	687,468	$12.69	Mar 2022
Issued in December 2017 Offering - common warrants	2,679,702	2,809,404	$3.85	Dec 2022
Issued in December 2017 Offering - underwriter warrants	87,274	87,274	$4.8125	Dec 2022
Issued in December 2017 Offering - pre-funded warrants	—	483,221	$0.05	No exp
Issued in May 2018 Private Placement - common warrants	1,528,668	—	$2.86	Nov 2023
Issued in May 2018 - underwriter warrants	142,676	—	$3.679	May 2023
Issued in July 2018 Private Placement - common warrants	958,152	—	$2.70	Jan 2024
Issued in July 2018 - underwriter warrants	103,186	—	$3.464	Jul 2023
Total equity-classified warrants	6,187,126	4,067,367		

Total outstanding warrants	7,497,642	5,452,923

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Note 5. Warrants (continued)

The table below is a summary of the Company's warrant activity during the nine months ended September 30, 2018:

	Number of warrants			Weighted-average exercise price
	Liability-classified	Equity-classified	Total	
Outstanding at December 31, 2017	1,385,556	4,067,367	5,452,923	$ 11.32
Granted	—	2,732,682	2,732,682	2.87
Exercised	—	(612,923)	(612,923)	0.85
Expired	(75,040)	—	(75,040)	37.50
Outstanding at September 30, 2018	1,310,516	6,187,126	7,497,642	$ 8.83

Accounting for Liability-Classified Warrants

The Company's liability-classified warrants were recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in warrant revaluation income (expense) in the Company's Condensed Consolidated Statements of Operations in each subsequent period. The change in the estimated fair value of the warrant liability for the three months ended September 30, 2018 and September 30, 2017, resulted in non-cash income of approximately $0.3 million and $5.0 million, respectively and for the nine months ended September 30, 2018 and September 30, 2017, the change in the estimated fair value of the warrant liability resulted in non-cash income (expense) of approximately $0.6 million and ($4.7) million, respectively.

Additionally, the liability-classified warrants are classified as either current or non-current on the Company's Condensed Consolidated Balance Sheets based on their contractual expiration date. The Company utilizes a Monte Carlo simulation valuation method to value its liability-classified warrants.

Assumptions Used In Determining Fair Value of Liability-Classified Warrants

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

Volatility. The Company estimates stock price volatility based on the Company's historical stock price performance over a period of time that matches the volume-weighted average expected remaining life of the warrants.

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

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

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

Scenarios. The probability of complex features of the warrants being triggered is subjective (no observable inputs or available market data) and based on internal and external information known to management at the valuation date. Such assumptions include, among other inputs, probabilities related to a change of control and when it might occur as well as probabilities related to a default under the provisions of the Notes and when it might occur.

Changes to the key assumptions or to the scenarios used in the valuation model, including the probability of key events, such as a change of control transaction, could have a material impact to the overall valuation of the warrant liability.

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Note 5. Warrants (continued)

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

($ in thousands except per share data)	September 30, 2018	December 31, 2017
Calculated aggregate value	$ 482	$ 1,073
Weighted average exercise price per share	$ 29.69	$ 30.11
Closing price per share of common stock	$ 2.36	$ 3.20
Volatility	91.8 %	92.2 %
Weighted average remaining expected life	2 years, 9 months	3 years, 4 months
Risk-free interest rate	2.80 %	2.00 %
Dividend yield	—	—

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Note 6. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company follows the guidance in ASC 820, Fair Value Measurement, to account for financial assets and liabilities measured on a recurring basis. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the nine months ended September 30, 2018.

The following fair value hierarchy table presents information about each major category of the Company’s financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017:

	September 30, 2018			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents, money market funds with less than 90 days maturity	$14,220	$ —	$—	$14,220
Total Assets	$14,220	$ —	$—	$14,220
Liabilities:				
Warrant liability	$—	$ —	$482	$482
Derivative liability	—	—	2,870	2,870
Total Liabilities	$—	$ —	$3,352	$3,352

	December 31, 2017			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents, money market funds with less than 90 days maturity	$14,670	$ —	$—	$14,670
Total Assets	$14,670	$ —	$—	$14,670
Liabilities:				
Warrant liability	$—	$ —	$1,073	$1,073
Derivative liability	—	—	3,136	3,136

Total Liabilities	$—	$ —	$4,209	$4,209

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Note 6. Fair Value Measurements (continued)

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

Common Stock Warrants - Warrant Liability

The reconciliation of the Company's 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, 2017	$1,073
Change in fair value of warrant liability	(591)
Balance at September 30, 2018	$482

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.

Bifurcated Compound Derivative - Derivative Liability

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

($ in thousands)	Derivative Liability
Balance at December 31, 2017	$ 3,136
Change in fair value of derivative liability	(266)
Balance at September 30, 2018	$ 2,870

The fair value of the derivative 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 4 for further discussion of the derivative liability.

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

Common Stock Warrants - Warrant Liability

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

assumptions to determine the fair value could result in a different fair value measurement at the reporting date.

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Note 6. Fair Value Measurements (continued)

Bifurcated Compound Derivative - Derivative Liability

The fair value of the derivative liability is based on Level 3 inputs. As discussed in Note 4, the Company uses a binomial lattice model to value the compound embedded derivative bifurcated from the Notes. The determination of fair value as of the reporting date is affected by the Company's stock price as well as assumptions regarding a number of subjective variables that do not have observable inputs or available market data to support the fair value. These variables include, but are not limited to, expected stock price volatility, changes in interest rates, assumptions regarding the adjusted conversion prices in the Notes, and early redemption or conversion of the Notes. The methods described above and in Note 4 may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, while the Company believes its valuation method is appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value could result in a different fair value measurement at the reporting date.

Fair Value of Certain Financial Assets and Liabilities

The Company believes that the fair values of its current assets and liabilities approximate their reported carrying amounts. The fair value of the long-term convertible promissory notes with embedded derivatives was approximately $14.6 million at September 30, 2018, based on Level 3 inputs, compared to a carrying value of $0, as a result of unamortized debt discounts.

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Note 7. Stock-Based Compensation

2009 Equity Incentive Plan

The Board adopted the 2009 Equity Incentive Plan (as amended to date, the Plan) effective September 3, 2009. The Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisers by providing equity-based incentives. The Plan allows for the issuance of up to 506,667 shares of the Company's common stock.

The types of awards that may be granted under the Plan include options (both non-qualified stock options and incentive stock options), stock appreciation rights, stock awards, stock units and other stock-based awards. The term of each award is determined by the Compensation Committee of the Board at the time each award is granted, provided that the term of the option does not exceed ten years. Vesting schedules for stock options vary, but generally vest 25% per year, over four years for employee options and on the one year anniversary date for non-employee director options. The Plan had 212,868 shares available for future grants as of September 30, 2018.

Accounting for Stock-Based Compensation

The Company recognizes non-cash compensation expense for stock-based awards based on their grant date fair value, determined using the Black-Scholes option-pricing model. During the nine months ended September 30, 2018 and 2017, the weighted average fair market value for options granted was $2.22 and $10.60, respectively.

Total stock-based compensation expense recognized using the straight-line attribution method and included in operating expenses in the Condensed Consolidated Statements of Operations was approximately $0.1 million and $0.1 million for the three months ended September 30, 2018 and 2017, respectively and approximately $0.4 million and $0.2 million for the nine months ended September 30, 2018 and 2017, respectively.

