ELITE PHARMACEUTICALS INC /NV/
Form 10-Q
February 11, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 001-15697

ELITE PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

NEVADA	**22-3542636**
(State or other jurisdiction of	(I.R.S. Employer

incorporation or organization) Identification No.)

165 LUDLOW AVENUE

07647

NORTHVALE, NEW JERSEY

(Address of principal executive offices) (Zip Code)

(201) 750-2646

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically 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 No

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	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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.

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 820,500,139 shares of common stock were issued and outstanding as of February 6, 2019.

PART 1 – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2018 (Unaudited)	March 31, 2018 (Audited)
ASSETS		
Current assets:		
Cash	$ 3,680,559	$ 7,179,237
Accounts Receivable, net of allowance for doubtful accounts of $-0- and $-0-, respectively	660,443	675,879
Inventory	4,192,385	4,898,001
Prepaid expenses and other current assets	897,817	949,284
Total current assets	9,431,204	13,702,401
Property and equipment, net of accumulated depreciation of $9,340,159 and $8,408,979, respectively	8,755,408	8,993,708
Intangible assets, net of accumulated amortization of $-0- and $-0-, respectively	7,713,001	7,713,001
Other assets:		
Restricted cash - debt service for NJEDA bonds	396,135	391,566
Security deposits	81,616	81,932
Total other assets	477,751	473,498
TOTAL ASSETS	$ 26,377,364	$ 30,882,608
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts Payable	$ 2,309,109	$ 1,658,137
Accrued expenses	3,031,398	1,788,571
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion, net of bond issuance costs	80,822	75,822
Loans payable, current portion	505,747	578,841
Total current liabilities	6,940,409	5,114,704

Long-term liabilities:		
Deferred revenue, net of current portion	492,223	1,252,223
Bonds payable, net of current portion and bond issuance costs	1,423,769	1,508,134
Senior secured promissory note - related party	1,200,000	1,200,000
Loans payable, net current portion	775,188	623,020
Derivative financial instruments - warrants	1,860,524	2,667,871
Other long-term liabilities	45,885	41,144
Total long-term liabilities	5,797,589	7,292,392
TOTAL LIABILITIES	12,737,998	12,407,096

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(continued)

	December 31, 2018 (Unaudited)	March 31, 2018 (Audited)
Mezzanine equity		
Series J convertible preferred stock; par value $0.01; 50 shares authorized, 24.0344 issued and outstanding as of December 31, 2018; 50 shares authorized, 24.0344 issued and outstanding as of March 31, 2018	$13,903,960	$13,903,960
Shareholders' equity:		
Common stock; par value $0.001; 995,000,000 shares authorized; 820,500,139 shares issued and 820,400,139 outstanding as of December 31, 2018; 802,626,761 shares issued and 802,526,761 shares outstanding as of March 31, 2018	820,502	802,629
Additional paid-in capital	148,364,099	146,602,502
Treasury stock; 100,000 shares as of December 31, 2018 and March 31, 2018; at cost	(306,841)	(306,841)
Accumulated deficit	(149,142,354)	(142,526,738)
TOTAL SHAREHOLDERS' EQUITY	(264,594)	4,571,552
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY	$26,377,364	$30,882,608

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2018	2017	2018	2017
Manufacturing Fees	$2,108,487	$2,083,826	$4,456,832	$4,160,949
Licensing Fees	585,479	451,628	1,767,881	1,700,856
Total revenue	2,693,966	2,535,454	6,224,713	5,861,805
Cost of revenue	1,771,136	1,419,829	3,890,086	3,049,830
Gross Profit	922,830	1,115,625	2,334,627	2,811,975
Operating expenses:				
Research and development	2,454,098	2,289,273	6,236,192	6,397,777
General and administrative	748,151	614,994	2,245,900	2,068,028
Non-cash compensation through issuance of stock options	36,547	37,961	109,641	208,719
Depreciation and amortization	321,164	232,358	891,390	567,554
Total operating expenses	3,559,960	3,174,586	9,483,123	9,242,078
Loss from operations	(2,637,130)	(2,058,961)	(7,148,496)	(6,430,103)
Other income (expense):				
Interest expense and amortization of debt issuance costs	(89,897)	(92,458)	(279,037)	(245,730)
Change in fair value of derivative instruments	380,976	605,448	807,347	4,767,884
Interest income	1,733	4,461	4,570	12,862
Other income, net	292,812	517,451	532,880	4,535,016
Income (loss) from operations before income taxes	(2,344,318)	(1,541,510)	(6,615,616)	(1,895,087)
Net benefit from sale of state net operating loss credits	-	1,051,329	-	1,051,329
Net income (loss)	(2,344,318)	(490,181)	(6,615,616)	(843,758)
Change in carrying value of convertible preferred share mezzanine equity	-	-	-	-
Net income (loss) attributable to common shareholders	(2,344,318)	(490,181)	(6,615,616)	(843,758)

Basic loss per share attributable to common shareholders	$(0.00)	$(0.00)	$(0.01)	$(0.00)
Diluted loss per share attributable to common shareholders	$(0.00)	$(0.00)	$(0.01)	$(0.01)
Basic weighted average Common Stock outstanding	819,412,807	788,442,363	811,603,678	796,647,284
Diluted weighted average Common Stock outstanding	819,468,881	795,122,364	811,659,752	803,327,285

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(UNAUDITED)

	Common Stock		**Additional Paid-In**	Treasury Stock		**Accumulated**	**Total Shareholders'**
	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance at March 31, 2018	802,626,761	$802,629	$146,602,502	100,000	$(306,841)	$(142,526,738)	$4,571,552
Net loss	-	-	-	-	-	(6,615,616)	(6,615,616)
Common Stock sold pursuant to the Lincoln Park purchase agreement	17,642,083	17,642	1,652,187	-	-	-	1,669,829
Common Stock issued as additional commitment shares pursuant to the LPC purchase agreement	231,295	231	23,222	-	-	-	23,453
Costs associated with raising capital	-	-	(23,453)	-	-	-	(23,453)
Non-cash compensation through the issuance of employee stock options	-	-	109,641	-	-	-	109,641
Balance at December 31, 2018	820,500,139	$820,502	$148,364,099	100,000	$(306,841)	$(149,142,354)	$(264,594)