Assumptions Used In Determining Fair Value of Stock Options

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

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

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

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

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

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Note 7. Stock-Based Compensation (continued)

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

	September 30, 2018		September 30, 2017	
Expected term	6 years		6 years	
Interest rate	2.61	%	1.95	%
Dividend rate	—		—	
Volatility	88.0	%	88.7	%

Stock Option Activity

The following table summarizes stock option activity for the nine months ended September 30, 2018:

	Number of shares	Weighted-average exercise price	Weighted- average remaining contractual term	Aggregate intrinsic value
Outstanding at December 31, 2017	217,926	$ 60.31	7 years, 3 months	$ —
Granted	84,800	2.99	9 years, 6 months	—
Exercised	—	—		—
Forfeited	(11,113)	6.12		—
Expired	(2,099)	51.46		—
Outstanding at September 30, 2018[(1)]	289,514	$ 45.67	7 years, 3 months	$ —
Exercisable at September 30, 2018	165,696	$ 73.64	5 years, 11 months	$ —

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

The total fair value of options vested during the nine months ended September 30, 2018 was approximately $0.5 million. Additionally, as of September 30, 2018, there was approximately $0.6 million of unrecognized compensation expense related to non-vested stock options which is expected to be recognized over a weighted-average period of approximately 1 year, 9 months.
The Company accounts for forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.
Note 8. Related Party Transactions

The Company and Precigen, Inc. (Precigen), a wholly owned subsidiary of Intrexon Corporation (Intrexon), are parties to two distinct exclusive channel collaboration agreements including the Exclusive Channel Collaboration Agreement entered into in October 2012 and amended in June 2013 and January 2014 (as amended, the 2012 ECC) and the Exclusive Channel Collaboration Agreement entered into in December 2015 (the 2015 ECC). Pursuant to these agreements, the Company engages Precigen for support services for the research and development of product candidates covered under the respective agreements and reimburses Precigen for its cost for time and materials for such work. Additionally, the Company’s future commitments pursuant to the 2012 ECC agreement includes potential cash royalties and the Company’s future commitments pursuant to the 2015 ECC agreement includes potential cash royalties and various developmental milestone payments. No royalties or milestone payments have been incurred to date.

For the three months ended September 30, 2018, the Company incurred total expenses of approximately $60,000 with Precigen as compared to approximately $1.0 million, for the three months ended September 30, 2017, for work performed

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(unaudited)

Note 8. Related Party Transactions (continued)

under the 2012 ECC. During the same periods, no expenses were incurred for work performed under the 2015 ECC. Of the $60,000 incurred during the three months ended September 30, 2018, approximately $10,000 related to direct expenses for work performed by Precigen and approximately $50,000 related to pass-through costs. Of the $1.0 million incurred in the three months ended September 30, 2017, approximately $0.3 million related to direct expenses for work performed by Precigen and approximately $0.7 million related to pass-through costs. The Company's FCX-007 and FCX-013 development programs are covered under the 2012 ECC and the Company's Arthritis and related conditions program is covered under the 2015 ECC.

For the nine months ended September 30, 2018, the Company incurred total expenses of approximately $0.4 million with Precigen as compared to approximately $4.2 million, for the nine months ended September 30, 2017. In addition to these costs, during the nine months ended September 30, 2018, the Company recorded an approximately $0.5 million reduction in pass through costs under the 2012 ECC, due to a reduction in the estimate of disputed amounts owed to a Precigen vendor for pass though costs. Of the $0.4 million incurred during the nine months ended September 30, 2018, approximately $0.1 million related to direct expenses for work performed by Precigen and approximately $0.3 million related to pass-through costs. Of the $4.2 million incurred in the nine months ended September 30, 2017, approximately $0.9 million related to direct expenses for work performed by Precigen and approximately $3.3 million related to pass-through costs. These costs are presented in the Company's "Condensed Consolidated Statement of Operations" as research and development expenses - related party.

As of September 30, 2018 and December 31, 2017, the Company had outstanding payables to Precigen of approximately $0.1 million and $2.3 million, respectively. These amounts are presented in the Company's "Condensed Consolidated Balance Sheets" as related party payable.

In the second quarter of 2017, Precigen notified the Company that it had received invoices for approximately $1.1 million in charges from a vendor who provided services to Precigen and which are passed-through to the Company under the 2012 ECC. Additional charges were presented after the second quarter of 2017, and the total of disputed charges at March 31, 2018, was approximately $1.4 million. The Company, Precigen and Precigen's vendor have resolved the dispute with the parties agreeing to settle all obligations for approximately $0.2 million. This is a reduction of approximately $0.5 million from the approximately $0.7 million recorded at December 31, 2017 for this liability and was recorded in the three months ended March 31, 2018. The approximately $0.2 million settlement amount was paid in the Company's third fiscal quarter of 2018.

Randal J. Kirk is the chairman of the board and chief executive officer of Intrexon and, together with his affiliates, owns more than 50% of Intrexon's common stock. Affiliates of Randal J. Kirk (including Intrexon) own approximately 18% of the Company's common stock. Additionally, two of the Company's directors, Julian Kirk (who is the son of Randal J. Kirk) and Marcus Smith, are employees of Third Security, LLC, which is an affiliate of Randal J. Kirk.

Affiliates of Randal J. Kirk (including Intrexon) participated in the Company's private placement of convertible debt securities in September 2016, more fully described in Note 4, and were issued an aggregate of $6,762,500 in principal of Notes and accompanying Warrants to purchase an aggregate of 450,835 shares of the Company's common stock. Affiliates of Randal J. Kirk (including Intrexon) participated in the Company's 2017 Series A Preferred Stock Offering (as defined below), more fully described in Note 10, and were issued an aggregate of 3,016 shares of Series A Preferred Stock (as defined below) and accompanying Series A Warrants to purchase 259,176 shares of the Company's common stock. Additionally, affiliates of Randal J. Kirk (including Intrexon) participated in the December 2017

Offering, and were issued an aggregate of 545,456 shares of the Company’s common stock and accompanying warrants to purchase 545,456 shares of the Company’s common stock.

Note 9. Loss Per Share

Basic loss per share is computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during that period. The diluted loss per share calculation gives effect to dilutive stock options, warrants, convertible preferred stock, convertible notes and other potentially dilutive common stock equivalents outstanding during the period. Diluted loss per share is based on the if-converted method or the treasury stock method, as applicable, and includes the effect from the potential issuance of common stock, such as shares issuable pursuant to the conversion of convertible preferred stock, convertible notes and the exercise of stock options and warrants, assuming the exercise of all "in-

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Note 9. Loss Per Share (continued)

the-money" common stock equivalents based on the average market price during the period. Common stock equivalents have been excluded where their inclusion would be anti-dilutive.

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

	Three months ended September 30,		Nine months ended September 30,	
($ in thousands except share and per share data)	2018	2017	2018	2017
Loss per share - basic:				
Net loss	$(2,859)	$ (115)	$(8,654)	$(19,140)
Less: Dividend paid in-kind to preferred stockholders	(85)	(82)	(250)	(182)
Less: Deemed dividend on preferred stock	(130)	(111)	(377)	(3,981)
Net loss attributable to common stockholders - basic	$(3,074)	$ (308)	$(9,281)	$(23,303)
Numerator for basic loss per share	$(3,074)	$ (308)	$(9,281)	$(23,303)
Denominator for basic loss per share	9,234,869	2,945,035	7,107,678	2,942,202
Basic loss per common share	$(0.33)	$ (0.10)	$(1.31)	$(7.92)
Loss per share - diluted:				
Numerator for basic loss per share	$(3,074)	$ (308)	$(9,281)	$(23,303)
Adjust: Warrant revaluation income for dilutive warrants	—	46	—	—
Net loss attributable to common stockholders - diluted	$(3,074)	$ (354)	$(9,281)	$(23,303)
Denominator for basic loss per share	9,234,869	2,945,035	7,107,678	2,942,202
Adjust: Incremental shares underlying dilutive “in the money” warrants outstanding	—	3,255	—	—
Denominator for diluted loss per share	9,234,869	2,948,290	7,107,678	2,942,202
Diluted net loss per common share	$(0.33)	$ (0.12)	$(1.31)	$(7.92)

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
“In the money” stock options	—	62,168	36,000	41,768
“Out of the money” stock options	289,514	161,102	253,514	152,688
“In the money” warrants	—	—	958,152	9,286
“Out of the money” warrants	7,497,642	2,072,951	6,539,490	2,072,951
Shares underlying convertible notes	1,056,068	1,056,068	1,056,068	1,056,068
Shares underlying convertible accrued interest on convertible notes	90,472	45,734	90,472	45,734
Shares underlying convertible preferred stock	728,000	704,000	728,000	704,000

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Note 10. Equity

Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock, at a par value of $0.001 per share, 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 the Company's 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.

Series A Convertible Preferred Stock

In March 2017, the Board authorized the issuance of 8,000 shares of preferred stock designated as Series A Convertible Preferred Stock (the Series A Preferred Stock). The rights, preferences and privileges of the Series A Preferred Stock are set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock dated March 7, 2017 (Certificate of Designation).

On March 7, 2017, the Company entered into a securities purchase agreement with certain of its existing accredited investors pursuant to which the Company agreed to sell a total of 8,000 units (the Units) for a purchase price of $1,000 per Unit, with each Unit consisting of (i) one share of the Series A Preferred Stock, with an initial stated value of $1,000 and which is convertible into shares of the Company's common stock with a conversion price of $11.6355 and (ii) a warrant to purchase up to a number of shares of the Company's common stock equal to 100% of the conversion shares issuable on March 7, 2017 pursuant to the shares of Series A Preferred Stock purchased by each investor (the Series A Warrants and, collectively, the 2017 Series A Preferred Stock Offering). See Note 5 for discussion of the Series A Warrants issued in connection with the 2017 Series A Preferred Stock Offering. The 2017 Series A Preferred Stock Offering closed on March 8, 2017 and resulted in gross proceeds of $8.0 million, before deducting offering costs.

The proceeds from the 2017 Series A Preferred Stock Offering (including offering costs) were allocated between the Series A Warrants and Series A Preferred Stock issued in the transaction based upon their respective fair values using the relative fair value (proportional) method. The fair value of the Series A Preferred Stock issued was calculated as the sum of (i) the value of the Series A Preferred Stock as if it had been converted into the Company's common stock on the issuance date and (ii) the value of a perpetual annuity paying a 4% dividend rate in conversion shares for five years and 8% thereafter. In connection with the valuation, the following assumptions were used: risk free interest rate of 3.15%, credit spread of 31.27% and a market yield of 34.42%. The application of the relative fair value method resulted in an allocation of gross proceeds to the Series A Preferred Stock of approximately $1.3 million, net of discounts of $3.0 million attributed to the warrants (See Note 5) and $3.7 million from a beneficial conversion feature. The discount attributed to the beneficial conversion feature was immediately amortized as the Series A Preferred Stock has no stated redemption date and is convertible at the issuance date. For the three months ended September 30, 2018 and 2017, the Company recognized approximately $0.1 million in both periods of amortization of the discount on the Series A Preferred Stock as deemed dividends charged to additional paid-in capital (in the absence of retained earnings). For the nine months ended September 30, 2018 and 2017, the Company recognized approximately $0.4 million and $4.0 million, respectively, of amortization of the discount on the Series A Preferred Stock as deemed

dividends charged to additional paid-in capital (in the absence of retained earnings). The value of the beneficial conversion feature is calculated as the difference between the effective conversion price of the Series A Preferred Stock and the fair market value of the common stock into which the Series A Preferred Stock are convertible at the commitment date.

The discount attributed to the warrants is being accreted using the effective interest method and charged as a deemed dividend to additional paid-capital (in the absence of retained earnings), over the five-year period of the Series A Preferred Stock in which the stated dividend rate is 4%. For the three months ended September 30, 2018 and 2017, the Company recognized approximately $0.1 million in both periods, in deemed dividends due to the accretion of the warrant discount. For the nine months ending September 30, 2018 and 2017, the Company recognized approximately $0.4 million and $0.2 million, respectively, in deemed dividends due to the accretion of the warrant discount.

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The 2017 Series A Preferred Stock Offering securities purchase agreement contains customary representations, warranties, and agreements by the Company. The securities purchase agreement also contains customary prohibitions on certain Company payments, the incurrence of certain senior and pari passu debt, certain affiliate transactions and the incurrence of certain liens.

Holders of the Series A Preferred Stock are entitled to receive cumulative dividends at a rate per share of 4% per annum (with such dividend rate increasing to 8% per annum on the five year anniversary of the original issuance of the Series A Preferred Stock), with such dividends compounded quarterly and payable only by way by increasing the stated value of the
Series A Preferred Stock in accordance with the terms of the Certificate of Designation. For the three and nine months ended September 30, 2018 cumulative dividends paid in-kind to holders of the Series A Preferred Stock were approximately $0.1 million and $0.3 million, respectively. For the three and nine months ended September 30, 2017 cumulative dividends paid in-kind to holders of the Series A Preferred Stock were approximately $0.1 million and $0.2 million respectively.

Shares of Series A Preferred Stock generally have no voting rights, except as required by law; provided, however, that without the prior written consent of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock, the Company may not: (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation; (ii) amend the Company's certificate of incorporation or other charter documents in any manner that adversely affects any rights of a holder of the Series A Preferred Stock; (iii) authorize or create any class of stock ranking as to redemption, distribution of assets upon liquidation or dividends senior to, or otherwise pari passu with, the Series A Preferred Stock; (iv) declare or make any dividends other than dividend payments or other distributions payable solely in the Company's common stock; or (v) enter into any agreement with respect to any of the foregoing.

Upon a liquidation, dissolution or winding up of the Company, the holders of the Series A Preferred Stock are entitled to receive out of the Company's assets, whether capital or surplus, an amount equal to such holder's then stated value for each share of Series A Preferred Stock before any distribution to the holders of the Company's common stock, any class or series of preferred stock and all other common stock equivalents other than those securities which are explicitly senior or pari passu to the Series A Preferred Stock in redemption, distribution of assets upon a liquidation or dividends. If there are insufficient assets to pay in full such amounts, then the available assets will be ratably distributed to the holders of the Series A Preferred Stock in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Common Stock

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

On May 24, 2018, the Company implemented the Reverse Stock Split, as authorized at the annual meeting of stockholders on May 23, 2018. The Reverse Stock Split became effective on May 24, 2018 at 5:00 pm and the Company's common stock began trading on Nasdaq on a post-split basis at the open of business on May 25, 2018. As of a result of the Reverse Stock Split, every five shares of the Company's issued and outstanding common stock were

combined into one share of its common stock, except to the extent that the Reverse Stock Split resulted in any of the Company's stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of $0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of the Company's common stock to satisfy the $1.00 minimum bid price requirement for continued listing on Nasdaq. By letter dated June 11, 2018, the Nasdaq Listing Qualification Department, confirmed that the Company's common stock was in compliance with listing requirements.

December 2017 Public Offering

On December 7, 2017, the Company entered into an underwriting agreement (the Underwriting Agreement) with Wainwright, relating to the sale of 1,542,832 shares of its common stock, pre-funded warrants to purchase an aggregate of 1,184,442 shares of the Company's common stock and common warrants to purchase up to an aggregate of 2,727,273 shares of the Company's common stock in connection with the December 2017 Offering. Each share of the Company's common stock or pre-funded warrant, as applicable, was sold together with a common warrant to purchase one share of the Company's common

stock at a combined effective price to the public of $3.85 per share and accompanying common warrant. At September 30, 2018, all of the pre-funded warrants had been exercised for 1,184,442 shares of the Company's common stock.

Pursuant to the Underwriting Agreement, the Company granted Wainwright a thirty day option, which option ended on January 6, 2018, to purchase up to 409,091 additional shares of the Company's common stock at a purchase price of $3.80 per share and/or common warrants to purchase up to an aggregate of 409,091 shares of the Company's common stock at a purchase price of $0.01 per common warrant with an exercise price of $3.85 per share, less the underwriting discounts and commissions. On December 8, 2017, Wainwright partially exercised this option by purchasing common warrants to purchase 82,118 shares of the Company's common stock. As additional compensation, the Company issued warrants to Wainwright to purchase 87,274 shares of the Company's common stock (the Underwriter Warrants). The Underwriter Warrants, which have an exercise price of $4.8125 per share, are exercisable for five years from the date of the Underwriting Agreement and may be exercised on a cashless basis in certain circumstances specified therein.

The Company and Wainwright completed the December 2017 Offering on December 11, 2017, resulting in approximately $9.3 million of net proceeds to the Company after deducting the underwriter's discounts and commissions and other estimated offering expenses payable by the Company.

The common warrants are exercisable immediately at an exercise price of $3.85 per share and will expire five years from the date of issuance. The pre-funded warrants are exercisable immediately at an exercise price of $0.05 per share and may be exercised until they are exercised in full, and as of September 30, 2018 all pre-funded warrants had been exercised. The exercise price and number of shares of the Company's common stock issuable upon exercise of the common warrants, pre-funded warrants and Underwriter Warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, among other events as described in the common warrants and pre-funded warrants.