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$(6,615,616)	$(843,758)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	941,814	706,759
Change in fair value of derivative financial instruments - warrants	(807,347)	(4,767,884)
Non-cash compensation accrued	1,365,000	925,000
Non-cash compensation from the issuance of Common Stock and options	109,641	208,719
Non-cash rent expense and lease accretion	4,738	7,820
Change in operating assets and liabilities:		
Accounts receivable	15,436	(227,181)
Inventory	705,616	1,117,023
Prepaid expenses and other current assets	(144,849)	(622,480)
Accounts payable, accrued expenses and other current liabilities	528,805	460,338
Deferred revenue and customer deposits	(760,000)	(760,000)
Net cash used in operating activities	(4,656,762)	(3,795,644)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(19,130)	(291,115)
Intellectual property costs	-	(85,518)
Net cash used in investing activities	(19,130)	(376,633)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of stock	1,669,829	1,208,100
Proceeds from cash warrant and options exercises	-	181,908
Payment of bond principal	(90,000)	(85,000)
Other loan proceeds (payments), net	(398,046)	(431,507)
Costs associated with raising capital	-	(49,956)
Net cash (used in) provided by financing activities	1,181,783	823,545
Net change in cash and restricted cash	(3,494,109)	(3,348,732)
Cash and restricted cash, beginning of period	7,570,803	10,983,774
Cash and restricted cash, end of period	$4,076,694	$7,635,042
Supplemental disclosure of cash and non-cash transactions:		

Cash paid for interest	$151,754	$67,573
Financing of equipment purchases and insurance renewal	$477,116	$498,604
Issuance of Senior Secured Promissory Note pursuant ANDA asset acquisition	---	$1,200,000
Commitment shares issued to Lincoln Park Capital	$23,453	$942,654
Retirement of Common Stock pursuant to the issuance of Series J convertible preferred shares	---	$20,378,631

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview

Elite Pharmaceuticals, Inc. (the "Company" or "Elite") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary Elite Laboratories, Inc. ("Elite Labs") which was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada. Elite Labs engages primarily in researching, developing and licensing proprietary orally administered, controlled-release drug delivery systems and products with abuse deterrent capabilities and the manufacture of generic, oral dose pharmaceuticals. The Company is equipped to manufacture controlled-release products on a contract basis for third parties and itself, if and when the products are approved. These products include drugs that cover therapeutic areas for pain, allergy, bariatric and infection. Research and development activities are done so with an objective of developing products that will secure marketing approvals from the United States Food and Drug Administration ("FDA"), and thereafter, commercially exploiting such products.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and in conformity with the instructions on Form 10-Q and Rule 8-03 of Regulation S-X and the related rules and regulations of the Securities and Exchange Commission ("SEC"). The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Elite Laboratories, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring accruals, which are, in the opinion of management, necessary for a fair presentation of such statements. The results of operations for the three and nine months ended December 31, 2018 are not necessarily indicative of the results that may be expected for the entire year.

Reclassifications

Certain reclassifications have been made to the prior period financial statements to conform to the current period financial statement presentation. These reclassifications had no effect on net earnings or cash flows as previously reported.

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC 280"), *Segment Reporting*, establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the Chief Executive Officer, who reviews the financial performance and the results of operations of the segments prepared in accordance with GAAP when making decisions about allocating resources and assessing performance of the Company.

The Company has determined that its reportable segments are products whose marketing approvals were secured via an Abbreviated New Drug Applications ("ANDA") and products whose marketing approvals were secured via a New Drug Application ("NDA"). ANDA products are referred to as generic pharmaceuticals and NDA products are referred to as branded pharmaceuticals.

There are currently no intersegment revenues. Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's condensed unaudited consolidated financial statements.

Revenue Recognition

The Company generates revenue from the development of pain management products, manufacturing of a line of generic pharmaceutical products with approved ANDA, commercialization of products either by license and the collection of royalties, or through the manufacture of formulations and the development of new products and the expansion of licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations. The Company also generates revenue through its focus on the development of various types of drug products, including branded drug products which require NDAs.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Under ASC 606, *Revenue from Contacts with Customers* ("ASC 606"), the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which is expected to be received in exchange for those goods or services. The Company recognize revenues following the five-step model prescribed under ASC 606: (i) identify contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenues when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Nature of goods and services

The following is a description of the Company's goods and services from which the Company generates revenue, as well as the nature, timing of satisfaction of performance obligations, and significant payment terms for each, as applicable:

a) Manufacturing Fees

The Company is equipped to manufacture controlled-release products on a contract basis for third parties, if and when the products are approved. These products include products using controlled-release drug technology and products utilizing abuse deterrent technologies. The Company also develops and markets (either on its own or by license to other companies) generic and proprietary controlled-release and abuse deterrent pharmaceutical products.

The Company recognizes revenue when the customer obtains control of the Company's product based on the contractual shipping terms of the contract. Revenue on product are presented gross because the Company is primarily

responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer.

b) License Fees

The Company enters into licensing and development agreements, which may include multiple revenue generating activities, including milestones payments, licensing fees, product sales and services. The Company analyzes each element of its licensing and development agreements in accordance with ASC 606 to determine appropriate revenue recognition. The terms of the license agreement may include payment to the Company of licensing fees, non-refundable upfront license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes revenue from non-refundable upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer. For those milestone payments which are contingent on the occurrence of particular future events (for example, payments due upon a product receiving FDA approval), the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2018.

In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the customer's products occurs.