In the event of certain transactions involving a sale of the Company, each holder of common warrants has the right, exercisable at its option, to require the Company to purchase such holder's common warrants at a price determined using a Black Scholes option pricing model as described in the common warrants. The shares of the Company's common stock or pre-funded warrants, as applicable, and the accompanying common warrants could only be purchased together in the December 2017 Offering but were issued separately.

May 2018 Registered Direct Offering and Private Placement

On May 29, 2018, in connection with the May 2018 Registered Direct Offering, the Company entered into securities purchase agreements (May 2018 Purchase Agreements) with certain institutional and accredited investors for the sale by the Company of 2,038,224 shares of the Company's common stock, par value $0.001 per share at a purchase price of $2.85 per share. Concurrently with the May 2018 Registered Direct Offering, and pursuant to the May 2018 Purchase Agreements, the Company in connection with the May 2018 Private Placement, also sold unregistered warrants exercisable for an aggregate of 1,528,668 shares of the Company's common stock, which represents 75% of the shares of the Company's common stock sold in the May 2018 Registered Direct Offering, for a purchase price of $0.125 per warrant and with an exercise price of $2.86 per share. Subject to certain ownership limitations, the warrants were exercisable upon issuance. The warrants will expire on the 5.5 years anniversary of the date of issuance. The May 2018 Purchase Agreements contain representations, warranties and covenants of the investors and the Company that are customary for transactions of this type.

The May 2018 Registered Direct Offering and the May 2018 Private Placement closed on May 31, 2018. The net proceeds from the transactions were approximately $5.3 million after deducting certain fees due to the placement agent and other estimated transaction expenses. In connection with the May 2018 Registered Direct Offering and the May 2018 Private Placement, the placement agent received warrants to purchase up to 7.0% of the aggregate amount of shares of Company common stock sold in the May 2018 Registered Direct Offering. The warrants issued to the placement agent have substantially the same terms as the warrants issued in the May 2018 Private Placement, except that the exercise price of the warrants issued to the placement agent is $3.679 per share and the term of the warrants issued to the placement agent is five years.

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Note 10. Equity (continued)

July 2018 Registered Direct Offering and Private Placement

On July 2, 2018, the Company entered into securities purchase agreements (July 2018 Purchase Agreements) with certain institutional and accredited investors for the sale by the Company of 1,474,080 shares of the Company's common stock, par value $0.001 per share at a purchase price of $2.69 per share (the July 2018 Registered Direct Offering). Concurrently with the July 2018 Registered Direct Offering, and pursuant to the July 2018 Purchase Agreements, the Company also sold unregistered warrants exercisable for an aggregate of 958,152 shares of the Company's common stock, which represents 65% of the shares of the Company's common stock sold in the July 2018 Registered Direct Offering, for a purchase price of $0.125 per warrant and with an exercise price of $2.70 per share (July 2018 Private Placement). Subject to certain ownership limitations, the warrants were exercisable upon issuance. The warrants will expire on the 5.5 years anniversary of the date of issuance.

The July 2018 Registered Direct Offering and the July 2018 Private Placement closed on July 5, 2018. The net proceeds from the transactions were approximately $3.6 million after deducting certain fees due to the placement agent and other estimated transaction expenses. In addition, the placement agent received warrants to purchase 103,186 shares of the Company's common stock. The warrants issued to the placement agent have substantially the same terms as the warrants issued in the July 2018 Private Placement, except that the exercise price of the warrants issued to the placement agent is $3.464 per share and the term of the warrants issued to the placement agent is five years.

On July 27, 2018, the Company filed a registration statement on Form S-1, registering the resale of shares of the Company's common stock underlying warrants issued in the May 2018 Private Placement and the July 2018 Private Placement. The Resale Registration Statement was declared effective by the SEC on August 8, 2018.

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

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

- our unaudited Condensed Consolidated Financial Statements and accompanying notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q (this Form 10-Q); and
- our audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for 2017 (2017 Form 10-K), as well as the information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2017 Form 10-K.

Overview

We are an autologous cell and gene therapy company focused on translating personalized biologics into medical breakthroughs for diseases affecting the skin and connective tissue. Our distinctive approach to personalized biologics is based on our proprietary autologous fibroblast technology. Fibroblasts are the most common cell in skin and connective tissue and are responsible for synthesizing extracellular matrix proteins, including collagen and other growth factors, that provide structure and support. Because fibroblasts naturally reside in the localized environment of the skin and connective tissue, they represent an ideal delivery vehicle for proteins targeted to these areas. We target the underlying cause of disease by using fibroblast cells from a patient's skin and genetically modifying them to create localized therapies that are compatible with the unique biology of the patient (i.e., which are autologous).

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

On April 18, 2018, we announced that our Board of Directors (the Board) would begin conducting a comprehensive review of strategic alternatives focused on maximizing stockholder value. We have engaged Canaccord Genuity LLC as our strategic financial advisor to assist with the review process. The Board has established a Special Committee to explore and evaluate potential strategic alternatives which may include a sale of our company, a business combination, a merger or reverse merger with another company, a strategic investment into our company, a sale, license or other disposition of corporate assets of our company or continuing with the current business plan. We have not set a timetable for completion of the review process. No decision has been made as to whether we will engage in a transaction or transactions, and there can be no assurance that this process will result in any transaction, or the terms or timing of any potential transaction.

Development Programs

Our current pipeline consists of the following product candidates, which we are developing in collaboration with Precigen Inc. (Precigen):

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Our most advanced product candidate, FCX-007, has entered the Phase 2 portion of a Phase 1/2 clinical trial for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). Our second gene therapy product candidate, FCX-013, is in development for the treatment of moderate to severe localized scleroderma. We submitted an investigational new drug (IND) application for FCX-013 to the United States Food and Drug Administration (FDA) in January 2018 and in March 2018, the FDA allowed the IND to progress to clinical trials. We initiated the first investigator site for clinical enrollment for an open label, single arm Phase 1/2 clinical trial in August 2018. In addition, we have a third program in the research phase for the treatment of arthritis and related conditions. See further discussion of our gene therapy product candidates under the heading “Development Programs” found in section “Item 1-Business” of the 2017 Form 10-K.

Precigen Collaborations

We collaborate with Precigen, a wholly owned subsidiary of Intrexon Corporation (Intrexon), a related party, through two distinct exclusive channel collaboration agreements consisting of the Exclusive Channel Collaboration Agreement entered into in October 2012 as amended (the 2012 ECC) and the Exclusive Channel Collaboration Agreement entered into in December 2015 (the 2015 ECC). Pursuant to these agreements, we engage Precigen for support services for the research and development of product candidates covered under the respective agreements and reimburse Precigen for its cost for time and materials for such work. We are developing FCX-007 and FCX-013 under the 2012 ECC and we are in the research phase for a gene-therapy treatment for arthritis and related conditions under the 2015 ECC. For additional details, see Note 8 in the accompanying Notes to the Condensed Consolidated Financial Statements included in this Form 10-Q and additional disclosures included in our 2017 Form 10-K.

FCX-007 for Recessive Dystrophic Epidermolysis Bullosa (RDEB)

RDEB is the most severe form of dystrophic epidermolysis bullosa (DEB), a congenital, progressive, devastatingly painful and debilitating genetic disorder that often leads to death. RDEB is caused by a mutation of the COL7A1 gene, the gene which encodes for type VII collagen (COL7), a protein that forms anchoring fibrils. Anchoring fibrils hold together the layers of skin, and without them, skin layers separate causing severe blistering, open wounds and scarring in response to friction, including normal daily activities like rubbing or scratching. Children who inherit this condition are often called “butterfly children” because their skin can be as fragile as a butterfly’s wings. We estimate that there are approximately 1,100 - 2,500 RDEB patients in the U.S. Currently, treatments for RDEB address only the sequelae, including daily bandaging (which can cost a patient in excess of $10,000 per month), hydrogel dressings, antibiotics, feeding tubes and surgeries.

Our lead product candidate, FCX-007, is in clinical development for the treatment of RDEB. FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for COL7 for localized treatment of RDEB and is being developed in collaboration with Precigen. By genetically modifying autologous fibroblasts ex vivo to produce COL7, culturing them and then treating blisters and wounds locally via injection, FCX-007 offers the potential to address the underlying cause of the disease by providing high levels of COL7 directly to the affected areas, thereby avoiding systemic treatment. In addition, we believe the autologous nature of the cells, localized delivery, use of an integrative vector and the low turnover rate of the protein will contribute to long-term persistence of the COL7 produced by FCX-007.