Disaggregation of revenue

In the following table, revenue is disaggregated by type of revenue generated by the Company and timing of revenue recognition. The table also includes a reconciliation of the disaggregated revenue with the reportable segments:

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2018	2017	2018	2017
NDA:				
Licensing fees	$250,000	$250,000	$750,000	$750,000
Total NDA revenue	250,000	250,000	750,000	750,000
ANDA:				

Manufacturing fees	$2,108,487	$2,083,826	$4,456,832	$4,160,949
Licensing fees	335,479	201,628	1,017,881	950,856
Total ANDA revenue	2,443,966	2,285,454	5,474,713	5,111,805
Total revenue	$2,693,966	$2,535,454	$6,224,713	$5,861,805

Collaborative Arrangements

Contracts are considered to be collaborative arrangements when they satisfy the following criteria defined in ASC 808, *Collaborative Arrangements*:

The parties to the contract must actively participate in the joint operating activity; and,

The joint operating activity must expose the parties to the possibility of significant risk and rewards, based on whether or not the activity is successful.

The Company entered into a sales and distribution licensing agreement with Epic Pharma LLC, (“Epic”) dated June 4, 2015 (the “2015 Epic License Agreement”), which has been determined to satisfy the criteria for consideration as a collaborative agreement, and is accounted for accordingly, in accordance with GAAP.

The Company entered into a Master Development and License Agreement with SunGen Pharma LLC dated August 24, 2016 (the “SunGen Agreement”), which has been determined to satisfy the criteria for consideration as a collaborative agreement, and is accounted for accordingly, in accordance with GAAP.

Cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks and money market instruments. The Company places its cash and cash equivalents with high-quality, U.S. financial institutions and, to date has not experienced losses on any of its balances.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Restricted Cash

As of December 31, 2018, and March 31, 2018, the Company had $396,135 and $391,566, respectively, of restricted cash, related to debt service reserve in regard to the New Jersey Economic Development Authority (“NJEDA”) bonds (see Note 5).

Accounts Receivable

Accounts receivable are comprised of balances due from customers, net of estimated allowances for uncollectible accounts. In determining collectability, historical trends are evaluated, and specific customer issues are reviewed on a periodic basis to arrive at appropriate allowances.

Inventory

Inventory is recorded at the lower of cost or market on a first-in first-out basis.

Long-Lived Assets

The Company periodically evaluates the fair value of long-lived assets, which include property and equipment and intangibles, whenever events or changes in circumstances indicate that its carrying amounts may not be recoverable.

Property and equipment are stated at cost. Depreciation is provided on the straight-line method based on the estimated useful lives of the respective assets which range from three to forty years. Major repairs or improvements are

capitalized. Minor replacements and maintenance and repairs which do not improve or extend asset lives are expensed currently.

Upon retirement or other disposition of assets, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is recognized in income.

Intangible Assets

The Company capitalizes certain costs to acquire intangible assets; if such assets are determined to have a finite useful life they are amortized on a straight-line basis over the estimated useful life. Costs to acquire indefinite lived intangible assets, such as costs related to ANDAs are capitalized accordingly.

The Company tests its intangible assets for impairment at least annually (as of March 31st) and whenever events or circumstances change that indicate impairment may have occurred. A significant amount of judgment is involved in determining if an indicator of impairment has occurred. Such indicators may include, among others and without limitation: a significant decline in the Company's expected future cash flows; a sustained, significant decline in the Company's stock price and market capitalization; a significant adverse change in legal factors or in the business climate of the Company's segments; unanticipated competition; and slower growth rates.

As of December 31, 2018, the Company did not identify any indicators of impairment.

Research and Development

Research and development expenditures are charged to expense as incurred.

Contingencies

Occasionally, the Company may be involved in claims and legal proceedings arising from the ordinary course of its business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred, and the amount can be reasonably estimated. If these estimates and assumptions change or prove to be incorrect, it could have a material impact on the Company's condensed consolidated financial statements. Contingencies are inherently unpredictable, and the assessments of the value can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it determines will not be realizable in the future.

Warrants and Preferred Shares

The accounting treatment of warrants and preferred share series issued is determined pursuant to the guidance provided by ASC 470, *Debt*, ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, as applicable. Each feature of a freestanding financial instruments including, without limitation, any rights relating to subsequent dilutive issuances, dividend issuances, equity sales, rights offerings, forced conversions, optional redemptions, automatic monthly conversions, dividends and exercise are assessed with determinations made regarding the proper classification in the Company’s financial statements.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. Under the fair value recognition provisions, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, based on the terms of the awards. The cost of the stock-based payments to nonemployees that are fully vested and non-forfeitable as at the grant date is measured and recognized at that date, unless there is a contractual term for services in which case such compensation would be amortized over the contractual term.

In accordance with the Company's Director compensation policy and certain employment contracts, director's fees and a portion of employee's salaries are to be paid via the issuance of shares of the Company's common stock, in lieu of cash, with the valuation of such share being calculated on a quarterly basis and equal to the average closing price of the Company's common stock.

Earnings (Loss) Per Share Applicable to Common Shareholders'

The Company follows ASC 260, *Earnings Per Share*, which requires presentation of basic and diluted earnings (loss) per share ("EPS") on the face of the income statement for all entities with complex capital structures and requires a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. In the accompanying financial statements, basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted EPS excluded all potential dilutive shares if their effect was anti-dilutive.

The following is the computation of earnings (loss) per share applicable to common shareholders for the periods indicated:

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2018	2017	2018	2017
Numerator				
Net loss attributable to common shareholders - basic	$(2,344,318)	$(490,181)	$(6,615,616)	$(843,758)
Effect of dilutive instrument on net loss	(380,976)	(605,448)	(807,347)	(4,767,884)
Net loss attributable to common shareholders - diluted	$(2,725,294)	$(1,095,629)	$(7,422,963)	$(5,611,642)
Denominator				
Weighted average shares of common stock outstanding - basic	819,412,807	788,442,363	811,603,678	796,647,284
Dilutive effect of stock options, warrants and convertible securities	56,074	6,680,001	56,074	6,680,001
Weighted average shares of common stock outstanding - diluted	819,468,881	795,122,364	811,659,752	803,327,285
Net income (loss) per share				
Basic	$(0.00)	$(0.00)	$(0.01)	$(0.00)
Diluted	$(0.00)	$(0.00)	$(0.01)	$(0.01)

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Fair Value of Financial Instruments

ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820") provides a framework for measuring fair value in accordance with generally accepted accounting principles.