FCX-007 has received Orphan Drug Designation for the treatment of DEB, including RDEB, Rare Pediatric Disease Designation for the treatment of RDEB and Fast Track Designation for the treatment of RDEB from the FDA.

In September 2018, the FDA’s Office of Orphan Products Development (OOPD) awarded a $1.4 million clinical trial research grant for Fibrocell’s continued development of FCX-007. This grant, which will be distributed over the next

four years, was awarded by the FDA through the OOPD's Orphan Products Clinical Trials Grants Program. This program supports the clinical development of products for use in rare diseases or conditions for which "no current therapy exists or where the proposed product will be superior to the existing therapy".

In October 2018, we completed a Type C meeting with the FDA to discuss the design of a Phase 3 clinical trial protocol for FCX-007. The meeting was facilitated by the current data in our ongoing Phase 1/2 clinical trial of FCX-007 and the recent publication of draft guidance from the FDA in the areas of gene therapy and epidermolysis bullosa. The FDA provided us with guidance on various design aspects of our proposed Phase 3 clinical trial. In addition, the FDA offered guidance on Chemistry, Manufacturing and Control requirements for the proposed Phase 3 clinical trial and a potential future Biologics License Application for FCX-007. Based on the feedback from this meeting, we plan to submit the protocol in the fourth quarter of 2018 and will provide details on the clinical trial design once it is finalized. We plan to continue the Phase 2 portion of the ongoing Phase 1/2

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clinical trial to collect additional data while submitting the Phase 3 protocol in parallel. Furthermore, we plan to initiate a Phase 3 clinical trial for FCX-007 in the first half of 2019.

To date, we have not yet received the official FDA meeting minutes from the Type C meeting and the preceding information may be altered or supplemented by the information contained in the official meeting minutes. We will provide further regulatory updates on FCX-007 after receipt of the official FDA minutes or other correspondence if there are material developments in such minutes or correspondence.

Phase 1/2 Trial of FCX-007 for RDEB

The primary objective of this open-label trial is to evaluate the safety of FCX-007 in RDEB patients. Additionally, the trial will assess (i) the pharmacology of FCX-007 through the presence of vector DNA or COL7 mRNA evaluation of COL7 expression and/or the presence of anchoring fibrils and (ii) the efficacy of FCX-007 through intra-subject paired analysis of target wound areas by comparing FCX-007 treated wounds to untreated wounds. Prior to treating pediatric patients in this trial, we were required to obtain allowance from the FDA by submitting evidence of FCX-007 safety and benefit in adult patients and data from our completed pre-clinical toxicology study. After submission of the requested data, the FDA granted allowance to include pediatric patients in the clinical trial in January 2018.

In May 2018, we reported on interim adult data and provided a Phase 1 trial update which included presenting at the 7th International Investigative Dermatology meeting on May 19, 2018. We reported that four adult patients (n=7 wounds) aged 20 to 37 were dosed with FCX-007 in the margins of and across targeted wounds, as well as in separate intact skin sites. Three patients received a single intradermal injection session at baseline. One patient received a second injection session in the remaining unhealed areas of wounds at 25 weeks post-administration, as allowed by the clinical trial protocol.

Safety data from these patients show FCX-007 was well-tolerated up to 52 weeks post-administration. There were no serious adverse events and no product related adverse events reported. No COL7 autoantibody response was noted. Various COL7 expression signals were detected throughout the data set using either immunofluorescence (IF) or immunoelectron microscopy (IEM) up to 52 weeks post-administration. Anchoring fibril structures have also been observed using IEM.

Wounds were evaluated during a monitoring period prior to dosing and they were observed to be open for up to eight months. Compared to the baseline measurement collected at Day 0 before the administration of FCX-007, the percentage of dosed wounds healing > 50% when compared to baseline were observed as follows:

- 100% (7/7) at 4 weeks post-administration
- 86% (6/7) at 12 weeks
- 67% (2/3) at 25/32 weeks
- 100% (1/1) at 52 weeks

A similar trend was also observed for treated wounds healing > 75% when compared to baseline. Untreated wounds of similar size to the treated wounds were selected and monitored as controls on each patient. The percentage of untreated control wounds healing > 50% when compared to baseline were observed as follows:

- 14% (1/7) at 4 weeks post-administration
- 17% (1/6) at 12 weeks
- 0% (0/2) at 25/32 weeks
- 0% (0/1) at 52 weeks

Based on safety, pharmacology and wound healing data from the Phase 1 portion of the trial, we have incorporated learnings on dose and administration in our clinical trial protocol, including an increase in the overall cells administered and a reduction of the interval between injections.

We completed the targeted enrollment of six patients in the Phase 2 portion of the Phase 1/2 clinical trial for FCX-007, and have over-enrolled by one patient for a total of seven patients. The Phase 2 population consists of one adult and six pediatric patients. We expect to report an interim data analysis for the Phase 1/2 trial, including available data from Phase 2 patients, in the first quarter of 2019. We plan to continue the Phase 2 portion of our ongoing Phase 1/2 clinical trial to collect additional data while submitting the Phase 3 clinical trial protocol to the FDA in parallel.

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We plan to use data from the Phase 1/2 clinical trial to also support a petition for Regenerative Medicine Advanced Therapy or Breakthrough Therapy Designation for FCX-007.

We have designated our existing, current good manufacturing practices (cGMP) cell therapy manufacturing facility in Exton, PA as the production site for FCX-007 in our IND application. The FCX-007 drug product dosed in the fourth quarter of 2017 was produced and distributed from our Exton, PA facility. This multi-product, gene therapy manufacturing facility will be used for the remaining clinical and, if approved, future commercial manufacture of FCX-007, as we have sufficient cGMP vector supply on hand and existing capacity to serve the U.S. market for RDEB. The approximately 13,000 square foot facility previously supported commercial autologous fibroblast manufacturing, with multiple FDA inspections conducted at the site. The facility includes cleanroom cell therapy manufacturing, quality control testing, cryogenic storage, shipping/receiving and warehousing space.

FCX-013 for Moderate to Severe Localized Scleroderma

Localized scleroderma is a chronic autoimmune skin disorder that manifests as excess production of extracellular matrix, specifically collagen, resulting in thickening of the skin and connective tissue. Localized scleroderma encompasses several subtypes which are classified based on the depth and pattern of the lesion(s). The moderate to severe forms of the disorder include any subtype that affects function or produces symptoms of discomfort, tightness and pain. Current treatments for localized scleroderma include systemic or topical corticosteroids which target inflammation, UVA light therapy and physical therapy. There are few treatment options that address excessive collagen accumulation in the skin and connective tissue. We estimate that there are approximately 90,000 patients in the U.S. considered to have moderate to severe localized scleroderma.

Our second clinical stage, gene therapy product candidate, FCX-013, is in development for the treatment of moderate to severe localized scleroderma. FCX-013 is an autologous fibroblast genetically-modified using lentivirus and encoded for matrix metalloproteinase 1 (MMP-1), the protein responsible for breaking down collagen. FCX-013 incorporates Precigen's proprietary RheoSwitch Therapeutic System® (RTS®), a biologic switch activated by an orally administered compound (Veledimex) to control protein expression at the site of localized scleroderma lesions. FCX-013 is designed to be injected under the skin at the location of the fibrotic lesions where the genetically-modified fibroblast cells will produce MMP-1 to break down excess collagen accumulation. With the FCX-013 therapy, the patient will take Veledimex to facilitate protein expression. Once the fibrosis is resolved, the patient will stop taking Veledimex which will halt further MMP-1 production.

We previously completed a proof-of-concept study for FCX-013 in which the primary objective was to determine whether FCX-013 had the potential to reduce dermal thickness in fibrotic tissue. In this study, FCX-013 was evaluated in a bleomycin-induced scleroderma model utilizing severe combined immunodeficiency (SCID) mice. Data from the study demonstrated that FCX-013 reduced dermal thickness of fibrotic tissue to levels similar to that of the non-bleomycin treated control and further reduced the thickness of the sub-dermal muscle layer. Based upon this data and the FDA's feedback to our pre-IND briefing package, we advanced FCX-013 into a pre-clinical dose-ranging study which has been completed.

In December 2017, we completed a good laboratory practice (GLP) toxicology/biodistribution study that assessed FCX-013 in a bleomycin fibrosis model using immunocompromised (NOD/SCID) mice. Data from this study showed no test article-related clinical observations, body weight changes, changes in clinical pathology parameters, gross observations or organ weight change. In addition, there was no significant vector biodistribution to target organs.

We submitted an IND for FCX-013 to the FDA in January 2018, and in March 2018, the FDA allowed the IND to progress to clinical trials. We initiated the first investigator site for clinical enrollment for an open label, single arm Phase 1/2 clinical trial in August 2018. The primary objective of the trial is to evaluate the safety of FCX-013.

Secondary analyses consist of several fibrosis assessments including histology, skin scores, ultrasound and additional measurements of targeted sclerotic lesions and control sites at various time points up to 16 weeks post-administration of FCX-013. We are targeting ten patients with any subtype of localized scleroderma are targeted for enrollment (approximately 5 patients per Phase). The Phase 1 portion will enroll adult patients, and dosing for the first three adult patients will be staggered prior to dosing the rest of the trial's population. We intend to include pediatric patients in the Phase 2 portion of the trial after submission and approval of safety and activity data from the adult Phase 1 patients from the FDA and the DSMB for the trial. We plan to manufacture FCX-013 at our Exton, PA cGMP manufacturing facility.

FCX-013 has received Orphan Drug Designation from the FDA for the treatment of localized scleroderma and Rare Pediatric Disease Designation and in September 2018, Fast Track Designation for moderate to severe localized scleroderma.

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Gene Therapy Research Program for Arthritis and Related Conditions

Arthritis is a broad term that covers a group of more than 100 different types of diseases that affect the joints, as well as connective tissues and organs, including the skin. According to the Centers for Disease Control and Prevention, arthritis-characterized by joint inflammation, pain and decreased range of motion-is the United States' most common cause of disability affecting more than 52 million adults as well as 300,000 children at a cost exceeding $120 billion.

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

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Financial Condition, Liquidity and Capital Resources

Financial Condition

We have experienced losses since our inception. As of September 30, 2018, we had an accumulated deficit of $187.5 million. The process of developing and commercializing our product candidates requires significant research and development efforts and clinical trial work, as well as significant manufacturing and process development. These activities, together with our selling, general and administrative expenses, are expected to continue to result in significant operating losses for the foreseeable future.

Our financial condition is summarized below as of the following dates and is intended to supplement the more detailed discussion that follows:

($ in thousands)	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 16,111	$ 17,417
Working capital:		
Total current assets	$ 16,405	$ 17,902
Less: Total current liabilities	1,811	4,425
Net working capital	$ 14,594	$ 13,477
Convertible notes payable (gross principal)	$ 18,003	$ 18,003
Stockholders' equity	$ 10,184	$ 9,007

Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents of $16.1 million and net working capital of $14.6 million as of September 30, 2018. Net working capital increased approximately $1.1 million, or 8.3%, from December 31, 2017 to September 30, 2018. This increase is the result primarily from the money raised in the May 2018 Registered Direct Offering and May 2018 Private Placement, and the July 2018 Registered Direct Offering and July 2018 Private Placement, (each as defined below), less the net loss incurred for the first nine months of 2018. We believe that our existing cash and cash equivalents will be sufficient to fund our operations into the fourth quarter of 2019. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. We will require additional capital to fund operations beyond that point and prior to our business achieving significant net cash from operations. Our future capital requirements may be substantial, and will depend on many factors, including, but not limited to:

- the results of our Board's analysis of strategic alternatives, including a potential sale of our company;
- the cost of clinical activities and outcomes related to our Phase 1/2 clinical trial for FCX-007 and our proposed Phase 3 clinical trial for FCX-007;
- the costs of clinical activities related to FCX-013, for which we received FDA allowance for our IND in the first quarter of 2018;
- the cost of additional pre-clinical studies and clinical trials in order to obtain regulatory approvals for our product candidates;
- the cost of regulatory submissions, as well as the preparation, initiation and execution of clinical trials in potential new clinical indications; and
- the cost of filing, surveillance around, prosecuting, defending and enforcing patent claims.

To meet our capital needs, we will consider multiple alternatives, including but not limited to equity financings, debt financings, corporate collaborations, partnerships and other strategic transactions and funding opportunities. However, there is no assurance that we will be able to complete any such transaction or obtain the additional required capital on acceptable terms or otherwise. Furthermore, the covenants under our convertible notes limit our ability to obtain additional debt financing. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, will result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our

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ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt or equity financing that we complete may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration or partnership arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs and modify our business strategy which may require us to, among other things:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives;
- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- sell or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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

These factors raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent registered public accounting firm relating to our Consolidated Financial Statements for the year ended December 31, 2017 found in the 2017 Form 10-K includes a paragraph related to the substantial doubt about our ability to continue as a going concern.

Nasdaq Deficiency Notice

On January 23, 2018, we received (the Notice) from the Nasdaq Capital Market (Nasdaq) that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock has been below $1.00 per share for 30 consecutive business days. On May 24, 2018, the Company implemented a one-for-five reverse split of its issued and outstanding shares of the Company’s common stock (the Reverse Stock Split), as authorized at the annual meeting of stockholders on May 23, 2018. The Reverse Stock Split became effective on May 24, 2018 at 5:00 pm and the Company’s common stock began trading on Nasdaq on a post-split basis at the open of business on May 25, 2018. As of a result of the Reverse Stock Split, every five shares of the Company’s issued and outstanding common stock were combined into one share of its common stock, except to the extent that the Reverse Stock Split resulted in any of the Company’s stockholders owning a fractional share, which was rounded up to the next highest whole share. In connection with the Reverse Stock Split, there was no change in the nominal par value per share of $0.001. The Reverse Stock Split was effectuated in order to increase the per share trading price of the Company’s common stock to satisfy the $1.00 minimum bid price requirement for continued listing on Nasdaq. On June 11, 2018, the Company received written notice from Nasdaq notifying the Company that the closing bid price for the Company's common stock had been at $1.00 per share or greater for a minimum of ten consecutive business days and accordingly, the Company had regained compliance with Nasdaq Listing Rule 5550(a)(2). All share and per share amounts of common stock, options and warrants in the accompanying financial statements and related footnotes, have been restated for all periods to give retroactive effect to the Reverse Stock Split. Accordingly, the Condensed Consolidated Statement of Stockholders’ Equity reflects the impact of the Reverse Stock Split by reclassifying from “Common Stock” to “Additional paid-in capital” an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split.

Nasdaq Equity Requirement

Nasdaq has the authority, pursuant to Nasdaq Listing Rule 5550(b)(1), to delist our common stock if our stockholders' equity falls below $2.5 million. As of September 30, 2018, our stockholders' equity was approximately $10.2 million. If our stockholders' equity is hereafter reduced below $2.5 million as a result of operating losses or for other reasons, we will fail to meet Nasdaq's stockholders' equity requirement. If that occurs, or if we are unable to demonstrate to Nasdaq's satisfaction that we will be able to sustain compliance with this requirement, Nasdaq may delist our common stock. In addition, even if we regain technical compliance with the stockholders' equity requirement, we will have to continue to meet other objective and subjective listing requirements to continue to be listed on Nasdaq, including the requirement that our common stock continues to trade above $1.00. For the nine months ended September 30, 2018, we incurred a net loss of approximately $8.7 million and

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used approximately $10.2 million in operating activities and had an accumulated deficit of $187.5 million as of September 30, 2018.

We are actively monitoring our stockholders' equity and will consider any and all options available to us to maintain compliance. There can be no assurance, however, that we will be able to maintain compliance and meet Nasdaq's minimum stockholders' equity requirements.