ASC 820 defines fair value as 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. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs).

The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described as follows:

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

Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3 – Inputs that are unobservable for the asset or liability.

Measured on a Recurring Basis

The following table presents information about our liabilities measured at fair value on a recurring basis, aggregated by the level in the fair value hierarchy within which those measurements fell:

	Amount at	Fair Value Measurement Using		
	Fair Value	Level 1	Level 2	Level 3
December 31, 2018				
Liabilities				
Derivative financial instruments - warrants	$1,860,524	$ -	$ -	$1,860,524
March 31, 2018				
Liabilities				
Derivative financial instruments - warrants	$2,667,871	$-	$ -	$2,667,871

See Note 11, for specific inputs used in determining fair value.

The carrying amounts of the Company’s financial assets and liabilities, such as cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, approximate their fair values because of the short maturity of these instruments.

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Non-Financial Assets that are Measured at Fair Value on a Non-Recurring Basis

Non-financial assets such as intangible assets, and property and equipment are measured at fair value only when an impairment loss is recognized. The Company did not record an impairment charge related to these assets in the periods presented.

Treasury Stock

The Company records treasury stock at the cost to acquire it and includes treasury stock as a component of shareholders' equity.

Recently Adopted Accounting Pronouncements

In November 2016, the FASB issued ASU No. 2016-18*, Restricted Cash (ASC 230): Statement of Cash Flows ("ASU No. 2016-18").* ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash and amounts generally described as restricted cash. Restricted cash will be included with cash and cash equivalents when reconciling the beginning of period and end of period balances on the statement of cash flows upon adoption of this standard. As a result of the adoption of the new guidance, the Company increased the beginning of year total amount shown on the condensed consolidated statement of cash flows by $391,566 and $389,081 for the nine months ended December 31, 2018 and 2017, respectively. These amounts represent the balance of restricted cash included in the consolidated balance sheets as of March 31, 2018 and 2017, respectively. Restricted cash is related to debt service reserve in regard to the NJEDA bonds (see Note 5).

As of April 1, 2018, the Company adopted ASU 2017-09, *Compensation-Stock Compensation (ASC 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. The new standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if the fair value, vesting conditions, or classification of

the award changes as a result of the change in terms or conditions. The adoption of this standard did not materially impact the Company's stock-based compensation expense as no awards were modified during the nine months ended December 31, 2018.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*, to clarify guidance on the classification of certain cash receipts and cash payments in the statement of cash flow. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. The Company's adoption of this standard as of April 1, 2018 had no impact to the Company's condensed consolidated financial statements for the nine months ended December 31, 2018.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (ASC 842)*, which is effective for public entities for annual reporting periods beginning after December 15, 2018. Under ASU 2016-02, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and 2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to ASC 842 (Leases), and ASU 2018-11, Leases (ASC 842), Targeted Improvements, which provide (i) narrow amendments to clarify how to apply certain aspects of the new lease standard, (ii) entities with an additional transition method to adopt the new standard, and (ii) lessors with a practical expedient for separating components of a contract. All ASUs are effective for annual periods and interim periods within those annual periods beginning after December 15, 2018 and is effective for the Company for the year ending March 31, 2020. The Company is currently evaluating the effects of ASU 2016-02 on its financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (ASC 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASC 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. This update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of ASC 606. The Company is evaluating the effect that this update will have on its financial statements and related disclosures.

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In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (ASC 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 removes certain disclosures, modifies certain disclosures and adds additional disclosures. The ASU is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the effect that this update will have on its financial statements and related disclosures.

Management has evaluated other recently issued accounting pronouncements and does not believe that any of these pronouncements will have a significant impact on our consolidated financial statements and related disclosures.

NOTE 2. INVENTORY

Inventory consisted of the following:

	December 31, 2018	March 31, 2018
Finished goods	$ 251,230	$229,204
Work-in-progress	-	297,350
Raw materials	3,941,155	4,371,447
	$ 4,192,385	$4,898,001

NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	December 31, 2018	March 31, 2018
Land, building and improvements	$2,845,731	$7,675,317
Laboratory, manufacturing and warehouse equipment	14,358,157	9,302,277
Office equipment and software	242,132	308,434
Furniture and fixtures	582,692	49,804
Transportation equipment	66,855	66,855
	18,095,567	17,402,687
Less: Accumulated depreciation	(9,340,159)	(8,408,979)
	$8,755,408	$8,993,708

Depreciation expense was $317,618 and $232,358 for the three months and $931,180 and $567,554 for the nine months ended December 31, 2018 and 2017, respectively.

NOTE 4. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets:

	December 31, 2018				
	Estimated Useful Life	**Gross Carrying Amount**	**Additions**	**Accumulated Amortization**	**Net Book Value**
Patent application costs	*	$465,684	$ -	$ -	$465,684
ANDA acquisition costs	Indefinite	7,247,317	-	-	7,247,317
		$7,713,001	$ -	$ -	$7,713,001

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	March 31, 2018				
	Estimated Useful Life	**Gross Carrying Amount**	**Additions**	**Accumulated Amortization**	**NetBook Value**
Patent application costs	*	$371,774	$93,910	$ -	$465,684
ANDA acquisition costs	Indefinite	6,047,317	1,200,000	-	7,247,317
		$6,419,091	$1,293,910	$ -	$7,713,001

Patent application costs were incurred in relation to the Company's abuse deterrent opioid technology. Amortization of the patent costs will begin upon the issuance of marketing authorization by the FDA. Amortization will then be calculated on a straight-line basis through the expiry of the related patent(s).

NOTE 5. NJEDA BONDS

During August 2005, the Company refinanced a bond issue occurring in 1999 through the issuance of Series A and B Notes tax-exempt bonds (the "NJEDA Bonds" and/or "Bonds"). During July 2014, the Company retired all outstanding Series B Notes, at par, along with all accrued interest due and owed.

In relation to the Series A Notes, the Company is required to maintain a debt service reserve. The debt serve reserve is classified as restricted cash on the accompanying unaudited condensed consolidated balance sheets. The NJEDA Bonds require the Company to make an annual principal payment on September 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal. The annual interest rate on the Series A Note is 6.5%. The NJEDA Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced bonds.