2017 Series A Preferred Stock Offering

On March 8, 2017, we completed the sale of 8,000 units (the Units) for a purchase price of $1,000 per Unit, with each Unit consisting of (i) one share of our Series A Convertible Preferred Stock (the Series A Preferred Stock), with an initial stated value of $1,000 that is convertible into shares of our common stock with a conversion price of $11.6355 and (ii) a warrant to purchase up to a number of shares of common stock equal to 100% of the conversion shares issuable on March 7, 2017 pursuant to the shares of Series A Preferred Stock purchased by each investor (collectively, the 2017 Series A Preferred Stock Offering) for the sale of $8.0 million to certain of our existing investors, including certain related parties such as Intrexon. After deducting offering expenses, net proceeds from the Series A Preferred Stock Offering, excluding the proceeds, if any, from the exercise of the warrants, was approximately $7.6 million.

2017 Common Stock and Warrant Offering

On December 11, 2017, we completed the sale of 1,542,832 shares of our common stock, pre-funded warrants to purchase an aggregate of 1,184,442 shares of our common stock and common warrants to purchase up to an aggregate of 2,727,273 shares of our common stock (the December 2017 Offering) for $10.5 million. After deducting offering expenses, net proceeds from the December 2017 Offering excluding the proceeds, if any, from the exercise of the warrants, was approximately $9.3 million.

May 2018 Registered Direct Offering and Private Placement

On May 31, 2018, we completed the sale of 2,038,224 shares of our common stock (the May 2018 Registered Direct Offering), and common warrants to purchase up to an aggregate of 1,528,668 shares of our common stock (the May 2018 Private Placement) for approximately $6.0 million. After deducting offering expenses, net proceeds from the May 2018 Registered Direct Offering and the May 2018 Private Placement was approximately $5.3 million.

July 2018 Registered Direct Offering and Private Placement

On July 5, 2018, we completed the sale of 1,474,080 shares of our common stock (the July 2018 Registered Direct Offering), and common warrants to purchase up to an aggregate of 958,152 shares of our common stock (the July 2018 Private Placement) for approximately $4.0 million. After deducting offering expenses, net proceeds from the July 2018 Registered Direct Offering and the July 2018 Private Placement was approximately $3.6 million.

For additional details, see Risks Related to Our Financial Position and Need for Additional Capital included within Part I, Item 1A, "Risk Factors" of our 2017 Form 10-K.

Cash Flows

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

	Nine months ended September 30,	
($ in thousands)	2018	2017

Net cash flows (used in) provided by:		
Operating activities	$(10,217)	$(12,879)
Investing activities	$(155)	$(348)
Financing activities	$9,066	$7,623

Operating Activities. Cash used in operating activities during the nine months ended September 30, 2018 was approximately $10.2 million, which is approximately $2.7 million, or 21% less than the nine months ended September 30, 2017. This decrease

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was primarily the result of lower costs related to the Phase 1/2 clinical trial for FCX-007, and lower costs related to the completed pre-clinical work on FCX-013.

Investing Activities. Cash used in investing activities during both the nine months ended September 30, 2018 and 2017 was related solely to equipment and leasehold improvement purchases.

Financing Activities. Cash provided by financing activities during the nine months ended September 30, 2018 was approximately $9.0 million from the May 2018 Registered Direct Offering and May 2018 Private Placement, and the July 2018 Registered Direct Offering and July 2018 Private Placement. Cash provided by financing activities during the nine months ended September 30, 2017 was approximately $7.6 million from the net proceeds from our Series A Preferred Stock Offering in March 2017.

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Results of Operations

Comparison of Three and Nine Months Ended September 30, 2018 and 2017

Research and Development Expense

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

Direct research and development costs, by major program, and indirect research and development costs, by major component, were as follows:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
($ in thousands)	2018	2017	% Change	2018	2017	% Change	
Direct costs:							
FCX-007	$477	$629	(24.2)%	$613	$3,602	(83.0)%	(1)
FCX-013	35	767	(95.4)%	375	1,832	(79.5)%	(2)
Other	5	25	(80.0)%	(36)	57	(163.2)%	(3)
Total direct costs	517	1,421	(63.6)%	952	5,491	(82.7)%	
Indirect costs:							
Regulatory costs	7	18	(61.1)%	19	79	(75.9)%	(4)
Compensation and related expense	500	527	(5.1)%	1,552	1,534	1.2 %	(5)
Other indirect R&D costs	580	672	(13.7)%	1,944	1,864	4.3 %	(6)
Total indirect costs	1,087	1,217	(10.7)%	3,515	3,477	1.1 %	
Total research and development expense	$1,604	$2,638	(39.2)%	$4,467	$8,968	(50.2)%	

(1) Costs for our FCX-007 program decreased approximately $0.2 million, or 24.2%, for the three months ended September 30, 2018 compared to the same period in 2017. The decrease for the three month period ended September 30, 2018 was related to decreased costs from (1) our clinical partner Precigen, as the Phase 1 portion of the clinical trial was substantially completed at the end of 2017 and (2) movement in-house of the manufacturing of the drug product used in our Phase 1/2 clinical trial of FCX-007 previously contracted to a third party manufacturer.

Costs for our FCX-007 program decreased approximately $3.0 million, or 83.0%, for the nine months ended September 30, 2018 compared to the same period in 2017. The decrease for the nine month period ended September 30, 2018 was related to decreased costs from (1) our clinical partner Precigen, as the Phase 1 portion of the clinical trial was substantially completed at the end of 2017; (2) movement in-house of the manufacturing of the drug product used in our Phase 1/2 clinical trial of FCX-007 previously contracted to a third party manufacturer and (3) a decrease of approximately $0.5 million in an estimate of costs to settle a dispute with one of Precigen’s vendors, for which a settlement was agreed to and was paid by us in the three months ended September 30, 2018.

Through September 30, 2018, we incurred approximately $25.4 million in direct research and development costs related to this program, life-to-date, which include non-cash expenses of $6.9 million in stock issuance costs associated with the 2012 ECC with Precigen. Other costs include product and assay development, key opinion leader development, pre-clinical studies and manufacturing, the design of the Phase 1/2 clinical trial protocol and recruiting patients. Going forward, research and development investments for this program are expected to support clinical product manufacturing, statistical analyses, report generation and future clinical trial costs.

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(2) Costs for our FCX-013 program decreased approximately $0.7 million, or 95.4%, for the three months ended September 30, 2018 compared to the same period in 2017. This decrease was related primarily to decreased costs from our clinical partner Precigen of approximately $0.7 million, as substantially all of the costs of the pre-clinical phase of the project were completed at the end of 2017.

Costs for our FCX-013 program decreased approximately $1.5 million, or 79.5%, for the nine months ended September 30, 2018 compared to the same period in 2017. This decrease was related primarily to decreased costs from our clinical partner Precigen of approximately $1.3 million, as substantially all of the costs of the pre-clinical phase of the project were completed at the end of 2017.

Through September 30, 2018, we incurred approximately $14.2 million in direct research and development costs related to this program, life-to-date, which include non-cash expenses of $6.4 million in stock issuance costs with the 2012 ECC with Precigen. Other costs include product and assay development and pre-clinical work, including execution of our proof-of concept and pre-clinical dose-ranging studies. Going forward, research and development investments for this program are expected to support ongoing product and assay development, pre-clinical study execution, key opinion leader development, National Institutes of Health Recombinant DNA Advisory Committee meeting preparation expenses, and the design and execution of clinical trials.

(3) Other costs were not significant for the three and nine months ended September 30, 2018 and 2017.

(4) Regulatory costs were not significant for the three and nine months ended September 30, 2018 and 2017.

(5) Compensation and related expense was comparable for both the three and nine months ended September 30, 2018 and September 30, 2017.

(6) Other indirect costs decreased approximately $0.1 million, or 13.7%, for the three months ended September 30, 2018, as compared to the same period in 2017. This decrease was the result primarily of decreased consulting expenses.

Other indirect costs were comparable for the nine months ended September 30, 2018 and September 30, 2017.

Selling, General and Administrative Expense

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

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
($ in thousands)	2018	2017	% Change	2018	2017	% Change	
Compensation and related expense	$431	$430	0.2 %	$1,306	$1,207	8.2 %	(1)
Severance expense	—	—	— %	—	137	(100.0)%	(2)
Professional fees	331	718	(53.9)%	1,140	1,680	(32.1)%	(3)
Facilities and related expense and other	739	810	(8.8)%	2,250	2,085	7.9 %	(4)
Total selling, general and administrative expense	$1,501	$1,958	(23.3)%	$4,696	$5,109	(8.1)%	

(1) Compensation and related expense were comparable for the three months ended September 30, 2018 and 2017.