The following tables summarize the Company's bonds payable liability:

	December 31, 2018	March 31, 2018
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,670,000	$1,760,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(95,000)	(90,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,575,000	$1,670,000
Bond offering costs	$ 354,453	$354,453
Less: Accumulated amortization	(189,045)	(178,409)
Bond offering costs, net	$ 165,408	$176,044
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	95,000	$90,000
Less: Bonds offering costs to be amortized in the next 12 months	(14,178)	(14,178)
Current portion of bonds payable, net of bond offering costs	$ 80,822	$75,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	1,575,000	$1,670,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(151,231)	(161,866)
Long term portion of bonds payable, net of bond offering costs	$ 1,423,769	$1,508,134

Amortization expense was $3,544 and $3,544 for the three months and $10,636 and $10,633 for the nine months ended December 31, 2018 and 2017, respectively.

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NOTE 6. LOANS PAYABLE

Loans payable consisted of the following:

	December 31, 2018	March 31, 2018
Equipment and insurance financing loans payable, between 5.7% and 12.73% interest and maturing between March 2019 and December 2023	$ 1,280,935	$ 1,201,861
Less: Current portion of loans payable	(505,747)	(578,841)
Long-term portion of loans payable	$ 775,188	$ 623,020

The interest expense associated with the loans payable was $28,025 and $29,853 for the three months and $86,765 and $70,634 for the nine months ended December 31, 2018 and 2017, respectively.

NOTE 7. RELATED PARTY SECURED PROMISSORY NOTE WITH MIKAH PHARMA LLC

For consideration of the assets acquired on May 15, 2017, the Company issued a Secured Promissory Note (the “Note”) to Mikah for the principal sum of $1,200,000. The Note matures on December 31, 2020 in which the Company shall pay the outstanding principal balance of the Note. Interest shall be computed on the unpaid principal amount at the per annum rate of ten percent (10%); provided, upon the occurrence of an Event of Default as defined within the Note, the principal balance shall bear interest from the date of such occurrence until the date of actual payment at the per annum rate of fifteen percent (15%). All interest payable hereunder shall be computed on the basis of actual days elapsed and a year of 360 days. Installment payments of interest on the outstanding principal shall be paid as follows: quarterly commencing August 1, 2017 and on November 1, February 1, May 1 and August 1 of each year thereafter. All unpaid principal and accrued but unpaid interest shall be due and payable in full on the Maturity Date. The interest expense associated with the Note was $30,000 for the three months and $90,000 for the nine months ended December 31, 2018. Accrued interest due and owing on this note was $195,000 and $105,000 as of December 31, 2018 and March 31, 2018, respectively.

NOTE 8. DEFERRED REVENUE

Deferred revenues in the aggregate amount of $1,505,566 as of December 31, 2018, were comprised of a current component of $1,013,333 and a long-term component of $492,223. Deferred revenues in the aggregate amount of $2,265,556 as of March 31, 2018, were comprised of a current component of $1,013,333 and a long-term component of $1,252,223. These line items represent the unamortized amounts of a $200,000 advance payment received for a TAGI licensing agreement with a fifteen-year term beginning in September 2010 and ending in August 2025 and the $5,000,000 advance payment Epic Collaborative Agreement with a five-year term beginning in June 2015 and ending in May 2020. These advance payments were recorded as deferred revenue when received and are earned, on a straight-line basis over the life of the licenses. The current component is equal to the amount of revenue to be earned during the 12-month period immediately subsequent to the balance date and the long-term component is equal to the amount of revenue to be earned thereafter.

NOTE 9. COMMITMENTS AND CONTINGENCIES

Occasionally, the Company may be involved in claims and legal proceedings arising from the ordinary course of its business. The Company records a provision for a liability when it believes that is both probable that a liability has been incurred, and the amount can be reasonably estimated. If these estimates and assumptions change or prove to be incorrect, it could have a material impact on the Company’s condensed consolidated financial statements. Contingencies are inherently unpredictable, and the assessments of the value can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

Operating Leases – 135 Ludlow Ave.

The Company entered into an operating lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey (the “135 Ludlow Ave. lease”). The 135 Ludlow Ave. lease is for approximately 15,000 square feet of floor space and began on July 1, 2010. During July 2014, the Company modified the 135 Ludlow Ave. lease in which the Company was permitted to occupy the entire 35,000 square feet of floor space in the building (“135 Ludlow Ave. modified lease”).

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The 135 Ludlow Ave. modified lease includes an initial term, which expired on December 31, 2016 with two tenant renewal options of five years each, at the sole discretion of the Company. On June 22, 2016, the Company exercised the first of these renewal options, with such option including a term that begins on January 1, 2017 and expires on December 31, 2021.

The 135 Ludlow Ave. property required significant leasehold improvements and qualifications, as a prerequisite, for its intended future use. Manufacturing, packaging, warehousing and regulatory activities are currently conducted at this location.

Rent expense is recorded on the straight-line basis. Rents paid in excess is recognized as deferred rent. Rent expense under the 135 Ludlow Ave. modified lease for the three months ended December 31, 2018 and 2017 was $54,909, and $164,727 for the nine months ended December 31, 2018 and 2017. Rent expense is recorded in general and administrative expense in the unaudited condensed consolidated statements of operations. Deferred rent as of December 31, 2018 and March 31, 2018 was $13,001 and $9,705, respectively and recorded as a component of other long-term liabilities.

The Company has an obligation for the restoration of its leased facility and the removal or dismantlement of certain property and equipment as a result of its business operation in accordance with ASC 410, *Asset Retirement and Environmental Obligations – Asset Retirement Obligations*. The Company records the fair value of the asset retirement obligation in the period in which it is incurred. The Company increases, annually, the liability related to this obligation. The liability is accreted to its present value each period and the capitalized cost is depreciated over the useful life of the related asset. Upon settlement of the liability, the Company records either a gain or loss. As of December 31, 2018, and March 31, 2018, the Company had a liability of $32,887 and $31,443, respectively and recorded as a component of other long-term liabilities.

NOTE 10. MEZZANINE EQUITY

Series J convertible preferred stock

On April 28, 2017, the Company created the Series J Convertible Preferred Stock ("Series J Preferred") in conjunction with the Certificate of Designations ("Series J COD"). A total of 50 shares of Series J Preferred were authorized, 24.0344 shares are issued and outstanding, with a stated value of $1,000,000 per share and a par value of $0.01 as of December 31, 2018.

The issued shares were pursuant to an Exchange Agreement with Nasrat Hakim, ("Hakim") a related party and the Company's President, CEO and Chairman of the Board of Directors Pursuant to the Exchange Agreement the Company exchanged 158,017,321 shares of Common Stock for 24.0344 shares of Series J Preferred and warrants to purchase 79,008,661 shares of common stock at $0.1521 per share. The aggregate stated value of the Series J Preferred issued was equal to the aggregate value of the shares of common stock exchanged, with such value of each share of Common Stock exchanged being equal to the closing price of the Common Stock on April 27, 2017. In connection with the Exchange Agreement, the Company also issued warrants to purchase 79,008,661 shares of common stock at $0.1521 per share, and such warrants are classified as liabilities on the accompanying unaudited condensed consolidated balance sheet as of December 31, 2018 (See Note 11).

Each Series J Preferred is convertible at the option of the holder into shares of common stock, that is the earlier of (i) the date that shareholder approval is obtained, and the requisite corporate action has been effected regarding a Fundamental Transaction (as defined in the Series J COD); or (ii) not less than three years subsequent to the Original Issue Date (the date of the first issuance of any shares of the Series J Preferred Stock) (the "Conversion Date"). The number of common shares is calculated by dividing the Stated Value of such share of Series J Preferred by the Conversion Price. The conversion price for the Series J Preferred shall equal $0.1521, subject to adjustment as discussed below.

Based on the current conversion price, the Series J Preferred is convertible into 158,017,321 shares of common stock. The conversion price is subject to the following adjustments: (i) stock dividends and splits, (ii) sale or grant of shares below the conversion price, (iii) pro rata distributions; or (iv) fundamental changes (merger, consolidation, or sale of all or substantially all assets).

If upon any Conversion Date there is not a sufficient number of authorized shares of Common Stock (that are not issued, outstanding or reserved for issuance) available to effect the entire conversion of the then outstanding shares of Series J Preferred Stock and the then outstanding common stock purchase warrants issued in conjunction therewith (an "Authorized Share Deficiency"), such conversion shall not exceed the Issuable Maximum (as defined in the Series J COD); however, the Company shall use its best efforts to obtain shareholder approval within two (2) years of the date of first issuance of Series J Preferred Stock to permit the balance of the conversion. If shareholder approval is not obtained due to an insufficient number of shareholder votes for passage, the Company shall continue to solicit for shareholder approval annually thereafter. As of December 31, 2018, the Company does not have a sufficient number of unreserved authorized shares to effect the entire conversion, notwithstanding that the earliest possible Conversion Date is April 28, 2020.

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Solely during any period of time during which an Authorized Share Deficiency exists commencing on or after the fourth anniversary of the Original Issue Date ("Dividend Commencement Date" and collectively the "Dividend Entitlement Period"), holders of Series J Preferred shall be entitled to receive, and the Company shall pay, dividends at the rate per share (as a percentage of the Stated Value per share) of 20% per annum, payable quarterly, in arrears, on January 1, April 1, July 1 and October 1, in cash or duly authorized, validly issued, fully paid and non-assessable shares of Series J Preferred, or a combination thereof (the amount to be paid in shares of Series J Preferred, the "Dividend Share Amount"). The form of dividend payments to each holder shall be made, at the option of the Holders, (i) in cash, to the extent that funds are legally available for the payment of dividends in cash, (ii) in shares of Series J Preferred Stock, or (iii) a combination thereof. The Series J Preferred shall rank senior to the common stock with respect to payment of dividends and pari passu to the common stock with respect to liquidation, dissolution or winding up of the Company.

The holders of the Series J Preferred shall have voting rights on any matter presented to the shareholders of the Company for their action or consideration at any meeting of shareholders of the Company (or by written consent of shareholders in lieu of meeting). Each holder shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series J Preferred held by the holder are convertible as of the record date for determining the shareholders entitled to vote on such matter regardless of whether an Authorized Share Deficiency Exists.

The Company has determined that the Series J Preferred host instrument was more akin to equity than debt and that the above identified conversion feature, subject to adjustments, was clearly and closely related to the host instrument, and accordingly bifurcation and classification of the conversion feature as a derivative liability was not required. The Company has accounted for the Series J Preferred as contingently redeemable preferred stock for which redemption is not probable. Accordingly, the Series J Preferred is presented in mezzanine equity based on their initial measurement amount (fair value), as required by ASC 480-10-S99, *Distinguishing Liabilities from Equity – SEC Materials*. No subsequent adjustment of the initial measurement amounts for these contingently redeemable Series J Preferred is necessary unless the redemption of the Series J Preferred becomes probable. Accordingly, the amount presented as temporary equity for the contingently redeemable Series J Preferred outstanding is its issuance-date fair value. The Series J Preferred was initially measured at its fair value, $13,903,960 at April 28, 2017.

The fair value of the Series J Preferred issued by the Company pursuant to the exchange agreement was calculated using a Monte Carlo Simulation of stock price and expected future behaviors related to shareholder approval provisions. The following are the key assumptions used in the Monte Carlo Simulation:

	April 28, 2017	
Fair value of the Company's common stock	$0.1521	
Conversion price	$0.1521	
Number of Series J Preferred issued	24.0344	
Fully diluted shares outstanding as of measurement date	923,392,780	
Risk-free rate	2.30	%
Volatility	90	%
Shareholder approval threshold	$0.1521	
Probability of approval is ending stock price is greater than threshold - midpoint	82.50	%
Probability of approval is ending stock price is less than threshold - midpoint	17.50	%
Trials	200,000	

Authorized, issued and outstanding shares, along with carrying value and change in value as of December 31, 2018 and March 31, 2018 are as follows:

	December 31, 2018	March 31, 2018
Shares authorized	50.000	50.000
Shares outstanding	24.0344	24.0344
Par value	$0.01	$0.01
Stated value	$1,000,000	$1,000,000
Conversion price	$0.1521	$0.1521
Common Stock to be issued upon conversion	158,017,321	158,017,321
Carrying value of Series J convertible preferred stock	$13,903,960	$13,903,960

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NOTE 11. DERIVATIVE FINANCIAL INSTRUMENTS – WARRANTS

The Company evaluates and accounts for its freestanding instruments in accordance with ASC 815, *Accounting for Derivative Instruments and Hedging Activities*.