Compensation and related expense increased approximately $0.1 million, or 8.2%, for the nine months ended September 30, 2018 as compared to the same period in 2017. This increase was due primarily to higher costs for stock compensation expense and partially offset by lower salary and salary related costs.

(2) Severance expense decreased approximately $0.1 million or 100%, for the nine months ended September 30, 2018 as compared to the same period in 2017. This decrease was attributable to the resignation and severance agreements with two members of management in the 2017 period. There was no such activity or expense in the 2018 period.

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(3) Professional fees decreased approximately $0.4 million, or 53.9%, for the three months ended September 30, 2018 as compared to the same period in 2017. This decrease was due primarily to decreased legal and accounting fees. Professional fees decreased approximately $0.5 million, or 32.1%, for the nine months ended September 30, 2018 as compared to the same period in 2017. This decrease was due primarily to decreased legal and accounting fees.

(4) Facilities and related expense and other, decreased approximately $0.1 million, or 8.8%, for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. This decrease was due primarily to reduced Board fees and industry conference costs. Facilities and related expense and other, increased approximately $0.2 million, or 7.9%, for the nine months ended September 30, 2018 as compared to the same period in 2017. This increase was due primarily to approximately $0.2 million of income recognized in the 2017 period, as a result of the release of certain reserves included in accrued expenses as of December 31, 2016.

Warrant Revaluation Income (Expense)

During the three months ended September 30, 2018 and 2017, we recorded non-cash income of approximately $0.3 million and $5.0 million, respectively, for warrant revaluation charges in our Condensed Consolidated Statements of Operations. The primary reason for the significant change between the warrant revaluation charges noted above was due to the decrease in our stock price (from $2.71 to $2.36) during the three months ended September 30, 2018 compared to the decrease (from $20.05 to $15.30) in our stock price during the three months ended September 30, 2017.

During the nine months ended September 30, 2018 and 2017, we recorded non-cash income of approximately $0.6 million and non-cash expense of approximately $4.7 million, respectively, for warrant revaluation charges in our Condensed Consolidated Statements of Operations. The primary reason for the significant change between the warrant revaluation charges noted above was due to the decrease in our stock price (from $3.20 to $2.36) during the nine months ended September 30, 2018 compared to the increase (from $9.45 to $15.30) in our stock price during the nine months ended September 30, 2017.

Due to the nature and inputs of the model used to assess the fair value of our outstanding warrants, it is normal to experience significant fluctuations from period to period. These fluctuations are due to a variety of factors including changes in our stock price, changes in the remaining contractual life of the warrants, and changes in management's estimated probability of certain events occurring that would impact the warrants.

Derivative Revaluation Income (Expense)

During the three months ended September 30, 2018 and 2017, we recorded non-cash derivative revaluation income of approximately $0.1 million and non-cash derivative revaluation expense of $0.3 million, respectively, for derivative liability revaluation charges in our Condensed Consolidated Statements of Operations related to a compound bifurcated derivative initially recorded in September 2016 in connection with the private placement of an aggregate of $18,087,500 in principal of convertible promissory notes and accompanying warrants to purchase an aggregate of 1,205,840 shares of our common stock to institutional and accredited investors (the 2016 Private Placement). The primary reason for the significant change between the derivative revaluation charges noted above was due to the decrease in our stock price (from $2.71 to $2.36) during the three months ended September 30, 2018 compared to the decrease (from $20.05 to $15.30) in our stock price during the three months ended September 30, 2017.

During the nine months ended September 30, 2018 and 2017, we recorded non-cash derivative revaluation income of approximately $0.3 million for both periods presented.

Due to the nature and inputs of the model used to assess the fair value of our compound bifurcated derivative, it is normal to experience significant fluctuations from period to period. These fluctuations are due to a variety of factors including changes in our stock price, changes in the remaining contractual life of the bifurcated derivative, and changes in management's estimated probability of certain events occurring that would impact the compound

bifurcated derivatives.

Interest Expense

During the three months ended September 30, 2018 and 2017, we recorded interest expense of approximately $0.2 million and $0.3 million, respectively, in our Condensed Consolidated Statements of Operations related to the convertible promissory notes that we issued in the 2016 Private Placement (the Convertible Notes) which bear interest at 4% per annum.

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The September 2017 period included approximately $0.1 million of debt amortization expense related to the conversion of approximately $0.1 million of principal value of the Convertible Notes into common stock of the Company.

During the nine months ended September 30, 2018 and 2017, we recorded interest expense of approximately $0.6 million in our Condensed Consolidated Statements of Operations related to the Convertible Notes.

Net Loss

Net loss increased approximately $2.8 million to $2.9 million for the three months ended September 30, 2018, as compared to a $0.1 million loss for the three months ended September 30, 2017. The increase in net loss was due primarily to an approximately $4.7 million decrease in warrants revaluation income, partially offset by an approximately $0.9 million decrease in related party research expenses, a decrease of approximately $0.5 million in selling, general and administrative expenses and an approximately $0.3 million decrease in derivative revaluation expense.

Net loss decreased approximately $10.4 million to $8.7 million for the nine months ended September 30, 2018, as compared to a $19.1 million loss for the nine months ended September 30, 2017. The decrease in net loss was due primarily to an approximately $5.3 million decrease in warrant revaluation expense, an approximately $4.3 million decrease in related party research expenses and a decrease of approximately $0.4 million in selling, general and administrative expenses.

Contractual Obligations

During the nine months ended September 30, 2018, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our 2017 Form 10-K.

Critical Accounting Policies

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

Our summary of significant accounting policies is described in Note 3 to our Consolidated Financial Statements contained in our 2017 Form 10-K. However, please refer to Note 3 in the accompanying Notes to the Condensed Consolidated Financial Statements contained in this Form 10-Q for updated policies and estimates, if applicable, that could impact our results of operations, financial position, and cash flows.

Recently Issued Accounting Pronouncements

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

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Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer (our principal executive officer and principal financial officer), have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of the end of the period covered by this Form 10-Q. Based upon that evaluation, our Chief Executive Officer (our principal executive officer and principal financial officer) concluded that, as of September 30, 2018, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and (b) such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer and principal financial officer), as appropriate to allow timely decisions regarding required disclosure.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarterly period ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any legal proceedings.

Item 1A. Risk Factors

You should carefully consider each of the risk factors set forth under the heading “Risk Factors” in our 2017 Form 10-K. 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.

Risks Related to our Financial Position and Need for Additional Capital

There can be no assurance that our review of strategic alternatives will result in any additional stockholder value, and speculation and uncertainty regarding the outcome of our review of strategic alternatives may adversely impact our business, financial condition and results of operations.

On April 18, 2018, we announced that our Board would begin conducting a review of strategic alternatives to maximize stockholder value. There can be no assurances that the strategic alternatives process will result in the announcement or consummation of any strategic transaction, or that any resulting plans or transactions will yield additional value for stockholders. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction and the availability of financing to potential buyers on reasonable terms. If we fail to successfully complete a strategic transaction, we may not be able to otherwise source adequate liquidity to fund our operations, meet our obligations (including our debt payment obligations) and continue as a going concern.

The process of exploring strategic alternatives could adversely impact our business, financial condition and results of operations. We could incur substantial expenses associated with identifying and evaluating potential strategic alternatives, including those related to equity compensation, severance pay and legal, accounting and financial advisory fees. In addition, the process may be time consuming and disruptive to our business operations, could divert the attention of management and the Board from our business, could negatively impact our ability to attract, retain and motivate key employees, and could expose us to potential litigation in connection with this process or any resulting transaction. Further, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to our future could cause our stock price to fluctuate significantly.

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

Other than as previously disclosed on our Current Reports on Form 8-K filed with the SEC, we did not issue any unregistered equity securities during the three months ended September 30, 2018.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Risk Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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Item 6. Exhibits.

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed on July 5, 2018)
4.2	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K, filed on July 5, 2018)
10.1	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed on July 5, 2018)
*31	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002
*32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

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SIGNATURES

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

FIBROCELL SCIENCE, INC.

By: /s/ John M. Maslowski
John M. Maslowski
President and Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: November 14, 2018