The Company issued warrants, with terms of five to seven years, to various corporations and individuals, in connection with the sale of securities, loan agreements and consulting agreements.

A summary of warrant activity is as follows:

	December 31, 2018		March 31, 2018	
	Warrant Shares	**Weighted Average Exercise Price**	**Warrant Shares**	**Weighted Average Exercise Price**
Balance at beginning of period	79,008,661	$ 0.1521	9,379,219	$ 0.0625
Warrants granted pursuant to the issuance of Series J convertible preferred shares	---	---	79,008,661	$ 0.1521
Warrants exercised, forfeited and/or expired, net	---	---	(9,379,219)	$ 0.0625
Balance at end of period	79,008,661	$ 0.1521	79,008,661	$ 0.1521

On April 28, 2017, the Company entered into an exchange agreement (the "*Exchange Agreement*") with Nasrat Hakim, the Chairman of the Board, President, and Chief Executive Officer of the Company, pursuant to which the Company issued to Mr. Hakim 23.0344 shares of its newly designated Series J Convertible Preferred Stock ("*Series J Preferred*") and Warrants to purchase an aggregate of 79,008,661 shares of its Common Stock (the "Series J Warrants" and, along with the Series J Preferred issued to Mr. Hakim, the "*Securities*") in exchange for 158,017,321 shares of Common Stock owned by Mr. Hakim. The fair value of the Series J Warrants was determined to be $6,474,674 upon issuance at April

28, 2017.

The Series J Warrants are exercisable for a period of 10 years from the date of issuance, commencing on the earlier of (i) the date that Shareholder Approval is obtained, and the requisite corporate action has been effected; or (ii) April 28, 2020. The initial exercise price is $0.1521 per share and the Series J Warrants can be exercised for cash or on a cashless basis. The exercise price is subject to adjustment for any issuances or deemed issuances of common stock or common stock equivalents at an effective price below the then exercise price. Such exercise price adjustment feature prohibits the Company from being able to conclude the warrants are indexed to its own stock and thus such warrants are classified as liabilities and measured initially and subsequently at fair value. The Series J Warrants also provide for other standard adjustments upon the happening of certain customary events. The Series J Warrants are not exercisable during any period when an Authorized Share Deficiency exists and will expire on the expiry date, without regards to the existence of an Authorized Shares Deficiency (see Note 10). As of December 31, 2018, the Company does not have a sufficient number of unreserved authorized shares to effect the entire conversion of the Series J Preferred, therefore the Series J Warrants are not currently exercisable.

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The fair value of the warrants issued by the Company pursuant to the issuance of Series J convertible preferred shares (79,008,661 warrant shares) was calculated using a Monte Carlo Simulation because of the probability assumptions associated with the Shareholder Approval provisions. The following are the key assumptions used in the Monte Carlo Simulation:

	December 31, 2018	March 31, 2018
Fair value of the Company's common stock	$0.0749	$0.1000
Initial exercise price	$0.1521	$0.1521
Number of common warrants	79,008,661	79,008,661
Fully diluted shares outstanding as of measurement date	819,489,750	791,516,930
Warrant term (in years)	8.33	9.08
Risk-free rate	2.63 %	2.72 %
Volatility	90.00 %	90.00 %
Shareholder approval threshold	$0.1580	$0.1580
Probability of approval is ending stock price is greater than threshold - midpoint	82.50 %	82.50 %
Probability of approval is ending stock price is greater than threshold - midpoint	17.50 %	17.50 %
Trials	99,998	100,000
Fair value of derivative financial instruments - warrants	$1,860,524	$2,667,871

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the nine months ended December 31, 2018 were as follows:

Balance as of March 31, 2018	$2,667,871
Change in fair value of derivative financial instruments - warrants	(807,347)
Balance as of December 31, 2018	$1,860,524

NOTE 12. SHAREHOLDERS' EQUITY

Lincoln Park Capital – April 10, 2014 Purchase Agreement

On April 10, 2014, the Company entered into a Purchase Agreement (the "2014 LPC Purchase Agreement") and a Registration Rights Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2014 LPC Purchase Agreement, Lincoln Park had agreed to purchase from the Company up to $40 million of common stock (subject to certain limitations) from time to time over a 36-month period.

Upon execution of the 2014 LPC Purchase Agreement, the Company issued 1,928,641 shares of its common stock to Lincoln Park as consideration for its commitment to purchase additional shares of our common stock under that agreement and were obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to $40 million of the Company's common stock is purchased by Lincoln Park.

The 2014 LPC Purchase Agreement expired on June 1, 2017. During the term of the 2014 LPC Purchase Agreement, the Company sold an aggregate of 110.6 million shares to Lincoln Park, for aggregate gross proceeds of approximately $27.0 million. In addition, the Company issued an aggregate of 3.2 million commitment shares.

Lincoln Park Capital – May 1, 2017 Purchase Agreement

On May 1, 2017, the Company entered into a purchase agreement (the "2017 LPC Purchase Agreement"), together with a registration rights agreement (the "2017 LPC Registration Rights Agreement"), with Lincoln Park.

Under the terms and subject to the conditions of the 2017 LPC Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of common stock, subject to certain limitations, from time to time, over the 36-month period commencing on June 5, 2017. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 500,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 1,000,000 shares, depending upon the closing sale price of the common stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than $1,000,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases under certain circumstances. Sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then outstanding shares of common stock.

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In connection with the 2017 LPC Purchase Agreement, the Company issued to Lincoln Park 5,540,551 shares of common stock and are required to issue up to 5,540,551 additional shares of Common Stock pro rata as the Company requires Lincoln Park to purchase shares under the 2017 LPC Purchase Agreement over the term of the agreement. Lincoln Park has represented to the Company, among other things, that it is an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")). The Company sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The 2017 LPC Purchase Agreement and the 2017 LPC Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the 2017 LPC Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the Common Stock and determinations by us as to the appropriate sources of funding for us and our operations. There are no trading volume requirements or, other than the limitation on beneficial ownership discussed above, restrictions under the 2017 LPC Purchase Agreement. Lincoln Park has no right to require any sales by the Company but is obligated to make purchases from the Company as directed in accordance with the 2017 LPC Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares.

The net proceeds received by us under the 2017 LPC Purchase Agreement will depend on the frequency and prices at which the Company sell shares of common stock to Lincoln Park. A registration statement on form S-3 was filed with the SEC on May 10, 2017 and was declared effective on June 5, 2017.

The Company, from time to time and at the Company's sole discretion but no more frequently than every other business day, could direct Lincoln Park to purchase (a "*Regular Purchase*") up to 500,000 shares of common stock on any such business day, increasing up to 800,000 shares, depending upon the closing sale price of the common stock, provided that in no event shall Lincoln Park purchase more than $760,000 worth of common stock on any single business day. The purchase price of shares of common stock related to the future Regular Purchase funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to ten business days leading up to such time), but in no event, will shares be sold to Lincoln Park on a day the Common Stock closing price is less than the floor price of $0.10 per share, subject to adjustment.

In addition to Regular Purchases, on any business day on which the Company has properly submitted a Regular Purchase notice and the closing sale price is not below $0.10, the Company may purchase (an "*Accelerated Purchase*") an additional "accelerated amount" under certain circumstances. The amount of any Accelerated Purchase cannot exceed the lesser of three times the number of purchase shares purchased pursuant to the corresponding Regular Purchase; and 30% of the aggregate shares of the Company's common stock traded during normal trading hours on the purchase date. The purchase price per share for each such Accelerated Purchase will be equal to the lower of (i) 97% of the volume weighted average price during the purchase date; or (ii) the closing sale price of the Company's common stock on the purchase date.

In the case of both Regular Purchases and Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of any sales of the Company's common stock to Lincoln Park.

The Company's sales of shares of common stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of common stock.

The Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties, agreements, and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, without limitation, market conditions, the trading price of the Common Stock and determinations by the Company as to appropriate sources of funding for the Company and its operations. There are no trading volume requirements or restrictions under the Purchase Agreement. Lincoln Park has no right to require any sales by the Company but is obligated to make purchases from the Company as it directs in accordance with the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of Company shares.

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. During the nine months ended December 31, 2018, a total of 17,642,083 shares were sold to Lincoln Park pursuant to the 2017 LPC Agreement for net proceeds totaling $1,669,829. In addition, 231,295 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Agreement.

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NOTE 13. STOCK-BASED COMPENSATION

Part of the compensation paid by the Company to its Directors and employees consists of the issuance of common stock or via the granting of options to purchase common stock.

Stock-based Director Compensation

The Company's Director compensation policy was instituted in October 2009 and further revised in January 2016, includes provisions that a portion of director's fees are to be paid via the issuance of shares of the Company's common stock, in lieu of cash, with the valuation of such shares being calculated on quarterly basis and equal to the average closing price of the Company's common stock.

During the nine months ended December 31, 2018, the Company did not issue any shares of common stock to its Directors in payment of director's fees.

During the nine months ended December 31, 2018, the Company accrued director's fees totaling $73,750, which will be paid via cash payments totaling $28,750 and the issuance of 490,494 shares of Common Stock.

As of December 31, 2018, the Company owed its Directors a total of $30,000 in cash payments and 627,283 shares of Common Stock in payment of director fees totaling $90,000 due and owing. The Company anticipates that these shares of Common Stock will be issued prior to the end of the current fiscal year.

Stock-based Employee/Consultant Compensation

Employment contracts with the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees and engagement contracts with certain consultants include provisions for a portion of each employee's salaries or consultant's fees to be paid via the issuance of shares of the Company's Common Stock, in lieu of cash, with the valuation of such shares being calculated on a quarterly basis and equal to the average closing price of the Company's Common Stock.

During the nine months ended December 31, 2018, the Company did not issue any shares pursuant to employment contracts with the Company's President and Chief Executive Officer, Chief Financial Officer or certain other employees. During the nine months ended December 31, 2018, the Company did not issue any shares pursuant to the engagement contracts with certain consultants.

During the nine months ended December 31, 2018, the Company accrued salaries totaling $603,750 owed to the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees which will be paid via the issuance of 6,580,791 shares of Common Stock.

As of December 31, 2018, the Company owed its President and Chief Executive Officer, Chief Financial Officer and certain other employees' salaries totaling $1,305,000 which will be paid via the issuance of 12,450,882 shares of Common Stock. The Company anticipates that 3,988,691 shares of Common Stock, representing salaries owed to the Company's Chief Financial Officer and certain other employees' salaries totaling $305,000 will be issued prior to the end of the current fiscal year.

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Options

Under its 2014 Stock Option Plan and prior options plans, the Company may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. All options have generally been granted at a price equal to or greater than the fair market value of the Company's Common Stock at the date of the grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant.

	Shares Underlying Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (in years)**	**Aggregate Intrinsic Value**
Outstanding at April 1, 2018	6,618,000	$ 0.16	6.1	$ 90,390
Forfeited and expired	(403,000)	$ 0.30		
Outstanding at December 31, 2018	6,215,000	$ 0.15	5.2	$ 14,700
Exercisable at December 31, 2018	5,668,334	$ 0.15	5.00	$ 14,700

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company common stock as of December 31, 2018 and March 31, 2018 of $0.0749 and $0.1000, respectively.

NOTE 14. CONCENTRATIONS AND CREDIT RISK

Revenues